Compassion Service Education
GKCT

6th Annual International Review on GI Cancers

22nd -23rd JULY 2023

Venue: **Hotel Courtyard by Marriott,** Andheri, Mumbai

ORGANISING TEAM

Dr. Anil Heroor
Director Surgical Oncology,
Fortis Hospital,
Mumbai

Dr. Tejinder Singh
Sr. Consultant Medical Oncologist,
Apollo Cancer Center,
Apollo Hospital, Mumbai

Dr. Adwaita Gore
Associate Director Medical Oncology,
Nanavati Max Super Speciality Hospital,
Mumbai

Click on below link to register
https://www.riverroute.in/gireview

Managed by riverroute®
Leaders in Streaming Modules

6th Annual International Review on GI Cancers

Compassion Service Education
GKCT

Dear Colleagues,

GKCT brings to you the 6th Edition of Annual Review in Gastrointestinal Cancer to be held on 22nd -23rd July 2023 at Hotel Courtyard Marriot, Mumbai.

The primary goal of this meeting is to guide practicing physicians on integrating the best and most current evidence into day-to-day routine care for patients with GI cancers. This meeting brings a practical perspective on how to optimize multidisciplinary care for some of the more complex clinical management decisions. Topics discussed include locoregional modalities, the role of minimally invasive procedures, and state-of-the-art treatment.

As we are aware chemotherapy dependency has maintains its validity in several gastrointestinal cancers and continues to be successfully explored, especially in academic trials. However,a number of biomarkers currently guide treatment decisions for patients with gastrointestinal neoplasms.Major technological advances in genomics have made it possible to identify critical genetic alterations in cancer, rendering oncology well along the path to “personalized cancer medicine”.

Image-guided surgery & minimally invasive treatment has evolved over the past several decades, which has led to reduced local recurrence rates and improved survival outcomes. The approach to diagnosis, staging, and selection of appropriate treatment modalities has become a multidisciplinary effort combining interventional endoscopy, surgery, and radiology tools needs to be discussed and implemented in our practice.

This meeting focuses on case-based and didactic presentations from national international experts in the treatment of the whole spectrum of gastrointestinal (GI) cancers, including esophageal, gastric, hepatocellular, pancreatic, small bowel, bile duct, anal and colorectal, and gallbladder. Our year in review session, hall mark surgical video sessions and case based panel discussion will provide an overview of exciting new research in the area of gastrointestinal tumours that may establish the stage for an innovative personalized management and precision medicine modalities for individualized care.

We are sure our attempt in understanding the various therapeutic interventions will pave the way for improved patient outcomes. We look forward to your active participation.

Regards

Dr. Anil Heroor
Director Surgical Oncology,
Fortis Hospital,
Mumbai

Dr. Tejinder Singh
Sr. Consultant Medical Oncologist
Apollo Cancer Center,
Apollo Hospital, Mumbai

Dr. Adwaita Gore
Associate Director Medical Oncology
Nanavati Max Super Speciality,
Mumbai

Click on below link to register
https://www.riverroute.in/gireview

Managed by riverroute®
Leaders in Streaming Modules

6th Annual International Review on GI Cancers

GKCT — Compassion Service Education

Day 1 | 22nd July 2023 Scientific Program

Session 1 : Esophageal/Gastric Cancers

09:00 am - 09:05 am	Welcome Address **Dr. Anil Heroor, Dr. Tejinder Singh** **Dr. Adwaita Gore**
09:05 am – 09:20 am	Chairpersons: **Dr. Rahul Chavan, Dr. Sagar Gayakwad** Surgical strategies for GEJ cancer **Speaker: Dr. Jitendra Mistry**
09:20 am – 09:35 am	Surgical strategies for Adenocarcinoma stomach - Current status and future directions **Speaker: Dr. Rajesh Shinde**
09:35 am – 09:50 am	Updates of radiation therapy in ESO/GEJ **Speaker: Dr. Rohit Malde**
09:50 am – 10:05 am	Chairpersons: **Dr. Bharat Parikh, Dr. Gauri Vidolkar** Current status and future perspective of targeted and systemic therapy for gastric cancer **Speaker: Dr. Udip Maheshwari**
10:05 am – 10:20 am	New Perspectives in Upper GI: Role of Immunotherapy in Advanced/Metastatic Gastroesophageal Adenocarcinomas **Speaker: Dr. Tanvi Sood**
10:20 am – 10:50 am	**Session Supported by BMS**
	Panel Discussion : Immunotherapy in Advanced/Metastatic Gastroesophageal Adenocarcinomas **Moderator: Dr. Krupa Shankar** **Panelists:** **Dr. Tejinder Singh, Dr. Amit Bhatt,** **Dr. Tanvi Sood, Dr. Kiran Tamkhane**

Click on below link to register
https://www.riverroute.in/gireview

Managed by riverroute® Leaders in Streaming Modules

6th Annual International Review on GI Cancers

GKCT — Compassion Service Education

Day 1 | 22nd July 2023 Scientific Program

Session 1 : Esophageal/Gastric Cancers

10:50 am – 11:35 am	Chairpersons: **Dr. Bharat Parikh, Dr. Adwaita Gore, Dr. Nilesh Lokeshwar**
	Tumor Board : Case Discussions & Overview
	Moderator: Dr. Bhawna Sirohi
	Panelists: Dr. Gauri Vidolkar, Dr. Madhu Devarasetty, Dr. Robin Thambudorai, Dr. Hollis Dsouza, Dr. Atul Narayankar, Dr. Kiran Tamkhane, Dr. Sachin Bhojankar, Dr. Yogen Chheda
11:35 am – 11:45 am	**Tea/Coffee Break**

Session 2 : Hepatobiliary Cancers

11:45 am – 12:00 pm	Chairpersons: **Dr. Vikram Raut, Dr. Mohammad Zaki**
	Molecular landscape of HPB cancers
	Speaker: Dr. Jay Mehta
12:00 pm – 12:15 pm	Integrating Surgical and Systemic Approaches to HCC
	Speaker: Dr. Mahesh Goel
12:15 pm – 12:30 pm	The Role of Transplant for Liver Limited Metastasis
	Speaker: Dr. Anurag Shrimal
12:30 pm – 12:45 pm	Unresectable to resectable HCC: Hype or reality
	Speaker: Dr. Hollis Dsouza
12:45 pm – 01:00 pm	**Session Supported by Glenmark**
	A new edge in CINV management: I. V. NEPA
	Speaker: Dr. Tejinder Singh
01:00 pm – 01:45 pm	**Lunch Break**
01:45 pm – 02:00 pm	Chairpersons: **Dr. Rajesh Yadav, Dr. Tejinder Singh**
	Optimal 1L therapies in HCC : How to select
	Speaker: Dr. B. K. Smruti

Click on below link to register
https://www.riverroute.in/gireview

Managed by riverroute® Leaders in Streaming Modules

6th Annual International Review on GI Cancers

GKCT — Compassion Service Education

Day 1 | 22nd July 2023 Scientific Program

02:00 pm – 02:45 pm	Case based panel discussion **Moderator: Dr. Mansi Khanderia** **Panelists:** **Dr. Ramakrishna Prabhu, Dr. Ketul Shah, Dr. Nimish Shah, Dr. Imran Shaikh, Dr. Gayatri Raheja, Dr. Ashutosh Kharche, Dr. Shriniwas Kulkarni, Dr. Daksh Chandra, Dr. Hollis Dsouza** Chairpersons : **Dr. Tejas Savdekar, Dr. N. Saileshwar**
02:45 pm – 03:00 pm	Role for Adjuvant Therapy in Resected BTC **Speaker: Dr. Uma Dangi**
03:00 pm – 03:15 pm	Focusing on immunotherapy in BTCs, where we're headed **Speaker: Dr. Mubarakunnisa Tonse**
03:15 pm – 03:30 pm	Personalised medicine – What is it and where are we with Cholangiocarcinoma: Is this the future? **Speaker: Dr. Shriniwas Kulkarni**
03:30 pm – 03:45 pm	Chairperson : **Dr. Sundaram Pillai, Dr. Aditya Manke, Dr. Gaurav Chaubal** Surgery for bile duct cancer: Can we improve outcomes? **Speaker: Dr. Ganesh Nagarajan**
03:45 pm – 04:30 pm	Case based panel discussion **Moderator: Dr. T. P. Sahoo** **Panelists: Dr. Darshana Rane, Dr. Sunil Chopade, Dr. Deepak Chhabra, Dr. Prasad Wagle, Dr. Rakesh Badhe, Dr. Sandeep De**

Click on below link to register
https://www.riverroute.in/gireview

Managed by riverroute® Leaders in Streaming Modules

6th Annual International Review on GI Cancers

GKCT — Compassion Service Education

Day 1 | 22nd July 2023 Scientific Program

Session 3 : Pancreatic Cancer / NET

	Chairpersons : **Dr. Prashant Kadam, Dr. Pratik Doshi, Dr. Hemant Patil**
04:30 pm – 04:45 pm	The Role of Surgery in Oligometastatic Pancreatico-Biliary Cancers **Speaker: Dr. Shraddha Patkar**
04:45 pm – 05:00 pm	First-Line Metastatic PDAC: Three Drugs or Two? **Speaker: Dr. Sandeep Goyle**
05:00 pm – 05:15 pm	Emerging and Promising Targeted Strategies in Advanced Pancreas Cancer **Speaker: Dr. Suhas Aagre**
05:15 pm – 06:00 pm	Case based panel discussion – Pancreatic Cancer **Moderator: Dr. Vikram Chaudhari** **Panelists: Dr. Pushkar Ingle, Dr. Suhas Aagre, Dr. Vijay Sharnagat, Dr. Dipalee Borade, Dr. Soumil Vyas, Dr. Aditya Punamiya**
	Chairerspons : **Dr. Mary Anne Joseph, Dr. Anand Zade**
06:00 pm – 06:15 pm	Evolving Use of PRRT in NETs **Speaker: Dr. Madhuri Mahajan**
06:15 pm – 06:30 pm	How I Treat Well-Differentiated, Grade 3 pNETs **Speaker: Dr. B. A. Krishna**
06:30 pm – 06:45 pm	**Hi – Tea Session**
06:45 pm – 07:15 pm	**Session Supported by Roche**
	Comprehensive genomic profiling enables precision oncology; Role of CGP in GI cancers **Speaker: Dr. Vaibhav Choudhary**

