Voveran® SR 100

Diclofenac Sodium Sustained Release with wax matrix

Dr.Reddy's

BASIC SUCCINCT STATEMENT: VOVERAN® SR 100/SR 75

Presentation: Gastro-resistant gelatin enrobed tablets of 50 mg (GE tab).; sustained-release tablets of 75 mg and 100 mg (SR tab.); Diclofenac free acid: dispersible tablets of 46.5 mg, corresponding to 50 mg diclofenac sodium (D tab.). **Indications:** • Inflammatory and degenerative forms of rheumatism: rheumatoid arthritis, ankylosing spondylitis, osteoarthritis and spondylarthritis, painful syndromes of the vertebral column, non-articular rheumatism. • Post-traumatic and post-operative pain, inflammation, and swelling, e.g., following dental or orthopaedic surgery. • Painful and/or inflammatory conditions in gynaecology, e.g., primary dysmenorrhoea or adnexitis. (SR tab). • Post-operative inflammation and pain, e.g., following dental or orthopedic surgery. • Painful post-traumatic inflammatory states, e.g., due to sprains. • Flare-up of osteoarthritis. (GE tab, D tab) • Acute attacks of gout. (GE tab, D tab) • Non-articular rheumatism. (GE tab, D tab) • Painful syndromes of the vertebral column. • Painful and/or inflammatory conditions in gynaecology, e.g., primary dysmenorrhea or adnexitis. (GE tab, D tab) • As an adjuvant in severe painful inflammatory infections of the ear, nose or throat, e.g., pharyngotonsillitis, otitis. In keeping with general therapeutic principles, the underlying disease should be treated with basic therapy, as appropriate. Fever alone is not an indication. (D Tab, GE Tab). **Dosage and administration: Dosage:** Dose to be individually adjusted, lowest effective dose to be given for the shortest duration. (For GE tab, SR tab., D tab.): Adults - 50 to 150 mg/day in divided doses (dysmenorrhoea : up to 200 mg/day for GE Tab., D tab.). Adolescents over 14 years of age: 0.5 to 2 mg/kg/day (juvenile rheumatoid arthritis up to 3 mg/kg/day for GE Tab.), with a maximum daily dose of 150 mg. (For D tab): Adults- Short-term treatment only. • **Special patient populations:** Patients with established heart disease or cardiovascular risk factors should only receive doses up to max. 100 mg daily if treated for more than 4 weeks. (SR Tab). **Contraindications:** • Active gastric or intestinal ulcer, bleeding or perforation. • Last trimester of pregnancy. • Hepatic failure. •Renal failure (GFR <15 mL/min/1.73m2). • Severe cardiac failure. • Known hypersensitivity to acetylsalicylic acid or other non-steroidal anti-inflammatory drugs (NSAIDs). **Warnings and precautions:** • Caution recommended in patients with symptoms/history of gastrointestinal (GI) disease and in elderly because of the risks of GI bleeding or perforation. To be discontinued if these conditions occur. • Combined use with protective agents to be considered in patients with history of ulcer, elderly and those requiring low dose acetylsalicylic acid. •Caution when used concomitantly with corticosteroids, anticoagulants, anti-platelet agents or SSRIs. • Caution recommended in patients with ulcerative colitis or Crohn's disease. • Treatment generally not recommended in patients with established heart disease or uncontrolled hypertension. If needed in patients with established heart disease, uncontrolled hypertension or significant cardiovascular risk factors, treat only after careful consideration and with dose adjustment and periodic re-evaluation, especially when treatment continues for more than 4 weeks. • Monitoring of blood counts recommended during prolonged treatment. • Monitoring recommended in patients with defects of haemostasis. • Caution recommended in patients with asthma, seasonal allergic rhinitis or chronic pulmonary diseases. • Risks of serious allergic reactions. To be discontinued if these conditions occur. • Caution recommended in patients with impaired hepatic function (including porphyria). • Monitoring of liver function during prolonged treatment. • Beware of severe fluid retention and edema. • Monitoring of renal function recommended in patients with history of hypertension, impaired cardiac or renal function, extracellular volume depletion, the elderly, patients