ZEDEX

References:

1. Stan K et al, Cough, cold and Allergy, Applied Pharmacology 2011.
2. Ron Eccles et al. Rational for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults, Journal of Respiratory diseases 2014, 4, 73-82
3. Mayuresh Kiran et.al. Efficacy aand safety of combination of Paracetamol, chlorpheneramine maleate, phenylephrine, sodium citrate and menthol in the symptomatic treatment of common cold and allergic rhinitis: phase IV clinical study, International Journal of Current Medical Arid Pharmaceutical Research, Vol.3, Issue, 05, pp.1804-1808, May 2017

ABPI:

COMPOSITION: Each 5ml of Zedex syrup consists of Dextromethorphan hydrobromide IP : 10 mg Chlorpheniramine maleate IP :2mg Flavored syrup base: qs

INDICATIONS: Cough suppressant, in dry cough and throat irritation

CONTRAINDICATIONS: Hypersensitivity to any of the ingredients. It should not be used as treatment for lower respiratory tract conditions including asthma and during an asthma attack **WARNINGS:** Keep this and all medications out of the reach of children. In case of accidental overdose, seek professional assistance. **PRECAUTIONS:** Pregnancy and Lactation It is not known whether Zedex Syrup can cause fetal harm or is excreted in human milk. Therefore, Zedex Syrup should be given to a pregnant or lactating woman only if clearly needed. Pediatric Use Safety and effectiveness in the pediatric population, under 2years, have not been established. **ADVERSEREACTIONS:** The components of Zedex are well tolerated and adverse effects are very rare. These may include dizziness, headache, sleep disturbances, rashes, and GI disturbance.

DOSAGE AND ADMINISTRATION: Adult-10ml 2-3 times/day.

BRO ZEDEX SYRUP

References:

Approved indication id for the symptomatic relief of bronchospasm in bronchial asthma & bronchitis

1. Vora A. et al., A cross sectional cohort Analyses Accessing Response to Levosalbutamol Bronchodilator Cough Formulation in Outpatient Community Setting of India: BUS'sanalyses.2016; Vol 64.
2. L. Subhrajit Evidence behind use of levosalbutamol over salbutamol to prevent cardiac side effects. Int J Contemp Pediatr. 2017 May: 4 (3):674-678
3. Rahaman A et.al., Levosalbutamol over Salbutamol for the treatment of Acute excebration of Asthma in Bangladesh Children. J of Allergy Ther. 2012 Vol(3)3;
4. Chattopadhyay S et. Al., Artificial sweeteners- A Review. J Food Sci Technol. 2014; 51(4): 611-621.

Data on File **CardioVascular Disease $ Gastro Intestinal

ABPI

COMPOSITION Each 5 ml syrup contains: Bromhexine IP 4 mg, Terbutaline IP 1.25mg, Guaiphenesin IP- 50 mg, Menthol IP 2.5 mg. Flavoured syrup base qs. **INDICATIONS** It is recommended for clinical relief of cough associated with bronchitis, bronchial asthma, emphysema and other bronchopulmonary

disorders where bronchospasm, mucus plugging and difficulty in expectoration coexist **CONTRAINDICATIONS** Hypersensitivity to any of the ingredients of the formulation. **PRECAUTIONS AND WARNINGS** General Use with cautions in patients who have renal and hepatic dysfunction, gastric or intestinal ulcer/irritation, heart disease, arrhythmias, glaucoma, liver diseases, recent fever, thyroid problem, seizures, drug or food allergies and diabetes. Guaiphenesin is possibly porphyrogenic and should be used with cautions in patient with porphyria. Pregnancy & Lactation The components of this medication may cross the placental barrier or get excreted in a breast milk therefore this medication should be used only when clearly needed during pregnancy & lactation. **ADVERSE REACTIONS** Mild Gastro intestinal disturbance and rarely palpitation, tremors, restlessness, headache, dizziness, insomnia and skin rashes maybe seen. Transient rise in serum transaminase may occur. **DOSAGE AND ADMINISTRATION** Adults: 2 teaspoonful (10 ml), 3-4 times/ day, Children: 6-12 years 1 Teaspoon (5ml)3-4 times/day, 2-6 years 1/4 - 1/2 teaspoonful (2.5 ml) 3-4 times a day.
Adapted from Brozedex PI latest version.