Click on below link to register
https://www.riverroute.in/gireview

Managed by riverroute® Leaders in Streaming Modules

6th Annual International Review on GI Cancers

GKCT — Compassion Service Education

Day 1 | 22nd July 2023 Scientific Program

07:15 pm – 07:45 pm	Session Supported by AstraZeneca
07:15 pm – 07:30 pm	Newer updates in the management of 1st Line BTC **Speaker: Dr. Sandeep Goyle**
07:30 pm – 07:45 pm	Newer updates in the management of advanced and unresectable HCC **Speaker: Dr. T. P. Sahoo**
07:45 pm – 08:25 pm	**Session Supported by Lilly Oncology**
07:45 pm – 08:05 pm	ESMO guidelines update and treatment sequencing in advanced gastric cancer **Speaker: Dr. Tejinder Singh**
08:05 pm – 08:25 pm	Cyramza clinical evidence in advanced gastric cancer + Cased based discussion **Speaker: Dr. Shivam Shingla**
08:25 pm – 08:45 pm	**Session Supported by Ethicon**
	Use of Powered devices- It's application and complication management **Speaker: Dr. Paresh Jain**
08:45 pm Onwards	**Dinner**

Click on below link to register
https://www.riverroute.in/gireview

Managed by riverroute® Leaders in Streaming Modules

6th Annual International Review on GI Cancers

Compassion Service Education
GKCT

Day 2 | 23rd July 2023 Scientific Program

Session 4 : Metastatic Colorectal Cancer

	Chairpersons: **Dr Vinne Soni, Dr. Tejinder Singh**
09:30 am – 09:45 am	How to Optimize the Selection of EGFR Inhibitors in Advanced Colorectal Cancers **Speaker: Dr. Pritam Kataria**
09:45 am – 10:00 am	Optimizing Response to Immune Checkpoint Inhibitors in dMMR/MSS CRC Malignancies **Speaker: Dr. Darshit Shah**
10:00 am – 10:15 am	BRAF Mutant Colorectal Cancer : Therapeutic Strategies to Overcome Resistance **Speaker: Dr. Rakesh Pinninti**
10:15 am – 10:30 am	Should Watch and Wait be standard of care in locally Advance Rectal Cancer? **Speaker: Dr. Ashwin Desouza**
10:30 am – 11:15 am	Case based panel discussion **Moderator: Dr. Avanish Saklani** **Panelists:** **Dr. Prashant Kerkar, Dr. Harshit Shah, Dr. Tanveer Majeed, Dr. Bhavin Visariya, Dr. Pushpak Chirmade, Dr. Imran Shaikh, Dr. Prabhat Bhargava**

Click on below link to register
https://www.riverroute.in/gireview

Managed by riverroute®
Leaders in Streaming Modules

6th Annual International Review on GI Cancers

Compassion Service Education
GKCT

Day 2 | 23rd July 2023 Scientific Program

Session 5 : Surgical Masterclass

	Chairpersons: **Dr. Makrand Bhole, Dr. Sachin Kadam**
11:15 am - 11:45 am	Robotic total esophagectomy with lymph node Dissection Video Presenter : **Dr. George Karimundackal** **Moderator: Dr. Suraj Pawar** **Panelists:** **Dr. Navin Bhambani, Dr. Nikhil Dharmadhikari, Dr. Devyani Niyogi, Dr. Nilesh Chordiya**
11:45 am – 12:15 pm	Robotic radical total gastrectomy with d2 Lymphadenectomy Video Presenter : **Dr. Manish Bhandare** **Moderator: Dr. Raj Nagarkar** **Panelists:** **Dr. Tushar Pawar, Dr. Jayesh Gori, Dr. Rajesh Saouji, Dr. Swapnil Kapote, Dr. Rajesh Shinde, Dr. Priya Eshpuniyani**
	Chairpersons: **Dr. Kailash Surnare, Dr. Shreyas Somnath**
12:15 pm – 12:45 pm	Laparoscopic Whipple Procedure Video Presenter : **Dr. Rajesh Bhojwani** **Moderator: Dr. Ganesh Nagarajan** **Panelists:** **Dr. Sujai Hegde, Dr. Vishnu Agarwal, Dr. Krunal Khobragade, Dr. Satish Kumar, Dr. Shishir Shetty**
12:45 pm – 01:15 pm	TaTME for cancer rectum Video Presenter : **Dr. Taha Shaikh** **Moderator: Dr. Avanish Saklani** **Panelists:** **Dr. Ghanish Panjwani, Dr. Amit Bagdia, Dr. Ajesh Raj Saxena, Dr. Satish Pawar, Dr Ninad Katdare**

Click on below link to register
https://www.riverroute.in/gireview

Managed by riverroute® Leaders in Streaming Modules

6th Annual International Review on GI Cancers

GKCT — Compassion Service Education

Academic Partners

Bristol Myers Squibb™

AstraZeneca

Roche

Lilly

ETHICON — PART OF THE Johnson & Johnson FAMILY OF COMPANIES — Shaping the future of surgery

zydus — Dedicated To Life

Glenmark oncology — It's Our Commitment

ALKEM Oncology

Emcure®

INTAS ONCOLOGY

Dr. Reddy's

FRESENIUS KABI — caring for life

SUN ONCOLOGY — a SUN PHARMA division

Cipla

NATCO

LUPIN ONCOLOGY — We Care...

HETERO HEALTHCARE

4baseCare — Together, We Beat Cancer

Click on below link to register
https://www.riverroute.in/gireview

Managed by riverroute® — Leaders in Streaming Modules

For the 1ST time in Upper GI Cancer in India,

START CONVERSATION IN YEARS

OPDYTA® (nivolumab)

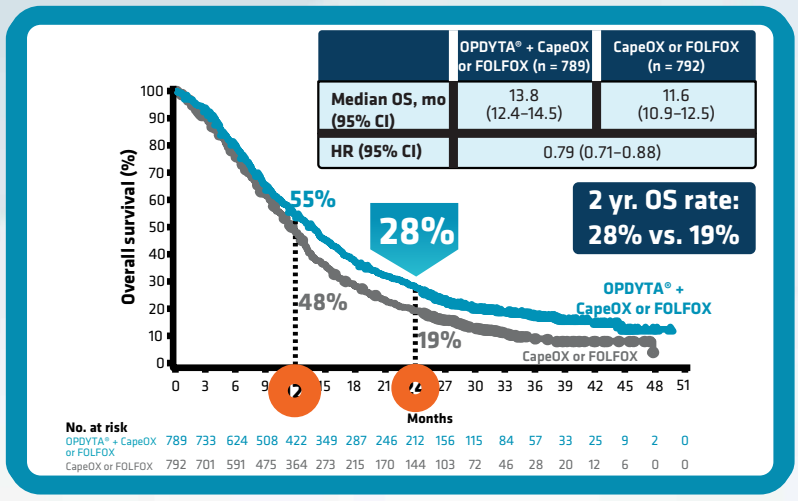
EXPECT MORE. DO MORE.

Overall Survival benefit was superior with OPDYTA® + FOLFOX or CapeOX in all comers including PDL1 CPS ≥ 5. 28% alive at 2-yr[1]

Response Rates were higher with OPDYTA® + FOLFOX or CapeOX, 58% responded including 11% complete responders among all comers[1]

Safety Profile was manageable with OPDYTA®+ FOLFOX or CapeOX where No new safety signals were observed with maintained quality of life[1]

OPDYTA® + FOLFOX or CapeOX demonstrated OS benefit in all randomized patients[1]



28% patients with advanced or metastatic Gastric cancer/GEJC/EAC including CPS ≥ 5 were alive at 2 years in OPDYTA® treated arm

Grade 3–4 treatment-related adverse events (TRAEs) occurred in 60% and 45% of patients with Opdyta plus FOLFOX or CapeOX vs. CapeOx[1]

The picture is fictitious may not be representative of general population.