treated with diuretics or drugs that impact renal function. • Caution is indicated in the elderly. • Avoid use with other systemic NSAIDs including COX-2 inhibitors. • May mask signs and symptoms of infection. Pregnancy and breast-feeding: • Must not be used during the third trimester of pregnancy. • Should not be used in the first and second trimester of pregnancy and by breast-feeding mothers. **Fertility:** • Not recommended to use in women attempting to conceive as it may impair female fertility. Adverse drug reactions: • Common undesirable effects are: Headache, dizziness, vertigo, nausea, vomiting, diarrhea, dyspepsia, abdominal pain, flatulence, decreased appetite, elevations (>3 times the upper normal limit) of serum aminotransferase enzymes (SGOT or AST, SGPT or ALT). • **Uncommon* undesirable effects are:** myocardial infarction, cardiac failure, chest pain, palpitations (*frequency reflects data from long-term treatment with a high dose of 150 mg/day). • **Rare undesirable effects are:** Hypersensitivity, anaphylactic and anaphylactoid reactions (including hypotension and shock), somnolence, asthma (including dyspnea), gastritis, gastrointestinal hemorrhage, hematemesis, hemorrhagic diarrhea, melena, gastrointestinal ulcer (with or without bleeding, gastrointestinal stenosis or perforation, which may lead to peritonitis), hepatitis, jaundice, liver disorder, urticaria, edema. • **Very rare undesirable effects are:** Thrombocytopenia, leukopenia, anemia (including hemolytic anemia and aplastic anemia), agranulocytosis, angioedema (including face edema), disorientation, depression, insomnia, nightmare, irritability, psychotic disorder, paresthesia, memory impairment, convulsion, anxiety, tremor, aseptic meningitis, dysgeusia, cerebrovascular accident, visual impairment*, blurred vision*, diplopia*, tinnitus, impaired hearing, hypertension, vasculitis, pneumonitis, colitis (including hemorrhagic colitis, ischemic colitis and exacerbation of ulcerative colitis or Crohn's disease), constipation, stomatitis, glossitis, esophageal disorder, intestinal diaphragm disease, pancreatitis, fulminant hepatitis, hepatic necrosis/ hepatic failure, bullous dermatitis, eczema, erythema, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), exfoliative dermatitis, alopecia, photosensivity reaction, purpura, Henoch-Schonlein purpura, pruritus, acute kidney injury (including acute renal failure), hematuria, proteinuria, nephrotic syndrome, tubulointerstitial nephritis, renal papillary necrosis. ***Visual effects:** If symptoms of visual disturbances occur during diclofenac treatment, an ophthalmological examination may be considered to exclude other causes. Interactions: • Monitoring of serum lithium or digoxin levels recommended if used concomitantly. • Caution with concomitant use of diuretics and antihypertensives (e.g. beta blockers, ACE inhibitors), methotrexate, other NSAIDs and corticosteroids, SSRIs.). • Dose of diclofenac to be reduced in patients receiving ciclosporin or tacrolimus. • Monitoring of serum potassium level if used concomitantly with drugs known to cause hyperkalemia (e.g. diuretics, ciclosporin, tacrolimus, trimethoprim. • Interactions with concomitant use of quinolone antibacterials, CYP2C9 inhibitors (e.g. voriconazole), and CYP2C9 inducers (e.g. rifampicin). • Monitoring recommended for patients receiving anticoagulants, anti-platelet agents as well as blood glucose level if used concomitantly with antidiabetics. • Cases of metabolic acidosis have been reported when diclofenac was co-administered with metformin, especially in patients with pre-existing renal impairment. • Monitoring of phenytoin plasma concentrations is recommended if used concomitantly. Packs: Voveran 50 GE: Box of 7x4x15 tablets. Voveran SR 100: Box of 25 X 15 tablets. Voveran SR 75: Box of 10 X 10 tablets. Voveran D: Box of 10 X 10 tablets. **Note:** For Further information, please write to Medical information cell, Branded Formulations, Dr. Reddy's Laboratories Ltd., 7-1-27, Ameerpet Hyderabad-500 016. Toll free No.: 1800 425 0014, e-mail: customerservices@drreddys.com. Warning: Not for veterinary use.