NISE

References:

Lal A, Gomber S, Talukdar B. Antipyretic effects of nimesulide, paracetamol and ibuprofen-paracetamol. Indian J Pediatr. 2000 Dec;67(12):865-70

1. Kress HG et al. Acute pain: a multifaceted challenge - the role of nimesulide, Curr Med Res Opin. 2016;32(1):23-36.
2. Data on File
3. MIDAS Data-2027
4. Arulrhaj et al. Effectiveness of Nimesulide in Acute Fever Management in Adults: Retrospective Electronic Medical Records Database Study Outcome in Outpatient Department; J Assoc Physicians India. 2021 Jul;69 (7):11-12.
5. Gautam and Lekha Saha, Br J Clin Pharmacol.2008 May; 65(5):Published onlineonline 2008 Feb 21.
6. National Health Portal Govt. of India. Available at https://www.nhp.gov.in/Complete-list-of-344-drugsbanned-by-the-Ministry-of-Health-and-Family-welfare_pg
7. **https://aidanindia.wordpress.com/**

ABPI

NAME OF MEDICINAL PRODUCT: NISE (Nimesulide) **DOSAGE FORM AND STRENGTH:** Each uncoated tablet contains: Nimesulide BP 100 mg Therapeutic Indication: In the short-term treatment of inflammatory conditions including joint disorders such as rheumatoid arthritis, posttraumatic and post-operative painful conditions and fever. **DOSAGE AND ADMINISTRATION:** The usual adult dose is 100 mg twice daily, orally. USE IN SPECIAL POPULATIONS: Patients with renal impairment: Patients with renal impairment should use nimesulide with caution. Patients with severe renal impairment should preferably avoid using nimesulide. Patients with hepatic impairment: Nimesulide should not be administered in moderate to severe hepatic impairment. Use in Asthmatic Patients: As with other NSAIDs, caution should be exercised while using nimesulide in patients with bronchial asthma. Pregnant and Lactating Women: Safety and effcacy of nimesulide in pregnant and lactating women have not been established. Therefore, nimesulide is not indicated for use in pregnant and lactating women. CONTRAINDICATIONS: Known hypersensitivity to nimesulide, History of hypersensitivity reactions (bronchospasm, rhinitis, urticaria) to aspirin or other NSAIDs, Patients with active peptic ulcer disease, Patients with hepatic or renal impairment, Pregnancy and lactation. PRECAUTIONS: Caution is advised when administering

warfarin and nimesulide concurrently. UNDESIRABLE EFFECTS: Among the adverse events reported with nimesulide, the common ones are gastrointestinal disturbances (epigastric pain, heartburn, nausea, diarrhea, vomiting), skin reactions (rash, pruritus) and CNS effects (dizziness, somnolence, headache). Nimesulide has been reported to cause hepatic adverse events, ranging from mild abnormal liver function to severe liver injuries including fatal hepatic failure in a few cases. Most of these patients were elderly women. It is reported that this adverse event appears to be idiosyncratic or immunologic in nature. Overdose: No information is available on overdosage with nimesulide.
Date: 30 Apr 2018

DOXT-SL

References:

1. Data on File (97.4% in IPD setting EMR analysis & upto 84% in OPD setting)
2. Shashank Joshi, Gifty Immanuel, S Arulrhaj, Mangesh Tiwaskar, Agam Vora, Srinivas Samavedam, Roadmap for the Management of Acute Undierentiated Febrile Illness: An Expert Discussion and Reviewof Available Guidelines, Journal of The Association of Physicians of India , Vol. 69, September 2021. Reference
3. Data on file
4. 4a: Information available at https://www.unmc.edu/intmed/divisions/id/asp/antibiogram/docs/antibiotic-chart.pdf. Accessed on 6.1.2022.
   4b: Madeleine E. Oliver ME, Hinks TSC. Azithromycin in viral infections. Rev Med Virol.2021;31:e2163.
   4c:Gendrot M et al. Molecules 2020, 25, 5064; doi:10.3390/molecules25215064.
   4d: Aguiar ACC et al. Mem Inst Oswaldo Cruz, Rio de Janeiro, 2012.107(7): 831-845.
   4e: Alam M et al. Cureus 12(8): e9658.
   4f: Bhattacharjee B. et al. Journal of Pharmacology and Therapeutic Research (2018) Volume 2, Issue 2. 14-17.
   4g: Ali AS et al. Arab J of Chem. 2021;14(3):102983.
   4h: M.Papich Saunders Handbook of Veterinary Drugs (Fourth Edition).
   4i: McMullanBJ.Aust Presc. 2015 38(3): 87-89.
   4j: Mason WH. Pediatric Annals.1996;25:11
5. Data on file