Ref: 1. Janjigian YY, et al. Lancet 2021;398:27-40

Abridged Prescribing Information (API): To be sold by retail on the prescription of a Registered Oncologist only. OPDYTA® 10 mg/mL concentrate for solution for infusion. Composition: One vial of 4 mL contains 40 mg of nivolumab; One vial of 10 mL contains 100 mg of nivolumab. **Therapeutic Indications:** Non-Small Cell Lung Cancer (NSCLC): As a single agent for the treatment of locally advanced or metastatic NSCLC after prior chemotherapy. Nivolumab, in combination with ipilimumab, is indicated for the first-line treatment of adult patients with metastatic NSCLC whose tumors express PD-L1 (≥1%) as determined by a validated test, with no EGFR or ALK genomic tumor aberrations. Nivolumab, in combination with ipilimumab and 2 cycles of platinum-doublet chemotherapy, is indicated for the first-line treatment of adult patients with metastatic or recurrent NSCLC, with no EGFR or ALK genomic tumor aberrations; Renal Cell Carcinoma (RCC): As a single agent for the treatment of patients with advanced RCC after prior therapy in adults and for the treatment of patients with intermediate or poor risk, previously untreated advanced renal cell carcinoma, in combination with ipilimumab; Squamous Cell Carcinoma of the Head and Neck (SCCHN): As monotherapy for the treatment of recurrent or metastatic SCCHN after platinum-based therapy; Melanoma: As a single agent for the treatment of patients with BRAF V600 wildtype unresectable or metastatic melanoma, as a single agent for the treatment of patients with BRAF V600 mutation positive unresectable or metastatic melanoma, For the treatment of patients with melanoma with lymph node involvement or metastatic disease who have undergone complete resection, in the adjuvant setting; Classical Hodgkin Lymphoma (cHL): For the treatment of adult patients with cHL that has relapsed or progressed after – autologous hematopoietic stem cell transplantation (HSCT) and brentuximab vedotin / 3 or more lines of systemic therapy that includes autologous HSCT; Urothelial Carcinoma (UC): For the treatment of patients with locally advanced or metastatic UC who have disease progression during or following platinum-containing chemotherapy OR have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy; Colorectal Cancer (CRC): As monotherapy for the treatment of adult and pediatric (12 years and older) patients with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic CRC that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. Esophageal Squamous Cell Carcinoma(ESCC): for the treatment of patients with unresectable advanced, recurrent, or metastatic ESCC after prior fluoropyrimidine- and platinum-based chemotherapy; Gastric Cancer, Gastroesophageal Junction Cancer, and Esophageal Adenocarcinoma (GC, GEJC or EAC): Nivolumab, in combination with fluoropyrimidine- and platinum-containing chemotherapy for the treatment of patients with advanced or metastatic gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma. Adjuvant treatment of Resected Esophageal or Gastroesophageal Junction Cancer (EC or GEJC): As monotherapy for the adjuvant treatment of completely resected esophageal or gastroesophageal junction cancer with residual pathologic disease in patients who have received neoadjuvant chemoradiotherapy (CRT). **Dosage and administration:** Nivolumab as monotherapy (NSCLC, RCC, SCCHN, melanoma, cHL, UC, CRC) : 3 mg/kg administered intravenously every 2 weeks over 30 minutes or Flat dosing: 240 mg every 2 weeks (30-minute intravenous infusion) or 480 mg every 4 weeks (30-minute intravenous infusion) Nivolumab as monotherapy for ESCC, EC and GEJC: Weight-based dosing - 3 mg/kg every 2 weeks over a period of 30 minutes Or Flat dosing- 240 mg every 2 weeks or 480 mg every 4 weeks, (30-minute intravenous infusion) For adjuvant treatment, the maximum duration of nivolumab is 12 months. Nivolumab in combination with fluoropyrimidine- and platinum-containing chemotherapy GC, GEJC and EAC: 360 mg Nivolumab intravenously over 30 minutes in combination fluoropyrimidine- and platinum-containing chemotherapy every 3 weeks or 240 mg nivolumab intravenously over 30 minutes in combination with fluoropyrimidine and platinum-based chemotherapy every 2 weeks until disease progression or unacceptable toxicity. The maximum treatment duration for nivolumab is 24 months. Nivolumab in combination with ipilimumab and platinum-based chemotherapy (NSCLC): The recommended dose is 360 mg nivolumab administered as an intravenous infusion over 30 minutes every 3 weeks in combination with 1 mg/kg ipilimumab administered as an intravenous infusion over 30 minutes every 6 weeks, and platinum chemotherapy administered every 3 weeks. **After completion of 2 cycles of chemotherapy,** treatment is continued with 360 mg nivolumab administered as an intravenous infusion every 3 weeks in combination with 1 mg/kg ipilimumab every 6 weeks until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression. Nivolumab in combination with ipilimumab (RCC): Combination phase: nivolumab 3 mg/kg over 30 minutes every 3 weeks for the first 4 doses incombination with ipilimumab 1 mg/kg over 30 minutes, followed by the single-agent phase. Single-agent phase: 3 mg/kg every 2 weeks over 30 minutes. or 240 mg every 2 weeks (30-minute intravenous infusion) or 480 mg every 4 weeks (30-minute intravenous infusion) The first dose of nivolumab monotherapy should be administered 3 weeks following the last dose of the combination of nivolumab and ipilimumabNivolumab in combination with ipilimumab (NSCLC): The recommended dose of nivolumab is 3 mg/kg administered intravenously over a period of 30 minutes every 2 weeks combined with ipilimumab 1 mg/kg administered intravenously over a period of 30 minutes every 6 weeks until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression. For all combination therapy When administered in combination with ipilimumab, with ipilimumab and chemotherapy, or with other therapeutic agents, nivolumab should be given first followed by ipilimumab (if applicable) and then chemotherapy or other therapeutic agents on the same day, **Safety related information Contraindications: None. Warnings and Precautions:** Recommended treatment modifications for nivolumab or nivolumab in**combination with ipilimumab Immune-related pneumonitis:** Withhold for grade 2 and permanently discontinue for grade 3 or 4 pneumonitis. **Immune-related colitis:** Withhold for Grade 2 diarrhoea or colitis. Withhold Nivolumab monotherapy for Grade 3 diarrhoea or colitis. Permanently discontinue nivolumab + ipilimumab for Grade 3 to 4 diarrhea or colitis. Permanently discontinue nivolumab monotherapy for Grade 4 diarrhea or colitis. Immune-related hepatitis: Monitor for change in liver function. Withhold for grade 2 and permanently discontinue for grade 3 or 4 elevation in aspartate aminotransferase (AST), alanine aminotransferase (ALT), or total bilirubin. Immune-related nephritis and renal dysfunction: Monitor for changes in renal function. Withhold for grade 2 or 3 and permanently discontinue for grade 4 serum creatinine elevation. **Immune-related endocrinopathies:** Monitor for changes in thyroid function. Initiate thyroid hormone replacement as needed. Monitor for hyperglycaemia. Withhold for symptomatic grade 2 or 3 and permanently discontinue for grade 4 hypophysitis. Withhold for grade 2 and permanently discontinue for grade 3 or 4 adrenal insufficiency. Withhold for symptomatic grade 2 or 3 and permanently discontinue for grade 4 hypothyroidism or hyperthyroidism. Withhold for grade 3 and permanently discontinue for grade 4 diabetes. **Immune-related skin adverse reactions:** Withhold for grade 3 rash or suspected Stevens- Johnson syndrome (SJS) or toxic epidermal necrolysis (TEN) and permanently discontinue for grade 4 rash or confirmed SJS/TEN. **Other immune-related adverse reactions:** Withhold for grade 3 (first occurrence) and permanently discontinue for grade 3 myocarditis, grade 4 or recurrent grade 3, persistent grade 2 or 3 despite treatment modification, inability to reduce corticosteroid dose to 10 mg prednisone or equivalent per day. When nivolumab is administered in combination with ipilimumab, if either agent is withheld, the other agent should also be withheld. If dosing is resumed after a delay, either the combination treatment or nivolumab monotherapy could be resumed based on the evaluation of the individual patient. Complications of allogeneic hematopoietic stem cell transplant (HSCT) after Nivolumab: Monitor for transplant-related complications, including GVHD. Fatal cases have been reported in clinical studies. Infusion reaction: Discontinue for severe and life-threatening infusion reactions. Patients with mild or moderate infusion reaction may receive nivolumab or nivolumab in combination with ipilimumab with close monitoring and use of premedication according to local treatment guidelines. Increased mortality in patients with multiple myeloma [not an approved indication] when a PD-1 blocking antibody is added to a thalidomide analogue and dexamethasone: Treatment of patients with multiple myeloma with a PD-1 blocking antibody in combination with a thalidomide analogue plus dexamethasone is not recommended outside of controlled clinical trials. **Drug Interactions:** Inhibition or induction of cytochrome P450 (CYP) enzymes or other drug metabolizing enzymes by coadministered medicinal product is not anticipated to affect the pharmacokinetics of nivolumab. The use of systemic corticosteroids and other immunosuppressants at baseline, before starting nivolumab, should be avoided. However, these can be used after starting nivolumab to treat immune-related adverse reactions. **Pregnancy:** Not recommended during pregnancy and in women of childbearing potential not using effective contraception unless the clinical benefit outweighs the potential risk. Women should be advised to use effective contraception for at least 5 months following the last dose of nivolumab. **Nursing Mothers:** Discontinue breastfeeding. **Pediatric Use:** The safety and efficacy have not been established. **Geriatric Use:** No dose adjustment is required for elderly patients (≥65 years). **Hepatic Impairment:** No dose adjustment is required in patients with mild or moderate hepatic impairment. **Renal Impairment:** No specific dose adjustment is necessary in patients with mild to moderate renal impairment. **Adverse Reactions:** Fatigue, rash, musculoskeletal pain, pruritus, diarrhea, nausea, cough, dyspnea, constipation, decreased appetite, back pain, arthralgia, upper respiratory tract infection, pyrexia, headache, abdominal pain, vomiting, neutropenia, hypothyroidism. Nivolumab is associated with immune-related adverse reactions. Most of these, including severe reactions, resolved following initiation of appropriate medical therapy or withdrawal of Nivolumab. **Overdose:** Closely monitor for signs and symptoms of adverse reactions and institute appropriate symptomatic treatment. **Storage:** Store in a refrigerator (2°C-8°C). Do not freeze. API based on prescribing information version 14.1 dated 15 Nov 2022 Issued - 16.01.2023 **Before prescribing, consult full prescribing information.**