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India BSS dtd 11 May 2022 based on international BSS dtd 5 Feb 2018.

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Voveran® 50 GE

Diclofenac Sodium (Gelatin Enrobed)

Dr.Reddy's

BASIC SUCCINCT STATEMENT: VOVERAN® 50 GE

Presentation: Gastro-resistant gelatin enrobed tablets of 50 mg (GE tab).; sustained-release tablets of 75 mg and 100 mg (SR tab.); Diclofenac free acid: dispersible tablets of 46.5 mg, corresponding to 50 mg diclofenac sodium (D tab.). **Indications:** • Inflammatory and degenerative forms of rheumatism: rheumatoid arthritis, ankylosing spondylitis, osteoarthritis and spondylarthritis, painful syndromes of the vertebral column, non-articular rheumatism. • Post-traumatic and post-operative pain, inflammation, and swelling, e.g., following dental or orthopaedic surgery. • Painful and/or inflammatory conditions in gynaecology, e.g., primary dysmenorrhoea or adnexitis. (SR tab). • Post-operative inflammation and pain, e.g., following dental or orthopedic surgery. • Painful post-traumatic inflammatory states, e.g., due to sprains. • Flare-up of osteoarthritis. (GE tab, D tab) • Acute attacks of gout. (GE tab, D tab) • Non-articular rheumatism. (GE tab, D tab) • Painful syndromes of the vertebral column. • Painful and/or inflammatory conditions in gynaecology, e.g., primary dysmenorrhea or adnexitis. (GE tab, D tab) • As an adjuvant in severe painful inflammatory infections of the ear, nose or throat, e.g., pharyngotonsillitis, otitis. In keeping with general therapeutic principles, the underlying disease should be treated with basic therapy, as appropriate. Fever alone is not an indication. (D Tab, GE Tab). **Dosage and administration: Dosage:** Dose to be individually adjusted, lowest effective dose to be given for the shortest duration. (For GE tab, SR tab., D tab.): Adults - 50 to 150 mg/day in divided doses (dysmenorrhoea : up to 200 mg/day for GE Tab., D tab.). Adolescents over 14 years of age: 0.5 to 2 mg/kg/day (juvenile rheumatoid arthritis up to 3 mg/kg/day for GE Tab.), with a maximum daily dose of 150 mg. (For D tab): Adults- Short-term treatment only. • **Special patient populations:** Patients with established heart disease or cardiovascular risk factors should only receive doses up to max. 100 mg daily if treated for more than 4 weeks. (SR Tab). **Contraindications:** • Active gastric or intestinal ulcer, bleeding or perforation. • Last trimester of pregnancy. • Hepatic failure. •Renal failure (GFR <15 mL/min/1.73m2). • Severe cardiac failure. • Known hypersensitivity to acetylsalicylic acid or other non-steroidal anti-inflammatory drugs (NSAIDs). **Warnings and precautions:** • Caution recommended in patients with symptoms/history of gastrointestinal (GI) disease and in elderly because of the risks of GI bleeding or perforation. To be discontinued if these conditions occur. • Combined use with protective agents to be considered in patients with history of ulcer, elderly and those requiring low dose acetylsalicylic acid. •Caution when used concomitantly with corticosteroids, anticoagulants, anti-platelet agents or SSRIs. • Caution recommended in patients with ulcerative colitis or Crohn's disease. • Treatment generally not recommended in patients with established heart disease or uncontrolled hypertension. If needed in patients with established heart disease, uncontrolled hypertension or significant cardiovascular risk factors, treat only after careful consideration and with dose adjustment and periodic re-evaluation, especially when treatment continues for more than 4 weeks. • Monitoring of blood counts recommended during prolonged treatment. • Monitoring recommended in patients with defects of haemostasis. • Caution recommended in patients with asthma, seasonal allergic rhinitis or chronic pulmonary diseases. • Risks of serious allergic reactions. To be discontinued if these conditions occur. • Caution recommended in patients with impaired hepatic function (including porphyria). • Monitoring of liver function during prolonged treatment. • Beware of severe fluid retention and edema. • Monitoring of renal function recommended in patients with history of hypertension, impaired cardiac