ABPI

COMPOSITION: Each capsule contains Doxycycline 100mg + Lactic acid bacillus spores-5billion THERAPEUTIC INDICATIONS: For adult patients prone to intra-abdominal bacterial infection & antibioticassociated diarrhoea. DOSAGE AND ADMINISTRATION: In Adults for the treatment of acute infections is twocapsules per day (as a single dose or in divided doses) followed by a maintenance dose of one capsule/day. In the management of more severe infections, two capsules daily should be giventhroughout treatment. CONTRAINDICATIONS: Doxycycline is contraindicated when hypersensitivity to any of the Tetracycline's. Drug interactions: Anticoagulant, co-administration of Tetracyclines with penicillin, Antacid, OC pills, Antiepileptic's etc. WARNINGS & PRECAUTIONS: During tooth development (lasthalf of pregnancy, infancy and childhood to the age of 8 years) may cause permanent discoloration of the teeth (yellow-gray-brown). Evaluate for Clostridium difficile-associated diarrhoea. Limit sun exposure. Overgrowth of non-susceptible organisms, including fungi & superinfection. Dosageadjustment required in patients with hepatic impairment. ADVERSE REACTIONS: In patients receiving tetracyclines include anorexia, nausea, vomiting, diarrhoea, rash, photosensitivity, urticaria, andhemolyticanemia. SPECIAL POPULATION: Can be prescribed in the elderly in the usual dosages. Not recommended for use in paediatric population due to complexity of dose calculations with a combined dosage form. Pregnancy Category D. Tetracyclines are excreted in human milk; Doxycycline use duringnursing should be avoided if possible. Further information available upon request.Date: March 20, 2020

OMEZ

References:

1. IMS IQVIA AUG 21 Data
2.https://pubmed.ncbi.nlm.nih.gov/?term=Omeprazole&filter=pubt.clinicaltrial&filter=hum_ani.humans&sort=date&size=200 As per literature search of "Omeprazole safety" in pubmed with filter of "Clinical trial + Human" on 4.10.2021
3. Sharma P, JAPI ;2018: 66: 72-78 (cross)
4. Yang H et al. Proton pump inhibitors use and risk of chronic kidney disease in diabetic patients. Diabetes Res Clin Pract. 2019 Jan;147:67-75. doi: 10.1016/j.diabres.2018.11.019. Epub 2018 Nov 27
5. S. Arhulraj, Mangesh Tiwaskar, T. S. Chandrasekar Acid-Peptic Disorder Management:- Omeprazole, A Safer Option: Thieme Publishing Group, Delhi.2020 p.7-36.