Bristol Myers Squibb™

For further information, please contact-

Bristol-Myers Squibb India Private Limited, 6th floor, Tower 1, One International Center, S.B. Marg, Elphinstone (W), Mumbai - 400013. Tel: + 91 22 6628 8600

1506-IN-2300015 Expiry date: 15 Feb. 2024

4baseCare

*Together, **We Beat** Cancer*

Emcure
SUCCESS THROUGH INNOVATION

Presenting

India's 1st FCM Brand

To optimize needs of Patients with

IRON DEFICIENCY ANEMIA (IDA)

Encicarb® 750

Ferric Carboxymaltose Injection

Optimum Dose for Optimum Results

Faster Hb rise

> 12 g/dL compared to 1 gm at Day 56[1]

Better iron reserves

replenishment compared to 1 gm[1]

Safe Infusion

750 mg was safe and well tolerated[1,2]

1. Barish CF, Koch T, Butcher A, Morris D, Bregman DB. Safety and Efficacy of Intravenous Ferric Carboxymaltose (750 mg) in the Treatment of Iron Deficiency Anemia: Two Randomized, Controlled Trials. Anemia. 2012;2012:172104..
2.Hussain I, Bhoyroo J, Butcher A, Koch TA, He A, Bregman DB. Direct Comparison of the Safety and Efficacy of Ferric Carboxymaltose versus Iron Dextran in Patients with Iron Deficiency Anemia. Anemia. 2013;2013:169107.

Prescribing Information

Composition: Each ml contains Ferric Carboxymaltose equivalent to elemental Iron 50 mg. **Presentation:** Vials of 15 ml. For further details, please consult the full prescribing information. **Indications:** For treatment of iron deficiency when oral iron preparations are ineffective or cannot be used. Dosage: The cumulative dose for repletion of iron using ferric carboxymaltose is determined based on the patient's body weight and haemoglobin (Hb) level and must not be exceeded. For Hb <10 g/dl- body weight 35 kg to <70 kg: 1500 mg, body weight ≥70 kg: 2000 mg. For Hb >10 g/dl - body weight 35 kg to <70 kg: 1000 mg, body weight ≥70 kg: 1500 mg. A cumulative iron dose of 500 mg should not be exceeded for patients with body weight < 35 kg. For overweight patients, a normal body weight/blood volume relation should be assumed when determining the iron requirement. Maximum tolerated single dose: 1000 mg of iron (20 ml) per day or 15 mg of iron (0.3 ml) per kg body weight. Do not administer 1000 mg of iron (20 ml) more than once a week. **Intravenous injection:** Undiluted solution up to 1000 mg iron. For doses greater than 200 and up to 500 mg iron, ferric carboxymaltose should be administered at a rate of 100 mg/min. For doses greater than 500 and up to 1000 mg iron, ferric carboxymaltose should be administered over 15 minutes. **Intravenous drip infusion:** Intravenous infusion up to a maximum single dose of 20 ml of Ferric Carboxymaltose Injection (1000 mg of iron). Ferric Carboxymaltose Injection must be diluted only in sterile 0.9% sodium chloride solution. A single maximum daily injection dose of 200 mg iron should not be exceeded in haemodialysis-dependent chronic kidney disease patients. **Contra-indications:** Contraindicated in cases of known hypersensitivity to Ferric Carboxymaltose Injection or to any of its excipients, anemia not attributed to iron deficiency (e.g. other microcytic anemia), evidence of iron overload or disturbances in utilization of iron, and in pregnancy in the first trimester. **Adverse reactions:** Headache, dizziness, nausea, abdominal pain, constipation, diarrhea, injection site reactions and rash are commonly reported adverse reactions. **Use in special population:** Pregnancy: A careful risk/benefit evaluation is required before use during pregnancy. Use during pregnancy may influence skeletal development in the fetus. **Lactation:** Based on limited data on nursing women it is unlikely that Ferric Carboxymaltose Injection represents a risk to the nursing child. **Overdosage:** May lead to accumulation of iron in storage sites eventually leading to haemosiderosis. Monitoring of iron parameters such as serum ferritin and transferrin saturation may assist in recognizing iron accumulation.

Emcure®
SUCCESS THROUGH INNOVATION

Emcure Pharmaceuticals Ltd.
Survey No. 255/2, Phase-I, M.I.D.C., Hinjawadi, Pune - 411057
Tel: +91 20 39821000 • Website: www.emcure.com
/emcurepharmaofficial /emcurepharma /emcurepharma

ENC/0723/14

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only.

For any medical query, please write to us on **emquest@emcure.co.in**
To report any adverse event or product complaint, please write to **Safety.IN@emcure.co.in**

HELSINN
Building quality cancer care toge

glenmark

5 YEARS OF Akynzeo® IN INDIA

A Journey from clinical trials to Real life experience

Tried, tested and trusted in India since 5 years[1]

Robust real world **Indian data of >1000 patients**[1,2*]

Established safety in more than **50,000 Indian patients**[3]

Scan here to access **ABPI**

Ref.: 1. World J Clin Oncol 2020; 11(8): 510-678 | 2. Vaswani, B., Dattatreya, P.S.et al. The effectiveness of NEPA in the prevention of chemotherapy-induced nausea vomiting among chemo naive patients in an Indian setting. BMC Cancer 21, 601 (2021)
3. Data on file | * Includes published and to be published Data

FRESENIUS KABI

caring for life

Relentless and Persistent endeavor towards better Quality & patient Safety

Fresenius Kabi Presents a comprehensive range of quality products

Nanoxel®
Paclitaxel Nanoparticle
Nano Edge Paclitaxel

Intaxel®
Paclitaxel

Daxotel™
Docetaxel
The Superior Choice

Irinotel®
Irinotecan
A Step Ahead

Oxitan™
Oxaliplatin
The Platinum Edge

VINELBINE®
Vinorelbine

CLADRIM™
Cladribine 10 mg Injection

THALIX®
Thalidomide Capsules USP

Fresenius Kabi India Pvt. Ltd.
A-3, MIDC, Ranjangaon Ganpati, Tal.- Shirur, Dist.- Pune - 412220 Maharashtra, India. Consumer Care No.- 09158898288
Website: www.fresenius-kabi.com E-mail id: fkipl@fresenius-kabi.com CIN : U24231PN1995PTC014017

Cipla

Caring for Life & Beyond...
With Innovator Legacy Brands

AVASTIN®
bevacizumab

Bringing Life to Survival

Herclon™
trastuzumab

Your partner for HER future

In treatment of **NHL & CLL**

RISTOVA
THE INNOVATOR'S RITUXIMAB

For the use of Oncologists/ Canc
er hospital/ Laboratory only

For Prescribing Information- Scan QR Code

Avastin | Herclon | Ristova

Valid till 20-Jun-2023 I M-IN-00001726

Cipla ONCOLOGY
Pioneering Cancer Care | Embracing Lives

For any further information, please contact:
Cipla Ltd., Regd. Office: Cipla House,
Peninsula Business Park, Ganpatrao Kadam Marg,
Lower Parel, Mumbai – 400013, India.
Website: www.cipla.com