or renal function, extracellular volume depletion, the elderly, patients treated with diuretics or drugs that impact renal function. • Caution is indicated in the elderly. • Avoid use with other systemic NSAIDs including COX-2 inhibitors. • May mask signs and symptoms of infection. Pregnancy and breast-feeding: • Must not be used during the third trimester of pregnancy. • Should not be used in the first and second trimester of pregnancy and by breast-feeding mothers. **Fertility:** • Not recommended to use in women attempting to conceive as it may impair female fertility. Adverse drug reactions: • Common undesirable effects are: Headache, dizziness, vertigo, nausea, vomiting, diarrhea, dyspepsia, abdominal pain, flatulence, decreased appetite, elevations (>3 times the upper normal limit) of serum aminotransferase enzymes (SGOT or AST, SGPT or ALT). • **Uncommon* undesirable effects are:** myocardial infarction, cardiac failure, chest pain, palpitations (*frequency reflects data from long-term treatment with a high dose of 150 mg/day). • **Rare undesirable effects are:** Hypersensitivity, anaphylactic and anaphylactoid reactions (including hypotension and shock), somnolence, asthma (including dyspnea), gastritis, gastrointestinal hemorrhage, hematemesis, hemorrhagic diarrhea, melena, gastrointestinal ulcer (with or without bleeding, gastrointestinal stenosis or perforation, which may lead to peritonitis), hepatitis, jaundice, liver disorder, urticaria, edema. • **Very rare undesirable effects are:** Thrombocytopenia, leukopenia, anemia (including hemolytic anemia and aplastic anemia), agranulocytosis, angioedema (including face edema), disorientation, depression, insomnia, nightmare, irritability, psychotic disorder, paresthesia, memory impairment, convulsion, anxiety, tremor, aseptic meningitis, dysgeusia, cerebrovascular accident, visual impairment*, blurred vision*, diplopia*, tinnitus, impaired hearing, hypertension, vasculitis, pneumonitis, colitis (including hemorrhagic colitis, ischemic colitis and exacerbation of ulcerative colitis or Crohn's disease), constipation, stomatitis, glossitis, esophageal disorder, intestinal diaphragm disease, pancreatitis, fulminant hepatitis, hepatic necrosis/ hepatic failure, bullous dermatitis, eczema, erythema, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), exfoliative dermatitis, alopecia, photosensivity reaction, purpura, Henoch-Schonlein purpura, pruritus, acute kidney injury (including acute renal failure), hematuria, proteinuria, nephrotic syndrome, tubulointerstitial nephritis, renal papillary necrosis. ***Visual effects:** If symptoms of visual disturbances occur during diclofenac treatment, an ophthalmological examination may be considered to exclude other causes. Interactions: • Monitoring of serum lithium or digoxin levels recommended if used concomitantly. • Caution with concomitant use of diuretics and antihypertensives (e.g. beta blockers, ACE inhibitors), methotrexate, other NSAIDs and corticosteroids, SSRIs.). • Dose of diclofenac to be reduced in patients receiving ciclosporin or tacrolimus. • Monitoring of serum potassium level if used concomitantly with drugs known to cause hyperkalemia (e.g. diuretics, ciclosporin, tacrolimus, trimethoprim. • Interactions with concomitant use of quinolone antibacterials, CYP2C9 inhibitors (e.g. voriconazole), and CYP2C9 inducers (e.g. rifampicin). • Monitoring recommended for patients receiving anticoagulants, anti-platelet agents as well as blood glucose level if used concomitantly with antidiabetics. • Cases of metabolic acidosis have been reported when diclofenac was co-administered with metformin, especially in patients with pre-existing renal impairment. • Monitoring of phenytoin plasma concentrations is recommended if used concomitantly. Packs: Voveran 50 GE: Box of 7x4x15 tablets. Voveran SR 100: Box of 25 X 15 tablets. Voveran SR 75: Box of 10 X 10 tablets. Voveran D: Box of 10 X 10 tablets. **Note:** For Further information, please write to Medical information cell, Branded Formulations, **Dr. Reddy's Laboratories Ltd.**, 7-1-27, Ameerpet Hyderabad-500 016. Toll free No.: 1800 425 0014, e-mail: customerservices@drreddys.com. Warning: Not for veterinary use.