ABPI

NAME OF MEDICINAL PRODUCT: OMEZ (Omeprazole Capsules IP 10/20 mg). DOSAGE FORM AND STRENGTH: Each capsule contains omeprazole IP 10/20 mg as enteric coated granules. Therapeutic Indications: Omeprazole capsule is indicated in the short-term treatment of duodenal ulcer, gastric ulcer, reflux oesophagitis and in the management of Zollinger-Ellison syndrome. DOSAGE AND ADMINISTRATION: Duodenal Ulcer: The recommended adult oral dose for the short-term treatment of duodenal ulcer is 20 mg once daily for 4 weeks. Sometimes the treatment may require an additional 4 weeks. Gastric Ulcer: The recommended adult dose is 40 mg once daily for 4 - 8 weeks. For prevention of relapse in patients with duodenal ulcer the recommended dose is Omeprazole 10mg, once daily, increasing to 20mg, once daily if symptoms return. For patients who are at risk from recurrent ulcer relapse i.e., those with Helicobacter pylori infection, younger patients (<60 years), patients whose symptoms persist for more than one year and smokers, long-term therapy should be initiated with omeprazole 20mg once daily, reducing to 10mg once daily, if necessary. Reflux oesophagitis: For the short-term treatment of reflux oesophagitis with only symptomatic gastroesophageal reflux disease (GERD) and no oesophageal lesions, the recommended adult dose is 20 mg once daily for 4 weeks. For patients with erosive oesophagitis and accompanying symptoms of GERD, the recommended dose is 20 mg once daily for 4-8 weeks. Omeprazole 40 mg/day can be used in patients with reflux oesophagitis refractory to other therapy. Healing usually occurs within 8 weeks. Patients can be continued at a dosage of 20 mg once daily. Maintenance of healing of erosive oesophagitis: The usual adult oral dose is 20 mg daily. Zollinger-Ellison syndrome: The recommended starting oral dose is 60 mg once daily. The doses can be varied with individual patient's need and treatment should be continued as long as clinically indicated.Doses up to 120 mg t.i.d have been administered. With doses above 80 mg daily, the dose should be divided and given twice daily. Omeprazole should be taken before food. USE IN SPECIAL POPULATIONS: Paediatric population: (1 to 16 years of age) Safety profile similar to that in adults, except that respiratory system events and fever were the most frequently reported reactions in pediatric studies. Older patients - No dosage adjustment is necessary for elderly patients. However, greater sensitivity of some older individuals cannot be ruled out. Renal insufficiency / dialysis - No dosage adjustment is necessary in patients with renal insufficiency. Hepatic impairment - Consider dose reduction, particularly for maintenance of healing of erosive esophagitis.
Further information available upon request.
Date: 30th January, 2020

OMEZ DSR

References :

#DCGI approved indication: For GERD not responding to Omeprazole.

1. Kubo, Ai et al. "Dietary guideline adherence for gastroesophageal reflux disease." BMC gastroenterology vol. 14 144. 14 Aug. 2014, doi:10.1186/1471-230X-14-144

2. A Comparison of Omeprazole, Lansoprazole and Pantoprazole in the Maintenance Treatment of Severe Reflux Oesophagitis; D Jaspersen, K L Diehl, H Schoeppner, P Geyer, E Martens, Aliment Pharmacol Ther, 12 (1), 49-52 Jan 1998

3. Data on File

ABPI

NAME OF MEDICINAL PRODUCT: OMEZ-DSR (Omeprazole and Domeperidone capsule). DOSAGE FORM AND STRENGTH: Each capsule contains omeprazole IP 20 mg as enteric coated pellets and domeperidone BP 30 mg as sustained release pellets and Excipient qs. THERAPEUTIC INDICATIONS: Omeprazole and Domeperidone are indicated for the treatment duodenal ulcers and gastric ulcers, reflux or ulcerative oesophagitis, Zollinger-Ellison syndrome, NSAID-induced ulcers and for the treatment of Gastroesophageal Reflux Disease (GERD) not responding to omeprazole alone. DOSAGE AND ADMINISTRATION: The usually recommended dose is a one capsule once daily. CONTRAINDICATIONS: Hypersensitivity to any component of the formulation. Contraindicated in pregnancy and in neonates. ADVERSE EFFECTS: The most commonly reported adverse reactions are headache, diarrhea, abdominal pain, nausea, flatulence, asthma, back pain, fever, fatigue, malaise and increased risk of enteric infections due to reduced acid secretion. WARNINGS AND PRECAUTIONS: In patients with severe liver impairment, the liver enzymes should be monitored regularly during treatment with omeprazole, particularly on long term use. If a rise in liver enzymes is observed, the formulation should be discontinued. DRUG INTERACTIONS: Omeprazole can prolong the elimination of diazepam; warfarin and phenytoin, drugs that are metabolized by oxidation in the in the liver and may interfere with absorption of ketoconazole, ampicillin esters and iron salts. Further information available upon request. Date: January 30, 2020