ALKEM Oncology

CETUXA

Cetuximab 100 mg/20 ml

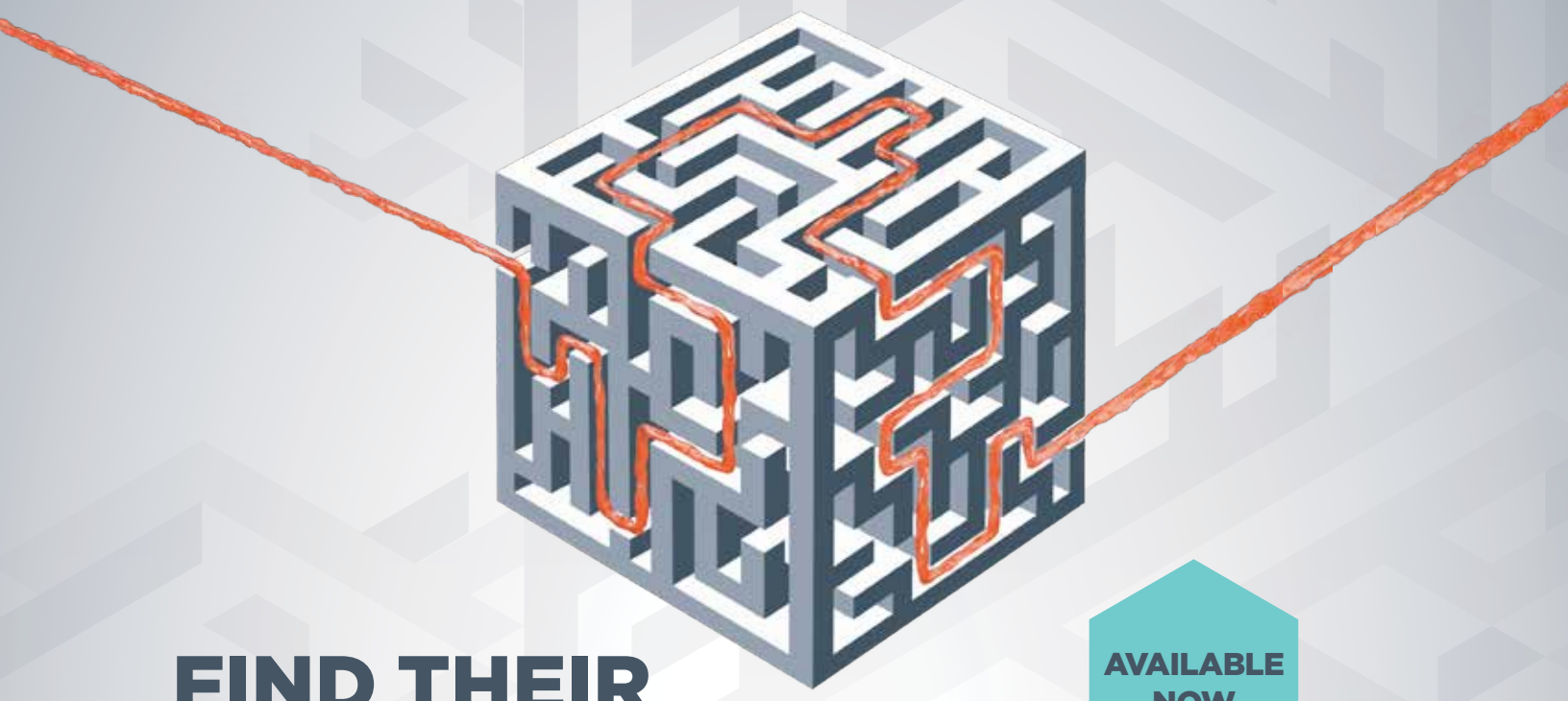
...adds hope

In locally advanced & metastatic head and neck cancer

- Established biosimilarity[1]
- Developed by Alkem Laboratories (Enzene Biosciences)
- Affordable

1. Data on file

FOUNDATIONONE® LIQUID CDx



FIND THEIR PERSONALISED PATH WITH LIQUID BIOPSY

AVAILABLE NOW

See a way forward for patients with solid tumours - using FoundationOne® Liquid CDx, our **FDA-approved liquid biopsy** comprehensive genomic profiling service, as a **minimally-invasive** option, **alternative or complementary** to FoundationOne CDx, at **optimal times beneficial to their treatment journey.**[1-3]

Covers 324 Genes	**Reports SNVs, Indels, amplifications and Gene fusions**	**Also reports Blood Tumour Mutation Burden (bTMBs) and Tumour Fraction**

Analytical And Clinical Validation Done Using Over 7500 Samples Assay Reproducibility Is 99.5%

For more information reach out to your Roche FMI PHC partner or email us at india.foundation@roche.com

Learn more at: www.foundationmedicine.in

Abbreviations:
CDx, companion diagnostic; **FDA,** US Food and Drug Administration; **TMB,** tumor mutational burden; **Indels,** Insertion-deletion mutation; **SNVs,** Single-nucleotide variants.

References:
1. Data on file: FoundationOne Liquid CDx Technical Specifications, 2020. Available at: www.eifu.online/FMI/190070862. **2.** Data on file: Clinical and analytical validation data file for FoundationOne Liquid CDx. **3.** FoundationOne Liquid CDx FDA Approval, 2020. Available at: https://www.foundationmedicine.com/press-releases/445c1f9e-6cbb-488b-84ad-5f133612b721 (Accessed August 2020). Foundation Medicine® and FoundationOne® are registered trademarks of Foundation Medicine®, Inc. Roche is the licensed distributor of Foundation Medicine® products outside of the United States.

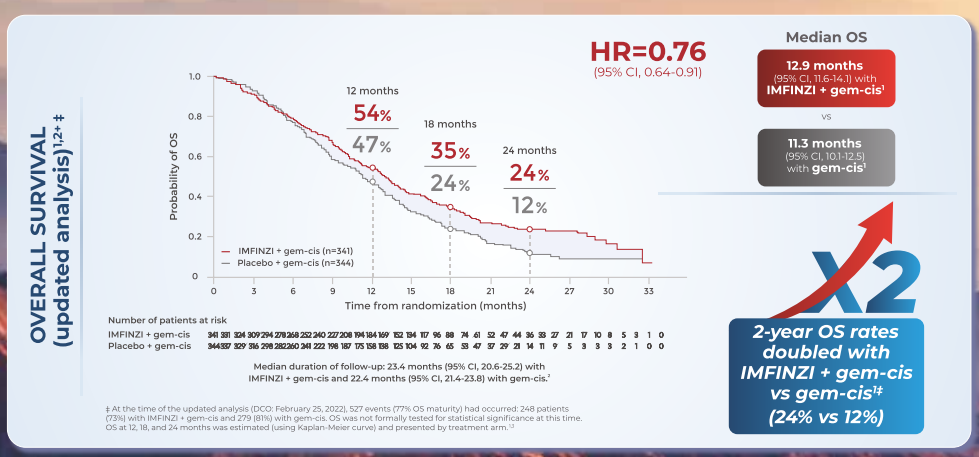
FOUNDATION MEDICINE® | Roche

See more, do more

AstraZeneca

THE FIRST AND ONLY APPROVED IMMUNOTHERAPY THAT OFFERS SUSTAINED AND DURABLE 2 YEAR'S* OVERALL SURVIVAL IN 1ST LINE LOCALLY ADVANCED OR METASTATIC BTC[1]

IMFINZI in combination with chemotherapy is indicated for the treatment of patients with locally advanced or metastatic biliary tract cancer (BTC).



IMFINZI™
durvalumab
Injection for Intravenous Use 50 mg/mL

FROM THE DEPTH OF THE OCEANS TO A NEW PEAK IN THE TREATMENT OF BILIARY TRACT CARCINOMA

1. IMFINZI [Prescribing Information]. Bangalore: AstraZeneca Pharma INDIA Limited **2.** Oh DY, He AR, Qin S, et al. Updated overall survival from the Phase 3 TOPAZ-1 study of durvalumab or placebo plus gemcitabine and cisplatin in patients with advanced biliary tract cancer. Poster presented at: 2022 ESMO Congress; September 9-13, 2022; Paris, France.
Version 9: 31 August 2022 [*As on 18/02/2023
BTC: Biliary Tract Carcinoma **OS:** Overall Survival **HR:** Hazard Ratio **CI:** Confidence Interval **DCO:** Death Certificates Only

Rx DURVALUMAB Solution for INFUSION (IMFINZI™) Vial 500 mg (500mg/10mL) and 120 mg (120 mg/2.4mL) For the use of a registered oncologist only, QUALITATIVE AND QUANTITATIVE COMPOSITION : Each mL contains 50 mg of IMFINZI. Each vial of 2.4 mL contains 120 mg of durvalumab. Each vial of 10 mL contains 500 mg of durvalumab. IMFINZI is a human immunoglobulin (IgG1 κ) monoclonal antibody. **THERAPEUTIC INDICATIONS:** Locally Advanced Non-small Cell Lung Cancer (NSCLC), IMFINZI is indicated for the treatment of patients with locally advanced, unresectable Non-small Cell Lung Cancer (NSCLC) whose disease has not progressed following platinum-based chemoradiation therapy, Small Cell Lung Cancer (SCLC)- IMFINZI in combination with etoposide and either carboplatin or cisplatin is indicated for the first-line treatment of patients with extensive-stage small cell lung cancer (ES-SCLC), Biliary Tract Cancer(BTC)- IMFINZI in combination with chemotherapy is indicated for the treatment of patients with locally advanced or metastatic biliary tract cancer (BTC). **POSOLOGY AND METHOD OF ADMINISTRATION: Locally Advanced NSCLC** - The recommended dose of IMFINZI is 10 mg/kg administered as an intravenous infusion every 2 weeks or 1500 mg every 4 weeks, until disease progression or unacceptable toxicity. Dose escalation or reduction is not recommended. Dose withholding or discontinuation may be required based on individual safety and tolerability. ES-SCLC 1500 mg in combination with chemotherapy, every 3 weeks (21 days) for 4 cycles, followed by 1500 mg every 4 weeks as monotherapy Until disease progression or unacceptable toxicity. **BTC** The recommended dose is 1500 mg in combination with chemotherapy every 3 weeks (21 days), followed by 1500 mg every 4 weeks as monotherapy until disease progression or unacceptable toxicity. **CONTRAINDICATIONS:** None. **WARNINGS & PRECAUTIONS** Given the mechanism of action of IMFINZI®, potential immune-mediated adverse reactions may occur. Patients should be monitored for signs and symptoms and managed as recommended in the full prescribing information. For suspected immune-mediated adverse reactions, adequate evaluation should be performed to confirm etiology or exclude alternate etiologies. Withholding of IMFINZI should be considered for Grade 3 immune-mediated adverse reactions, unless clinical judgment indicates discontinuation. Systemic corticosteroids should be considered. Permanently discontinue IMFINZI for life-threatening (Grade 4) immune-mediated adverse reactions. **Special patient populations Paediatric and adolescents** The safety and effectiveness of IMFINZI have not been established in children and adolescents aged less than 18 years. **Elderly (≥65 years)** No dose adjustment is required for elderly patients (≥65 years of age) **Renal Impairment** Based on a population pharmacokinetic analysis, no dose adjustment of IMFINZI is recommended in patients with mild or moderate renal impairment. **Hepatic Impairment** Based on a population pharmacokinetic analysis, no dose adjustment of IMFINZI is recommended for patients with mild or moderate hepatic impairment. IMFINZI has not been studied in patients with severe hepatic impairment. **Fertility, Pregnancy and Lactation Pregnancy** Durvalumab is not recommended during pregnancy and in women of childbearing potential not using effective contraception during treatment and for at least 3 months after the last dose. **Breast-feeding** Because of the potential for adverse reactions in breastfed infants from durvalumab, advise lactating women not to breastfeed during treatment and for at least 3 months after the last dose. **Fertility** There are no data on the potential effects of durvalumab on fertility in humans. In repeat-dose toxicology studies with durvalumab in sexually mature cynomolgus monkeys of up to 3 months duration, there were no notable effects on the male and female reproductive organs. **Interaction with other medicinal products and other forms of interaction** Durvalumab is an immunoglobulin, therefore no formal pharmacokinetic drug-drug interaction studies have been conducted with durvalumab. **PHARMACOLOGICAL PROPERTIES Pharmacodynamic properties Mechanism of Action** Durvalumab is a fully human, high affinity, immunoglobulin G1 kappa (IgG1κ) monoclonal antibody that selectively blocks the interaction of PD-L1 with PD-1 and CD80 (B7.1) while leaving PD-1/PD-L2 interaction intact. Durvalumab does not induce antibody dependent cell mediated cytotoxicity (ADCC). Selective blockade of PD-L1/PD-1 and PD-L1/CD80 interactions enhances anti-tumour immune responses. These anti-tumour responses may result in tumour elimination. In preclinical studies, PD-L1 blockade led to increased T-cell activation and decreased tumour size. **Pharmacokinetic properties** Pharmacokinetic (PK) exposure increased more than dose-proportionally (non-linear PK) at doses <3 mg/kg and dose proportionally (linear PK) at doses ≥ 3 mg/kg. Steady state was achieved at approximately 16 weeks. Based on population PK analysis that included 1878 patients in the dose range of ≥ 10 mg/kg Q2W, the geometric mean steady state volume of distribution [Vss] was 5.64 L. The terminal half-life (t1/2), based on baseline CL, was approximately 18 days. **Incompatibilities:** Durvalumab- No incompatibilities between IMFINZI and 9 g/L (0.9%) sodium chloride or 50 g/L (5%) dextrose in polyvinylchloride or polyolefin IV bags have been observed. IMFINZI infusion solution must not be mixed with other drug products. Do not co-administer other drugs through the same intravenous line. **Instructions for handling and disposal** -Preparation of solution. IMFINZI is supplied as a single-dose vial and does not contain any preservatives, aseptic technique must be observed. Visually inspect drug product for particulate matter and discoloration. IMFINZI is clear to opalescent, colorless to slightly yellow solution. Discard the vial if the solution is cloudy, discolored or visible particles are observed. Do not shake the vial. Administration - Administer infusion solution intravenously over 60 minutes through an intravenous line containing a sterile, low-protein binding 0.2 or 0.22 micron in-line filter. **For full prescribing information, please contact: AstraZeneca Pharma India Limited, Block N1, 12th Floor Manyata Embassy Business Park Rachenahalli, Outer Ring Road Bangalore – 560045.** www.astrazenecaindia.com Based on prescribing information Version 9, dated 31 Aug 2022