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India BSS dtd 11 May 2022 based on international BSS dtd 5 Feb 2018.

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Voveran® Emulgel®

Diclofenac Diethylamine Gel 1.16%

BASIC SUCCINCT STATEMENT: VOVERAN® EMULGEL®

Presentation: Oily emulsion in an aqueous gel, containing 1.16% diclofenac diethylamine (corresponding to 1% diclofenac sodium). **Indications:** •Post-traumatic inflammation of the tendons, ligaments, and joints, e.g. due to sprains, strains, and bruises. •Localized forms of soft-tissue rheumatism, e.g. tendovaginitis, bursitis, shoulder-hand syndrome, and periarthropathy. •Localized forms of degenerative rheumatism, e.g. osteoarthrosis of the peripheral joints and vertebral column. **Dosage and administration:** Adults: Voveran Emulgel is applied locally to the skin 3 or 4 times daily and rubbed in gently. For example, 2 to 4 g Voveran Emulgel (cherry- to walnut-sized mass) are sufficient to treat an area of about 400 to 800 cm^2. Special populations: No dosage adjustment of the starting dose is required. **Contraindications:** •Known hypersensitivity to diclofenac or to any of the excipients. •Third trimester of pregnancy. •Known hypersensitivity to aspirin or to other non-steroidal anti-inflammatory drugs (NSAIDs). **Warnings and precautions:** •Do not apply to diseased skin, open wounds or injuries. •Avoid contact with the eyes and mucous membranes. •Discontinue the treatment if a skin rash develops after applying the product.•Do not take by mouth. •Do not use with occlusive dressing. •Systemic side effects cannot be excluded when the product is applied to large areas of skin for prolonged periods of time. **Pregnancy and breast-feeding:** •Contraindicated in the third trimester of pregnancy •Avoid use during pregnancy. •Not recommended during breast-feeding. **Special excipients:** •Voveran Emulgel contains propylene glycol, which may cause mild, localized skin irritation in some people. **Adverse drug reactions:** Common (≥1 to <10%): Rash, eczema, erythema, dermatitis (including contact dermatitis), pruritus. Rare (≥0.01 to <0.1%): Bullous dermatitis. Very rare (<0.01%): Pustular rash, hypersensitivity (including urticaria), asthma, photosensitivity reaction, angioedema. Interactions: None known. Packs: Tube of 21 gm, 30 gm and 50 gm. **Warning:** Not for veterinary use. **Note:** For Further information, please write to Medical information cell, Branded Formulations, Dr. Reddy's Laboratories Ltd., 7-1-27, Ameerpet Hyderabad-500 016. Toll free No.: 1800 425 0014, e-mail: customerservices@drreddys.com

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India BSS version dtd 21 Jul 16 revised on 19 Nov 18 based on international BSS dtd 26 May 16 effective from 19 Nov 18.