OMEZ DSR PLUS

ABPI

COMPOSITION: Enteric Coated Esomeprazole 40mg and Domperidone Sustained Release 30mg Capsules. INDICATION: Omez DSR is indicated for the treatment of adult patients with gastro esophageal reflux disease (GERD) not responding to esomeprazole alone. CONTRAINDICATIONS: Omez DSR is contraindicated in patients with known hypersensitivity to Esomeprazole or other substituted benzimidazoles or to Domperidone or other dopamine antagonists or to any excipients used in the formulation. Omez DSR should not be used whenever stimulation of gastrointestinal motility might be dangerous such as in the presence of gastrointestinal hemorrhage, mechanical obstruction, or perforation. Omez DSR is contraindicated in patients with prolactinoma (a prolactin releasing pituitary tumour). SPECIAL WARNINGS AND PRECAUTIONS FOR USE: Carcinogenesis, Mutagenesis, Impairment of Fertility. Esomeprazole-Symptomatic response to Esomeprazole therapy does not exclude the presence of gastric malignancy. Atrophic gastritis has been noted occasionally in gastric corpus biopsies from patients treated long term with omeprazole, of which Esomeprazole is an enantiomer. Domperidone was administered to mice for 18 months and rats for 24 months in carcinogenicity studies. No dose-related effects were observed except for an increased incidence of malignant mammary tumours at 25 times the maximum human dose in female mice and rats and an increased incidence of pituitary tumours at 25 times the maximum human dose in male rats. No evidence for mutagenic potential was seen in dominant lethal studies in male and female mice, micronucleus tests

in female mice and female rats. a study of chromosomal aberrations in human lymphocytes, a sex-linked recessive lethal test on Drosophila melanogaster, and in the Ames metabolic activation test with Salmonella typhimurium. UNDESIRABLE EFFECTS: Proton Pump Inhibitors associated Acute Kidney Injury: Acute kidney injury has been reported with the use of Proton pump inhibitors (PPIs) including Pantoprazole, Omeprazole, Lansoprazole, Esomeprazole, Rabeprazole etc. Esomeprazole-Common adverse events reported with Esomeprazole in clinical trials include headache, nausea, vomiting, diarrhoea, abdominal pain, flatulence, constipation and dry mouth. Other less commonly reported adverse effects include dizziness, insomnia, allergic reactions, asthenia, bowel irregularity, urticaria, etc. The incidence of treatment-related adverse events during 6-month maintenance treatment with Esomeprazole was similar to placebo. There were no differences in types of related adverse events seen during maintenance treatment up to 12 months compared to short-term treatment. Domperidone-The most frequent reactions to Domperidone are those related to elevated prolactin levels including breast tenderness, galactorrhoea, gynaecomastia and amenorrhoea. These effects are dose-related and gradually resolve after lowering the dose or discontinuing treatment. Other rarely reported adverse reactions include headache, diarrhoea, dizziness, mild and transient abdominal cramps, dry mouth and drowsiness. Rare allergic reactions, such as rash and urticaria, have also been reported. Extrapyramidal reactions occur very rarely in adults and usually resolve completely and spontaneously after cessation of treatment. DOSAGE AND ADMINISTRATION: In patients with normal hepatic or renal function: Depending on the severity, 1 capsule of Esomeprazole 40mg + SR Domperidone 30mg orally once daily for upto 4 weeks. In patients with mild-to-moderate hepatic and renal impairment: 1 capsule of Esomeprazole Domperidone 30mg orally once daily for upto 4 weeks. Patients receiving Omez DSR should be evaluated on a weekly basis. Following clinical resolution, patients should be shifted to either a proton pump inhibitor or a prokinetic agent alone for maintenance therapy.

ATARAX

References:
1. Global IMS as accessed on 01-02-2021
2. Khashayar F. et al. Antihistamine. StatPearls (Internet). Treasure Island (FL): StatPearls Publishing: 2021-Jan
3. Atarax API, Version number: NCDS02(SI), Version date: 17 June, 2013.
4. SMRC data: MAT Oct 2020
5. API. Data on file.
6. As adapted from www.drugs.com as on 26-05-2021.