For the use of registered oncologist only

AstraZeneca

AstraZeneca Pharma India Limited,
Block N1, 12th Floor, Manyata Embassy Business Park, Outer Ring Road, Bangalore - 560045
www.astrazeneca.com

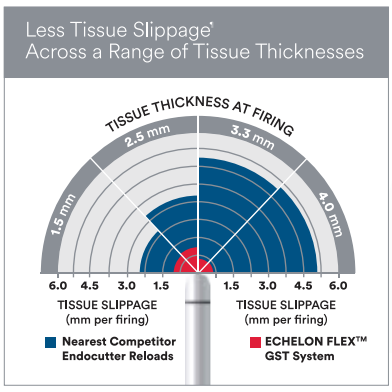
Approval ID : IN-11306 | Approval Date : 24/02/2023 | Expiry Date : 24/02/2025

Echelon™ with GST Reloads

A Better Grip on Movement

Now experience the least tissue slippage during firing

The ECHELON FLEX™ GST System* is uniquely designed for better grip to provide you the least tissue slippage during firing. Its enhanced end effector and proprietary reloads with Gripping Surface Technology now deliver 4X less tissue slippage‡ and reliable staple formation across a range of tissue thickness.§



Harmonic

HARMONIC ACE®+7 Shears

with Advanced Hemostasis

Adaptive Tissue Technology

- Delivers energy intelligently
- Utilizes an advanced algorithm
- Responds to changing tissue conditions
- Provides enhanced audible feedback

Advanced Hemostasis mode

- Congulates vessels up to 7mm in diameter with the use of the Advanced Hemostasis hand control button

241140-230225

* System components include ECHELON FLEX™ Powered Plus Stapler and ENDOPATH ECHELON™ Reloads with Gripping Surface Technology

† Benchtop testing in porcine stomach tissue. Mean tissue movement from after clamping on tissue to after firing ECHELON FLEX Powered Plus Stapler (PSEE60A) and ECHELON Reload with GST vs ENDO GIA™ ULTRA Handle (EGIAUSTND) and Endo GIA™ Reload with Tri-Staple™ Technology at 1.5, 2.5, 3.3 and 4.0mm tissue thicknesses (1.5mm; GST60B 1.067mm vs EGIA60AMT 2.452mm p<0.001; 2.5mm: GST60G 1.148mm vs EGIA60AMT 3.261mm p<0.001; 3.3mm: GST60T 0.642mm vs EGIA60AMT 4.806mm p<0.001; 4.0mm: GST60T 0.654mm vs EGIA60AXT 5.116mm p<0.001).

‡ Benchtop testing in porcine stomach tissue. Mean tissue movement from after clamping on tissue to after ENDOPATH ECHELON™ Powered Plus Stapler (PSEE60A) and ECHELON Reload with GST vs ENDO GIA™ ULTRA Handle (EGIAUSTND) and Endo GIA™ Reload with Tri-Staple™ Technology at 3.3 and 4.0mm tissue thicknesses (3.3mm: GST60T 0.642mm vs EGIA60AMT 4.806mm p<0.001; 4.0mm: GST60T 0.654mm vs EGIA60AXT 5.116mm p<0.001).

§ Porcine tissue thickness ranging from 1.0mm to 4.0mm measured at 8g/mm² prior to firing. Tissue comfortably compressed to closed staple height per IFU.

¶ Benctop testing in porcine stomach tissue. Mean tissue movement from after clamping on tissue to after firing ECHELON FLEX Powered Plus Stapler (PSEE60A) and ECHELON Reload with GST vs nearest competitoe endocutter technology at 15, 2.5, 3.3 and 4.0mm tissue thicknesses.

Please refer to product Instructions For Use (IFU) for complete product information including warnings, precautions and adverse events.
Login www.jmedir.com for additional Medical Information request (MIR) or email to MIRIndia@its.jnj.com

ETHICON
Johnson & Johnson SURGICAL TECHNOLOGIES

Reimagining how we heal™

S-One Trio 15 mg / 20 mg

Tegafur + Gimeracil + Oteracil Potassium

Coming Together for Better Tomorrow

Tegafur

Prodrug of 5-fluorouracil (5-FU) Replacement for infusional 5-FU therapy

Oteracil

Modulator to reduce unwanted 5-FU-induced gastrointestinal toxicity, as it is related to phosphorylation of 5-FU

Gimeracil

Modulator to enhance the efficacy of tegafur by inhibiting catabolism and subsequent inactivation of 5-FU by inhibiting the enzyme DPD, so that concentrations of 5-FU are maintained for a longer period of time