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Voveran maXgel™

Diclofenac Diethylamine Gel IP 2.32 % w/w

Dr.Reddy's

BASIC SUCCINCT STATEMENT: VOVERAN® Maxxgel™

Presentation: Oil emulsion in an aqueous gel. 100 g of Voveran Maxxgel 2.32% contains 2.32 gm of the active substance diclofenac diethylamine, which corresponds to 2 gm diclofenac sodium. **Indications:** • For the local symptomatic treatment of: Post-traumatic inflammation of the tendons, ligaments, muscles, and joints. • Localized forms of rheumatism & soft-tissue rheumatism. **Dosage and administration:** Adults: Depending on the size of the affected site to be treated 2-4 g (a circular shaped mass approximately 2.0-2.5 cm in diameter) should be applied 2 times daily (preferably morning and evening). The maximum daily dose is 8 g. Therefore the maximum weekly dose is 56 g. Not to be used for more than 7 days unless recommended by a doctor. **Special populations:** Paediatrics: Dosage recommendations and indications for the use of Voveran Maxxgel in children have not been established. Geriatrics (Patients aged 65 or above): There is no evidence to suggest that elderly patients require different dosages or experience side effects different from those in younger patients. Renal and Hepatic impairment: There is no evidence to suggest that renally and/or hepatically impaired patients require a different dosage. **Contraindications:** •Known hypersensitivity to the active substance or to any of the excipients. • Voveran Maxxgel is also contraindicated in patients in whom attacks of asthma, urticaria, or acute rhinitis are precipitated by acetylsalicylic acid or other non-steroidal anti-inflammatory drugs (NSAIDs). • D u r i n g the last trimester of pregnancy. **Warnings and precautions:** •Voveran Maxxgel 2.32% should be applied only to intact, non-diseased skin and not to skin wounds or open injuries. • It should not be used with occlusion. It should not be allowed to come into contact with the eyes or mucous membranes, and should never be taken by mouth. • Voveran Maxxgel can be used with non-occlusive bandages but should not be used with an airtight occlusive dressing. • Patients with a history of, or active, peptic ulceration. Some possibility of gastro-intestinal bleeding in those with a significant history of this condition has been reported in isolated cases. Like other drugs that inhibit prostaglandin synthetase activity, diclofenac and other NSAIDs can precipitate bronchospasm if administered to patients suffering from or with a previous history of asthma or allergic disease. Discontinue if rash develops. •Special excipient of Voveran Maxxgel contains propylene glycol, which may cause mild, localized skin irritation in some people. **Adverse drug reactions:** Very Rare: Infections and Infestations (rash pustular), Immune system disorder (Hypersensitivity), Respiratory, thoracic and mediastinal disorders (asthma), Skin and Subcutaneous tissue disorder (Photosensitivity reaction) Rare: Dermatitis bullous. Common: Dermatitis (including contact dermatitis), rash, erythema, eczema, pruritus. **Interactions:** Since systemic absorption of diclofenac from topical application is very low, interactions are very unlikely. Warning: Not for veterinary use. **Packs:** Tube of 30 gm. **Note:** For Further information, please write to Medical information cell, Branded Formulations, Dr. Reddy's Laboratories Ltd., 7-1-27, Ameerpet Hyderabad-500 016. Toll free No.: 1800 425 0014.

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India BSS dated 20 Dec 2017 India BSS dated 20 Dec 2017 revised on and effective from 19 Nov 18.

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Voveran® TPM™ gel

Dr. Reddy's

BASIC SUCCINCT STATEMENT: VOVERAN® TPM™ gel

Presentation: The base of Voveran TPM gel is Tocopheryl Phosphate Mixture (TPM) containing 1.16% diclofenac diethylamine (corresponding to 1% diclofenac sodium). **Indications:** •Post-traumatic inflammation of the tendons, ligaments, and joints, e.g. due to sprains, strains, and bruises. •Localised forms of soft-tissue rheumatism, e.g. tendovaginitis, bursitis, shoulder-hand syndrome, and periarthropathy. •Localised forms of degenerative rheumatism, e.g. osteoarthrosis of the peripheral joints and vertebral column. • Osteoarthritis. •Rheumatoid arthritis. **Dosage:** Voveran® TPM gel is applied locally to the skin 3 or 4 times daily and rubbed in gently. For example, 2 to 4 g Voveran TPM gel (cherry- to walnut-sized mass) are sufficient to treat an area of about 400 to 800 cm^2. **Contraindications:** •Hypersensitivity to diclofenac or to any of the excipients. •Known hypersensitivity to acetylsalicylic acid (aspirin) or to other non-steroidal anti-inflammatory drugs. •Third trimester of pregnancy. **Precautions/Warnings:** •Do not apply to diseased skin, open wounds or injuries. •Avoid contact with the eyes and mucous membranes. •Do not take by mouth. •Do not use with occlusive dressing. •Systemic side effects cannot be excluded when the product is applied to large areas of skin for prolonged periods of time. •Avoid use during pregnancy. • The treatment should be discontinued if a skin rash develops after applying the product. **Interactions:** None known. **Adverse reactions:** Common (≥1 to <10%): Rash, eczema, erythema, dermatitis (including contact dermatitis), pruritus. Rare (≥0.01 to <0.1%): Bullous dermatitis. Very rare (<0.01%): Pustular rash, hypersensitivity (including urticaria), asthma, photosensitivity reaction, angioedema. **Packs:** Tube of 30 gm. **Warning:** Not for veterinary use. **Note:** For Further information, please write to Medical information cell, Branded Formulations, Dr. Reddy's Laboratories Ltd., 7-1-27, Ameerpet Hyderabad-500 016. Toll free No.: 1800 425 0014, e-mail: customerservices@drreddys.com