ABPI

NAME OF THE MEDICINAL PRODUCT: 1) Atarax 10 mg film-coated tablet. 2) Atarax 25 mg filmcoated tablet. 3) Atarax 2 mg/ml syrup. 4) Atarax 6 mg/ml oral drops. QUALITATIVE AND QUANTITATIVE COMPOSITION: 1) Each film-coated tablet of Atarax 10 mg contains 10 mg of hydroxyzine dihydrochloride. 2) Each film

coated tablet of Atarax 25 mg contains 25 mg of hydroxyzine dihydrochloride. 3) Each ml of Atarax syrup contains 2 mg of hydroxyzine dihydrochloride. 4) Each ml of Atarax oral drops contains 6mg of hydroxyzine dihydrochloride. Atarax 25 mg/ ml solution for injection. QUALITATIVE AND QUANTITATIVE COMPOSITION: Each ml of Atarax solution for injection contains 25 mg of hydroxyzine dihydrochloride, and an ampoule containing 2 ml of solution for injection contains 50 mg of hydroxyzine dihydrochloride. Pharmaceutical Form: Solution for injection: Clear, colourless solution. Pharmaceutical Form: 10 mg film-coated tablet: White, round, film-coated tablet. 25 mg filmcoated tablet: White, oblong, film-coated tablet, with a bisect line. Syrup: Clear, colourless solution. Oral drops: Clear, colourless solution. THERAPEUTIC INDICATIONS: Atarax is indicated in the symptomatic treatment of pruritus, the symptomatic treatment of anxiety in adults and the premedication before surgery. Posology and method of administration: Adults: For symptomatic treatment of pruritus: Starting dose of 25 mg before resting, to be followed if necessary with doses up to 25 mg 3 to 4 times daily. For symptomatic treatment of anxiety: 50 mg/day in 3 separate administrations of 12.5-12.5- 25 mg; in more severe cases doses of upto 300 mg/day can be used. For premedication before surgery: 50 to 200 mg/day in 1or 2 administrations: single administration 1 hour before surgery, which may be preceded by 1 administration the night before anaesthesia. Children (from 12 months) For symptomatic treatment of pruritus: From 12 months to 6 years old: 1 mg/kg/day up to 2.5 mg/kg/day in divided doses, Over 6 years old 1 mg/kg/day up to 2 mg/kg/day in divided doses. For premedication before surgery: Single administration of 1 mg/kg 1 hour before surgery, which may be preceded by 1 mg/kg the night before anaesthesia. CONTRAINDICATIONS: 1) History of hypersensitivity to any of the constituents of Atarax, to cetirizine, to other piperazine derivatives, to aminophylline, or to ethylenediamine. 2) Patients suffering from porphyria. 3) Patients with pre-existing prolonged QT interval 4) Pregnancy and breast-feeding. Special Warning and Precautions for Use: Atarax should be administered cautiously in patients with increased potential for convulsions. The content of sucrose in Atarax 6mg/ml oral solution and Atarax 2 mg/ml syrup should be taken into consideration in patients with diabetes mellitus. The tablets include lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose mal-absorption should not take this medicine. The syrup contains 0.75 g of sucrose per ml. Patients with rare hereditary problems of fructose intolerance, glucosegalactose mal-absorption or sucrose-isomaltase insufficiency should not take this medicine. UNDESIRABLE EFFECTS: General disorders and administration site conditions: fatigue, Nervous system disorders: sedation, Psychiatric disorders: agitation, confusion, Gastro-intestinal disorders: nausea. OVERDOSE: Symptoms observed after an important overdose are mainly associated with excessive anticholinergic load, CNS depression or CNS paradoxical stimulation. They include nausea, vomiting, tachycardia, pyrexia, somnolence, impaired pupillary reflex, tremor, confusion, or hallucination. This may be followed by depressed level of consciousness, respiratory depression, convulsions, hypotension, or cardiac arrhythmia. Deepening coma and cardiorespiratory collapse may ensue.
Keep out of reach of children. Please refer to the full prescribing information before usage.
Available on request from Dr. REDDY'S LABORATORIES LTD.,

For further information, please write to medical information cell,
Branded Formulations,
Dr. REDDY'S LABORATORIES LTD.,
7-1-27, Ameerpet, Hyderabad - 500 016. Telangana Toll-Free No.: 1800 425 0014.