Increased Convenience

Reduced Toxicity

Enhanced Efficacy

ABRIDGED PRESCRIBING INFORMATION: S-One Trio 15/20 mg
COMPOSITION: Each hard capsule contains 15 mg tegafur, 4.35 mg gimeracil and 11.8 mg oteracil (as monopotassium) and 70.20 mg lactose monohydrate and Excipient with known effect. Each hard capsule contains 20 mg tegafur, 5.8 mg gimeracil and 15.8 mg oteracil (as monopotassium) and 93.6 mg lactose monohydrate. INDICATIONS: Tegafur, Gimeracil and Oteracil (TGO) Capsules is indicated in adults for the treatment of advanced gastric cancer when given in combination with cisplatin. DOSAGE AND ADMINISTRATION: The recommended standard dose of Tegafur/gimeracil/oteracil when administered in combination with cisplatin is 25 mg/m2 (expressed as tegafur content) twice daily, morning and evening, for 21 consecutive days followed by 7 days rest (1 treatment cycle). This treatment cycle is repeated every 4 weeks. CONTRAINDICATIONS: Hypersensitivity to any of the active substances (tegafur, gimeracil, and oteracil) or to any of the excipients. History of severe and unexpected reactions to fluoropyrimidine therapy. Known dihydropyrimidine dehydrogenase (DPD) deficiency. Pregnancy and breast-feeding. Severe bone marrow suppression (severe leukopenia, neutropenia, or thrombocytopenia). End stage renal disease patients requiring dialysis. Co-administration of other fluoropyrimidines with Tegafur/gimeracil/oteracil. Treatment within 4 weeks with DPD inhibitors, including sorivudine or its chemically related analogues such as brivudine. WARNINGS AND PRECAUTIONS: Dose limiting toxicities include diarrhoea and dehydration. Most adverse reactions are reversible and can be managed by symptomatic therapy, dose interruptions and dose reductions. Bone marrow suppression: Treatment related bone marrow suppression, including neutropenia, leukopenia, thrombocytopenia, anaemia, and pancytopenia, has been reported among patients treated with Tegafur/gimeracil/oteracil in combination with cisplatin. Patients with low white blood cell counts should be monitored carefully for infection and risk of other complications of neutropenia and treated as medically indicated (e.g., with antibiotics, granulocyte-colony stimulating factor [G-CSF]). Patients with low platelet counts are at increased risk for bleeding and should be monitored carefully. Hepatitis B reactivation: Administration of tegafur/gimeracil/oteracil in hepatitis B virus carriers, HBc antigen-negative and HBc antibody positive patients, or HBs antigen-negative and HBs antibody positive patients may result in reactivation of hepatitis B. Patients should be tested for HBV infection before initiating treatment with Tegafur/gimeracil/oteracil. Diarrhoea: Patients with diarrhoea should be carefully monitored and given fluid and electrolyte replacement if they become dehydrated. Prophylactic treatment for diarrhoea should be administered as indicated. Standard anti-diarrhoeal therapy (e.g., loperamide) and intravenous fluids/electrolytes should be initiated early when diarrhoea develops. Dose suspension/adjustment should be implemented with the occurrence of Grade 2 or higher diarrhoea if symptoms persist despite adequate treatment. Dehydration: Patients with anorexia, asthenia, nausea, vomiting, diarrhoea, stomatitis, and gastrointestinal obstruction should be monitored closely for signs of dehydration. Dehydration should be managed aggressively with rehydration and other appropriate measures. If Grade 2 (or higher) dehydration occurs, treatment should be immediately suspended, and the dehydration corrected. Renal toxicity: Treatment with Tegafur/gimeracil/oteracil in combination with cisplatin may be associated with a transient decline of glomerular filtration rate caused primarily by pre-renal factors (e.g., dehydration, electrolyte imbalance, etc). Adverse reactions of Grade 3 or higher such as increased blood creatinine, decreased creatinine clearance, toxic nephropathy, and acute renal failure have all been reported in patients receiving Tegafur/gimeracil/oteracil in combination with cisplatin. Severe renal impairment: Treatment with Tegafur/gimeracil/oteracil is not recommended in patients with severe renal impairment due to possibly higher incidence of adverse events of the blood and lymphatic system and the possibility of unexpectedly higher exposure to 5-FU because of fluctuations in renal function in these patients. Ocular toxicity: The most common treatment-related ocular disorders among patients in studies treated with Tegafur/gimeracil/oteracil in combination with cisplatin were lacrimal disorders (8.8%), including increased lacrimation, dry eye, and acquired dacryostenosis. Most ocular reactions will resolve or improve with suspension of medicinal product and proper treatment (instillation of artificial tears, antibiotic eye drops, implantation of glass or silicone tubes in lacrimal punctus or canaliculi, and/or use of spectacles rather than contact lenses). Dihydropyrimidine dehydrogenase (DPD) deficiency: DPD activity is rate limiting in the catabolism of 5-fluorouracil. Patients with DPD deficiency are therefore at increased risk of fluoropyrimidines related toxicity including for example stomatitis, diarrhoea, mucosal inflammation, neutropenia, and neurotoxicity. DPD-deficiency related toxicity usually occurs during the first cycle of treatment or after dose increase. DRUG INTERACTIONS: Brivudine: Brivudine must not be administered concomitantly with Tegafur/gimeracil/oteracil. Fatal cases have been reported following capecitabine interaction. Other fluoropyrimidines: Co-administration of other fluoropyrimidines such as capecitabine, 5-FU, tegafur, or flucytosine can lead to additive toxicities, and is contraindicated. CYP2A6 inhibitors: As CYP2A6 is the major enzyme responsible for the conversion of tegafur to 5-FU, co-administration of a known CYP2A6 inhibitor and Tegafur/gimeracil/oteracil should be avoided as effectiveness of Tegafur/gimeracil/oteracil could be decreased. Coumarin-derivative anticoagulant: The activity of a coumarin-derivative anticoagulant was enhanced by Tegafur/gimeracil/oteracil. Caution is advised as co-administration of Tegafur/gimeracil/oteracil and coumarin anticoagulation therapy may increase the risk of bleeding. Phenytoin: Fluoropyrimidines may increase phenytoin plasma concentration when administered concomitantly with phenytoin causing phenytoin toxicity. Food: Administration of Tegafur/gimeracil/oteracil with a meal reduced exposure to oteracil and gimeracil, with a more pronounced effect for oteracil than for gimeracil. It should be taken with water at least 1 hour before or 1 hour after a meal. ADVERSE REACTIONS: The most common side effects reported in the pivotal study were anemia, neutropenia, vomiting, diarrhea, abdominal pain, weight decrease, anorexia, and fatigue. PRESENTATION: Tegafur 15 mg, Gimeracil 4.35 mg and Oteracil 11.8 mg Capsule. Tegafur 20 mg, Gimeracil 5.8 mg and Oteracil 15.8 mg Capsule. STORAGE: Store below 30°C. Keep all medicines out of the reach and sight of children.
Please refer full prescribing information before using any product.

INTAS ONCOLOGY

INTAS PHARMACEUTICALS LTD.

Corporate House, Magnet Park, Near Sola Bridge, S.G.Highway,
Thaltej, Ahmedabad-380054, Gujarat, INDIA | Website : www.intaspharma.com

LUPIN ONCOLOGY
We Care...

GIVE YOUR HEAD AND NECK CANCER PATIENTS A CHANCE TO WIN THE TOUGHEST BATTLE

INTRODUCING

Rx Lupitux

Cetuximab 100 mg/ 20 ml Injection

Proven Bio-similarity Data*

- **Efficacy***
  Non-inferior to Innovator Cetuximab
- **Safety***
  Comparable to Innovator
- **Immunogenicity***
  Comparable to Innovator

For the use of Registered Medical Practitioner, Hospital or Laboratory only

Reference: *Data on file

Abridged Prescribing Information

Composition: Cetuximab 100 mg/20 mL (r-DNA origin). Solution for Intravenous Infusion in Vial | **Indication:** Cetuximab is indicated for the treatment of patients with squamous cell cancer of the head and neck. **Dosage and administration:** Prior to the first infusion, patients must receive premedication with an antihistamine and a corticosteroid at least 1 hour prior to administration of cetuximab. This premedication is recommended prior to all subsequent infusions. Cetuximab is administered once a week. The initial dose is 400 mg cetuximab per m2 body surface area. All subsequent weekly doses are 250 mg cetuximab per m2 each. In patients with locally advanced squamous cell cancer of the head and neck, cetuximab is used concomitantly with radiation therapy. It is recommended to start cetuximab therapy one week before radiation therapy and to continue cetuximab therapy until the end of the radiation therapy period. In patients with recurrent and/or metastatic squamous cell cancer of the head and neck, cetuximab is used in combination with platinum-based chemotherapy followed by cetuximab as maintenance therapy until disease progression. Chemotherapy must not be administered earlier than 1 hour after the end of the cetuximab infusion. The initial dose should be given slowly and speed of infusion must not exceed 5 mg/min. The recommended infusion period is 120 minutes. For the subsequent weekly doses, the recommended infusion period is 60 minutes. The infusion rate must not exceed 10 mg/min. Paediatric population- There is no relevant use of cetuximab in the paediatric population in the granted indications. | **Contraindications:** Cetuximab is contraindicated in patients with known severe (grade 3 or 4) hypersensitivity reactions to cetuximab. Before initiation of combination treatment, contraindications for concomitantly used chemotherapeutic agents or radiation therapy must be considered. | **Adverse drug reactions:** The main undesirable effects of cetuximab are skin reactions, which occur in more than 80% of patients, hypomagnesaemia which occurs in more than 10% of patients and infusion-related reactions, which occur with mild to moderate symptoms in more than 10% of patients. Other very common to common side effects includes - Dehydration, in particular secondary to diarrhoea or mucositis, hypocalcaemia, anorexia which may lead to weight decrease, Headache, Conjunctivitis; nausea; vomiting; increase in liver enzyme levels (ASAT, ALAT, AP). **Warnings & Precautions:** Infusion-related, including anaphylactic reactions - Severe infusion-related reactions, including anaphylactic reactions, may commonly occur, in some cases with fatal outcome. Occurrence of a severe infusion-related reaction requires immediate and permanent discontinuation of cetuximab therapy and may necessitate emergency treatment. Some of these reactions may be anaphylactic or anaphylactoid in nature or represent a cytokine release syndrome (CRS). A close monitoring of patients, particularly during the first administration, is required. Special attention is recommended for patients with reduced performance status and pre-existing cardio- pulmonary disease. Respiratory disorders - Cases of interstitial lung disease (ILD), including fatal cases, have been reported, with the majority of patients from the Japanese population. Confounding or contributing factors, such as concomitant chemotherapy known to be associated with ILD, and preexisting pulmonary diseases were frequent in fatal cases. Such patients should be closely monitored. In the event of symptoms (such as dyspnoea, cough, fever) or radiographic findings suggestive of ILD, prompt diagnostic investigation should occur. If interstitial lung disease is diagnosed, cetuximab must be discontinued and the patient be treated appropriately. Cardiovascular disorders- An increased frequency of severe and sometimes fatal cardiovascular events and treatment emergent deaths has been observed in the treatment of non-small cell lung cancer, squamous cell carcinoma of the head and neck and colorectal carcinoma. In some studies, association with age ≥ 65 years or performance status has been observed. When prescribing cetuximab, the cardiovascular and performance status of the patients and concomitant administration of cardiotoxic compounds such as fluoropyrimidines should be taken into account. | **Drug interactions:** In combination with platinum-based chemotherapy, the frequency of severe leukopenia or severe neutropenia may be increased. In combination with fluoropyrimidines, the frequency of cardiac ischaemia including myocardial infarction and congestive heart failure as well as the frequency of hand-foot syndrome (palmar-plantar erythrodysaesthesia) were increased compared to that with fluoropyrimidines. In combination with capecitabine and oxaliplatin, the frequency of severe diarrhoea may be increased. **Pregnancy and Lactation:** It is strongly recommended that Cetuximab be given during pregnancy or to any women not employing adequate contraception only if the potential benefit for the mother justifies a potential risk to the foetus. It is recommended that women do not breast-feed during treatment with Cetuximab and for 2 months after the last dose, Because it is not known whether cetuximab is excreted in breast milk. | **Pharmacokinetics:** When cetuximab was administered at an initial dose of 400 mg/m2 body surface area, the mean volume of distribution was approximately equivalent to the vascular space (2.9 L/m2 with a range of 1.5 to 6.2 L/m2). The mean Cmax (± standard deviation) was 185±55 mcg/mL. The mean clearance was 0.022 L/h per m² body surface area. Cetuximab has a long elimination half-life with values ranging from 70 to 100 hours at the target dose. Cetuximab serum concentrations reached stable levels after three weeks of cetuximab monotherapy. Mean peak cetuximab concentrations were 155.8 mcg/mL in week 3 and 151.6 mcg/mL in week 8, whereas the corresponding mean trough concentrations were 41.3 and 58.4 mcg/mL, respectively. In a study of cetuximab administered in combination with irinotecan, the mean cetuximab trough levels were 50.0 mcg/mL in week 12 and 49.4 mcg/mL in week 36.