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India BSS version dtd 25 Jul 16 revised on 21 Nov 18 based on full prescribing information dtd 25 Jul 16 effective from 21 Nov 18.

Voveran® 1ml aq
Diclofenac Sodium 75mg/1ml
injection

Dr.Reddy's

BASIC SUCCINCT STATEMENT: VOVERAN® 1 ml AQ

Presentation: Diclofenac sodium: ampoules of 75 mg/1 ml for i.m, I.V use (inj.) **Indications:** For management of painful conditions in post-operative cases, rheumatoid arthritis and osteoarthritis. **Dosage and administration:** Dose to be individually adjusted. Adverse effects may be minimized by using the lowest effective dose for the shortest duration necessary. Adults- 1 or at the most 2 ampoules (i.m. or i.v.) daily as initial therapy for not more than 2 days. Ampoules must not be given as an i.v. bolus injection. Before i.v. infusion dilute contents of 1 ampoule with 100 to 500 mL of saline 0.9% or glucose 5% and buffering with sodium bicarbonate should be done. I. V administration should be done as slow infusion over 30min to 2hrs. Total maximum daily dose is 150 mg. The directions for intramuscular injection both for intradeltoid and intragluteal must be followed in order to avoid damage to a nerve or other tissue at the injection site. **Contraindications:** •Known hypersensitivity to the active substance or any of the other excipients. •Active gastric or intestinal ulcer, bleeding or perforation. •Last trimester of pregnancy. Hepatic and renal failure (GFR <15 mL/min/1.73 m2). •Severe cardiac failure. •Like other non-steroidal anti-inflammatory drugs (NSAIDs), Voveran 1ml is also contraindicated in patients in whom attacks of asthma, urticaria, or acute rhinitis are precipitated by acetylsalicylic acid or other NSAIDs. **Warnings and precautions:** •Caution recommended in patients with symptoms/history of gastrointestinal (GI) disease and in elderly because of the risks of GI bleeding or perforation. To be discontinued if these conditions occur. •Combined use with protective agents to be considered in patients with history of ulcer, elderly and those requiring low dose acetylsalicylic acid. •Caution when used concomitantly with corticosteroids, anticoagulants, anti-platelet agents •Caution recommended in patients with ulcerative colitis or Crohn's disease. •Treatment generally not recommended in patients with established heart disease or uncontrolled hypertension. If needed in patients with established heart disease, uncontrolled hypertension or significant cardiovascular risk factors, treat only after careful consideration and with dose adjustment and periodic re-evaluation, especially when treatment continues for more than 4 weeks. •Monitoring of blood counts recommended during prolonged treatment. •Monitoring recommended in patients with defects of haemostasis. •Caution recommended in patients with asthma, seasonal allergic rhinitis or chronic pulmonary diseases. •Special caution recommended for parenteral use in patients with bronchial asthma (INJ only). •Risks of serious allergic reactions. To be discontinued if these conditions occur. •Caution recommended in patients with impaired hepatic function (including porphyria). •Monitoring of liver function during prolonged treatment. •Beware of severe fluid retention and edema. •Monitoring of renal function recommended in patients with history of hypertension, impaired cardiac or renal function, extracellular volume depletion, the elderly, patients treated with diuretics or drugs that impact renal function. •Avoid use with other systemic NSAIDs including COX-2 inhibitors. •May mask signs and symptoms of infection. **Pregnancy:** The use of diclofenac has not been studied in pregnancy; hence must not be used in first two trimesters of pregnancy unless the potential benefit to the mother outweighs the risk to the foetus. Avoid usage after 30 weeks of gestation. Not recommended in new born babies and children. **Lactation:** Like other NSAIDS, diclofenac passes into the breast milk in small amounts. Therefore should not be administered during breast feeding in order to avoid adverse effects in the infant. **Fertility:** Like other NSAIDS, diclofenac may impair female fertility; hence it should not be used in women attempting to conceive. **Elderly:** Caution is indicated on basic medical terms. **Drug Interactions:** •Monitoring of serum lithium or digoxin levels recommended if used concomitantly. •Caution with concomitant use of diuretics and antihypertensives (e.g. beta blockers, ACE inhibitors), methotrexate, other NSAIDs and corticosteroids, SSRIs.). •Dose of diclofenac to be reduced in patients receiving ciclosporin or tacrolimus. •Monitoring of serum potassium level if used concomitantly with drugs known to cause hyperkalemia (e.g. diuretics, ciclosporin, tacrolimus, trimethoprim. •Interactions with concomitant use of quinolone antibacterials, CYP2C9 inhibitors (e.g. voriconazole), and CYP2C9 inducers (e.g. rifampicin). •Monitoring recommended for patients receiving anticoagulants, anti-platelet agents as well as blood glucose level if used concomitantly with antidiabetics. •Cases of metabolic acidosis have been reported when diclofenac was co-administered with metformin, especially in patients with pre-existing renal impairment. •Monitoring of phenytoin plasma concentrations is recommended if used concomitantly. **Adverse Reactions:** Injection site reaction, injection site pain, injection site induration. Headache, dizziness, vertigo, nausea, vomiting, diarrhea, dyspepsia, abdominal pain, flatulence, decreased appetite, transaminases increased, rash. • Myocardial infarction, cardiac failure, chest pain, palpitations.• Hypersensitivity, anaphylactic and anaphylactoid reactions (including hypotension and shock), somnolence, asthma (including dyspnea), gastritis, gastrointestinal hemorrhage, hematemesis, hemorrhagic diarrhea, melena, gastrointestinal ulcer (with or without bleeding, gastrointestinal stenosis or perforation, which may lead to peritonitis), hepatitis, jaundice, liver disorder, urticaria, edema, injection site necrosis.•Thrombocytopenia, leukopenia, anemia (including hemolytic anemia and aplastic anemia), agranulocytosis, angioedema (including face edema), disorientation, depression, insomnia, nightmare, irritability, psychotic disorder, paresthesia, memory impairment, convulsion, anxiety, tremor, aseptic meningitis, dysgeusia, cerebrovascular accident, visual impairment, blurred vision, diplopia, tinnitus, impaired hearing, hypertension, vasculitis, pneumonitis, colitis (including hemorrhagic colitis, ischemic colitis and exacerbation of ulcerative colitis or Crohn's disease), constipation, stomatitis, glossitis, esophageal disorder, intestinal diaphragm disease, pancreatitis, fulminant hepatitis, hepatic necrosis/ hepatic failure, bullous dermatitis, eczema, erythema, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), exfoliative dermatitis, alopecia, photosensivity reaction, purpura, Henoch-Schonlein purpura, pruritus, acute kidney injury (including acute renal failure), hematuria, proteinuria, nephrotic syndrome, tubulointerstitial nephritis, renal papillary necrosis, injection site abscess. **Packaging information:** 1 ml glass ampoule.