KETOROL

References:

1. Sadghein A, et al. J Endod. 1999; 25(4):257-259
2. IMS quintile period June MAT 2029
3. *Jena A, et al. J Conserv Dent. 2013; 16(2):171-174. * IANB success rate(pain/no pain-VAS)

ABPI

Ketorolac 10mg dispersible tablet

COMPOSITION: Each uncoated dispersible tablets contains: Ketorolac Tromethamine USP 10 mg. Indications: Short-term management of moderate postoperative pain. The maximum duration of treatment is seven days. DOSAGE & ADMINISTRATION Ketorolac tablets are recommended for short-term use only (up to 7 days) and are not recommended for chronic use. Adults: 20mg once followed by 10 mg every 6 hrs, not exceeding 40 mg in a day. For patients receiving parenteral ketorolac, and who are converted to ketorolac oral tablets, the total combined daily dose should not exceed 90 mg and the oral component should not exceed 40 mg on the day the change of formulation is made. Elderly: A longer dosing interval, e.g. 6-8 hourly, is advisable in the elderly. Use in Children Safety and efficacy of ketorolac has not been studied in children less than 18 years of age. CONTRAINDICATIONS: Ketorolac is contraindicated in patients with previously demonstrated hypersensitivity to Ketorolac, any of its excipients; with a history of asthma; Children and adolescents aged less than 18 years; active peptic ulcer, or any history of gastrointestinal bleeding, ulceration or perforation; severe heart failure, hepatic failure and renal failure; moderate or severe renal impairment (serum creatinine >160 µmol/l); pregnancy, labour, delivery and lactation; intraoperatively because of the increased risk of bleeding; suspected or confirmed cerebrovascular bleeding, high risk of haemorrhage or bleeding, including coagulation disorders, patients on anticoagulants, including warfarin and low dose heparin; patients currently receiving ASA or other NSAIDs, oxpentifylline, probenecid or lithium salts. Ketorolac is contraindicated in patients with the complete or partial syndrome of nasal polyps, angioedema or bronchospasm. SPECIAL WARNINGS AND PRECAUTIONS FOR USE: The long-term administration of ketorolac tromethamine is not recommended as the incidence of side-effects increases with the duration of treatment. USE IN SPECIFIC POPULATIONS: Use in Pregnancy and Lactation: Not recommended during pregnancy or lactation. Use in Children - Not recommended for use in children under age 16. Use in the Elderly: Extra caution and the lowest effective dose should be used. ADVERSE REACTIONS: Renal Events: acute renal failure, flank pain with or without hematuria and/or azotemia, nephritis, hyponatremia, hyperkalemia, hemolytic uremic syndrome, urinary retention. Hypersensitivity reactions: bronchospasm, laryngeal edema, asthma, hypotension, flushing, rash, anaphylaxis, and anaphylactoid reactions. Gastrointestinal Events: gastrointestinal hemorrhage, peptic ulceration, gastrointestinal perforation, pancreatitis, melena. Hematologic Events: postoperative wound hemorrhage, rarely requiring blood transfusion, thrombocytopenia, epistaxis, leukopenia. Central Nervous System: Convulsions, hallucinations, hyperkinesia, hearing loss, aseptic meningitis, extrapyramidal symptoms. Hepatic Events: hepatitis, liver failure, cholestatic jaundice Cardiovascular: pulmonary edema, hypotension, flushing. Dermatology: Lyell's syndrome, Stevens-Johnson syndrome, exfoliative dermatitis, maculopapular rash, urticarial. OVER DOSAGE: Overdose is associated with abdominal pain, nausea, vomiting, hyperventilation, peptic ulcers and/or erosive gastritis, gastrointestinal bleeding, and renal dysfunction which have generally resolved after discontinuation of dosing.

Dated: 21st March, 2022

Further information is available on request.