zydus
Dedicated To Life

We bring
accessible innovation for improved patient care

Introduced for the 1st time in the world

Bryxta™ 300

Bevacizumab 300mg/12ml

- Avoid significant reduction in drug wastage & offer price benefit to the patients
- Improve patient compliance
- Reduce the burden of overall cost of therapy

The only Bevacizumab biosimilar with a comprehensive range.

Rx Bevacizumab Injection Bryxta™ — **Abridged Prescribing Information**

Concentrate for solution for Infusion

300 mg/12mL, single use vial

Description: Bryxta™ is a recombinant humanized monoclonal antibody (containing 1307 amino acids) produced in Chinese hamster ovary cell line. VEGF is a signal protein which stimulates vasculogenesis and angiogenesis. Bevacizumab binds to VEGF, and there by inhibits the binding of VEGF to its receptors, Flt-1 (VEGFR-1) and KDR (VEGFR-2) on the surface of endothelial cells. Because of which vascularization of tumours regresses and formation of new tumour vasculature inhibited.

Therapeutic Indication: Metastatic colorectal cancer, Non-squamous Non-small cell Lung Cancer, Glioblastoma, Metastatic Breast Cancer, Metastatic Renal Cell Carcinoma, Persistent, Recurrent, or Metastatic Carcinoma of the Cervix, Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancer. **Contraindications:** Bryxta™ is contraindicated in patients with hypersensitivity to bevacizumab (active ingredient), excipients, Chinese Hamster Ovary (CHO) cell products, recombinant human or humanized antibodies and pregnancy. **Special Warnings And Precautions For Use:** Gastrointestinal (GI) perforations and Fistulae, GI-vaginal Fistulae, Non-GI Fistulae, wound healing and Surgery complications, Hypertension, Posterior Reversible Encephalopathy Syndrome (PRES), Proteinuria, Arterial Thromboembolism, Venous thromboembolism, Hemorrhage, pulmonary hemorrhage/hemoptysis, Congestive heart failure (CHF), Neutropenia and Infections, Hypersensitivity reactions/ infusion reactions, Systemic effects following Intravitreal use, Eye Disorder, Osteonecrosis of the jaw (ONJ) AND Ovarian failure/fertility. **Fertility, Pregnancy and Lactation:** Women of childbearing potential: Women of childbearing potential have to use effective contraception during (and up to 6 months after) treatment. Bryxta™ is contraindicated in pregnancy. Women must discontinue breast feeding during therapy and not breastfeed for at least six months following the last dose of Bryxta™. **Effects On Ability to Drive and Use machines:** If patients are experiencing symptoms that affect their vision or concentration, or their ability to react, they should be advised not to drive and use machines until symptoms abate. **Overdose:** Severe migraine if dose > 20mg/kg, IV every 2 weeks.

Clinical Trial of Bryxta™ in Indian Patients: Total 248 subjects randomized in this trial, 169 subjects in Bryxta™ and 79 subjects in Bevacizumab (Originator). Total 52 subjects were enrolled in pharmacokinetic assessment, 28 subjects in Bryxta™ and 24 subjects in Bevacizumab (Originator) to have 26 completed subjects in each group for pharmacokinetic assessment after cycle 1. Of which 13 subjects from Bryxta™ and 16 subjects in Bevacizumab (Originator) completed pharmacokinetic assessment after Cycle 6. The primary endpoint was to compare ORR, the sum of complete response (CR) and partial response (PR) at end of study (Cycle 6, day 127) in Bryxta™ with Bevacizumab (Originator), as assessed by Response Evaluation criteria in Solid Tumors (RECIST 1.1). The tumor response evaluation for target lesion and non target lesion in Bryxta™ group was comparable to Bevacizumab (Originator). Majority of subjects had PR (60.00% vs 64.58%) followed by stable disease (30.59% vs 31.25%) at the end of Cycle 6 (Day 127). Summary of best overall response by treatment for per protocol population in Bryxta™ group and Bevacizumab (originator) group was comparable and majority of subjects showed partial response (62.35% vs 70.83%) followed by stable disease (32.94% vs 29.17%). There was no statistical significant difference (p>0.05) observed between test group and reference group. Bryxta™ and Bevacizumab (Originator) were well tolerated by subjects and comparable in safety profiles. The immunogenicity of Bevacizumab following intravenous infusion of Bryxta™ and Bevacizumab (Originator) in Non-small cell lung cancer (NSCLC) subjects was assessed. The incidences of immunogenicity in test product treated group were marginally lower compared to the reference drug product treated subjects (59% vs 73%). The Secondary efficacy variable was to evaluate pharmacokinetics (Cmax and AUC0-t) following IV infusions of Bryxta™ and Bevacizumab (Originator) till Day 22 before the administration of second dose with Bevacizumab in subjects with non-small cell lung cancer (NSCLC) after single dose. The pharmacokinetic assessment of the Ln-transformed Bevacizumab Cycle-1 data showed the 90% confidence intervals for the ratio of the Test geometric least square mean to Reference geometric least square mean are within the 80.00% to 125.00% limits of Cmax (97.99%,120.41) and AUC0-t (93.70%, 122.03%).

Preclinical Safety Data of Bryxta™: Preclinical studies for Bryxta™ were performed as per GLP standards. In acute toxicity studies, Bryxta™ revealed a good safety margin in terms of mortality over the acute dose of 625 mg/kg in mice & 500 mg/kg in rats by intravenous route and were approximately 5X (in mice) and 8X (in rats) of the human equivalent dose. No mortality, apparent signs of toxicity, adverse changes in body weights and gross pathological lesions were noticed in both mice and rats when compared to vehicle-control group. Bryxta™ did not induce any dermal sensitization in guinea pigs. No adverse local tolerance effects were noticed at the site of injection in both rats and rabbits. Comparative studies with repeated biweekly intravenous administration with Bryxta™ was conducted in rats and rabbits over a period of four weeks at dose levels which was 1X, 2.5X & 5X of the human equivalent dose. No differences were noticed in these studies in comparison to reference medicinal product, in both rats and rabbits. No delayed toxicity was noticed during treatment of recovery period of two weeks. The immunogenic response in Bryxta™ treated groups was comparable to that of reference medicinal product treated group. The no observed adverse effect level (NOAEL) of similar biologic of Bevacizumab was considered to be more than 5X of human equivalent dose (310 mg/kg in rats and 155 mg/kg in rabbits) by intravenous administration.

Pharmaceutical Particulars: The active ingredients is bevacizumab and it contains excipients viz;a, a-Trehalose dihydrate, sodium phosphate monobasic monohydrate, Sodium phosphate dibasic anhydrous, polysorbate 20 and water for injections. **Incompatibilities:** Dextrose (5%) solution should not be used since it causes aggregation of the protein. **Storage:** Its shelf life is 24 months. It should be stored at 2°C - 8°C and protect from light. The infusion solution is physically and chemically stable for 77hrs. (Do not store above 30°C). **Special instruction for use, Handing And Disposal:** Aseptic techniques should be used prior to administration, Bryxta™ should be inspected visually for particulate matter and discoloration. The necessary amount of bevacizumab should be withdrawn and diluted to the required administration volume with sodium chloride 9 mg/ml (0.9%) solution for injection. The final concentration should be kept within the range of 1.4 mg/ml to 16.5 mg/ml. Bryxta™ can be diluted with 0.9% sodium chloride solution for Injection to a total volume of 100ml. Any unused medicinal product should be disposed off. **MANUFACTURED BY:** Cadila Healthcare Ltd., Ahmedabad.

6th Annual International

Review on GI Cancers

Compassion Service Education
GKCT

Conference managed by:

riverroute®
Leaders in Streaming Modules

Mr. Yash Jain

Conference Secretariat

rrcg.yash@gmail.com

Mobile +91 77189 50974

Click on below link to register
https://www.riverroute.in/gireview

Managed by riverroute®
Leaders in Streaming Modules