Note: For Further information, please write to Medical information cell, Branded Formulations, Dr. Reddy's Laboratories Ltd., 7-1-27, Ameerpet Hyderabad-500 016. Toll free No.: 1800 425 0014, e-mail: customerservices@drreddys.com.

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Warning: Not for veterinary use.

For the use of a registered medical practitioner or a hospital or a laboratory only.

India BSS dated 16 Jan 19 updated on 14 Nov 19.

Voveran® D

Diclofenac Free Acid (Dispersible)

BASIC SUCCINCT STATEMENT: VOVERAN-D®

Presentation: Gastro-resistant gelatin enrobed tablets of 50 mg (GE tab).; sustained-release tablets of 75 mg and 100 mg (SR tab.); Diclofenac free acid: dispersible tablets of 46.5 mg, corresponding to 50 mg diclofenac sodium (D tab.). **Indications:** • Inflammatory and degenerative forms of rheumatism: rheumatoid arthritis, ankylosing spondylitis, osteoarthritis and spondylarthritis, painful syndromes of the vertebral column, non-articular rheumatism. • Post-traumatic and post-operative pain, inflammation, and swelling, e.g., following dental or orthopaedic surgery. • Painful and/or inflammatory conditions in gynaecology, e.g., primary dysmenorrhoea or adnexitis. (SR tab). • Post-operative inflammation and pain, e.g., following dental or orthopedic surgery. • Painful post-traumatic inflammatory states, e.g., due to sprains. • Flare-up of osteoarthritis. (GE tab, D tab) • Acute attacks of gout. (GE tab, D tab) • Non-articular rheumatism. (GE tab, D tab) • Painful syndromes of the vertebral column. • Painful and/or inflammatory conditions in gynaecology, e.g., primary dysmenorrhea or adnexitis. (GE tab, D tab) • As an adjuvant in severe painful inflammatory infections of the ear, nose or throat, e.g., pharyngotonsillitis, otitis. In keeping with general therapeutic principles, the underlying disease should be treated with basic therapy, as appropriate. Fever alone is not an indication. (D Tab, GE Tab). **Dosage and administration: Dosage:** Dose to be individually adjusted, lowest effective dose to be given for the shortest duration. (For GE tab, SR tab., D tab.): Adults - 50 to 150 mg/day in divided doses (dysmenorrhoea : up to 200 mg/day for GE Tab., D tab.). Adolescents over 14 years of age: 0.5 to 2 mg/kg/day (juvenile rheumatoid arthritis up to 3 mg/kg/day for GE Tab.), with a maximum daily dose of 150 mg. (For D tab): Adults- Short-term treatment only. • **Special patient populations:** Patients with established heart disease or cardiovascular risk factors should only receive doses up to max. 100 mg daily if treated for more than 4 weeks. (SR Tab). **Contraindications:** • Active gastric or intestinal ulcer, bleeding or perforation. • Last trimester of pregnancy. • Hepatic failure. •Renal failure (GFR <15 mL/min/1.73m2). • Severe cardiac failure. • Known hypersensitivity to acetylsalicylic acid or other non-steroidal anti-inflammatory drugs (NSAIDs). **Warnings and precautions:** • Caution recommended in patients with symptoms/history of gastrointestinal (GI) disease and in elderly because of the risks of GI bleeding or perforation. To be discontinued if these conditions occur. • Combined use with protective agents to be considered in patients with history of ulcer, elderly and those requiring low dose acetylsalicylic acid. •Caution when used concomitantly with corticosteroids, anticoagulants, anti-platelet agents or SSRIs. • Caution recommended in patients with ulcerative colitis or Crohn's disease. • Treatment generally not recommended in patients with established heart disease or uncontrolled hypertension. If needed in patients with established heart disease, uncontrolled hypertension or significant cardiovascular risk factors, treat only after careful consideration and with dose adjustment and periodic re-evaluation, especially when treatment continues for more than 4 weeks. • Monitoring of blood counts recommended during prolonged treatment. • Monitoring recommended in patients with defects of haemostasis. • Caution recommended in patients with asthma, seasonal allergic rhinitis or chronic pulmonary diseases. • Risks of serious allergic reactions. To be discontinued if these conditions occur. • Caution recommended in patients with impaired hepatic function (including porphyria). • Monitoring of liver function during prolonged treatment. • Beware of severe fluid retention and edema. • Monitoring of renal function recommended in patients with history of hypertension, impaired cardiac or renal function, extracellular volume depletion, the elderly, patients treated with diuretics or drugs that impact renal function. • Caution is indicated in the elderly. • Avoid use with other systemic NSAIDs including COX-2 inhibitors. • May mask signs and symptoms of infection. Pregnancy and breast-feeding: • Must not be used during the third trimester of pregnancy. • Should not be used in the first and second trimester of pregnancy and by breast-feeding mothers. **Fertility:** • Not recommended to use in women attempting to conceive as it may impair female fertility. Adverse drug reactions: • Common undesirable effects are: Headache, dizziness, vertigo, nausea, vomiting, diarrhea, dyspepsia, abdominal pain, flatulence, decreased appetite, elevations (>3 times the upper normal limit) of serum aminotransferase enzymes (SGOT or AST, SGPT or ALT). • **Uncommon* undesirable effects are:** myocardial infarction, cardiac failure, chest pain, palpitations (*frequency reflects data from long-term treatment with a high dose of 150 mg/day). • **Rare undesirable effects are:** Hypersensitivity, anaphylactic and anaphylactoid reactions (including hypotension and shock), somnolence, asthma (including dyspnea), gastritis, gastrointestinal hemorrhage, hematemesis, hemorrhagic diarrhea, melena, gastrointestinal ulcer (with or without bleeding, gastrointestinal stenosis or perforation, which may lead to peritonitis), hepatitis, jaundice, liver disorder, urticaria, edema. • **Very rare undesirable effects are:** Thrombocytopenia, leukopenia, anemia (including hemolytic anemia and aplastic anemia), agranulocytosis, angioedema (including face edema), disorientation, depression, insomnia, nightmare, irritability, psychotic disorder, paresthesia, memory impairment, convulsion, anxiety, tremor, aseptic meningitis, dysgeusia, cerebrovascular accident, visual impairment*, blurred vision*, diplopia*, tinnitus, impaired hearing, hypertension, vasculitis, pneumonitis, colitis (including hemorrhagic colitis, ischemic colitis and exacerbation of ulcerative colitis or Crohn's disease), constipation, stomatitis, glossitis, esophageal disorder, intestinal diaphragm disease, pancreatitis, fulminant hepatitis, hepatic necrosis/ hepatic failure, bullous dermatitis, eczema, erythema, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), exfoliative dermatitis, alopecia, photosensivity reaction, purpura, Henoch-Schonlein purpura, pruritus, acute kidney injury (including acute renal failure), hematuria, proteinuria, nephrotic syndrome, tubulointerstitial nephritis, renal papillary necrosis. ***Visual effects:** If symptoms of visual disturbances occur during diclofenac treatment, an ophthalmological examination may be considered to exclude other causes. Interactions: • Monitoring of serum lithium or digoxin levels recommended if used concomitantly. • Caution with concomitant use of diuretics and antihypertensives (e.g. beta blockers, ACE inhibitors), methotrexate, other NSAIDs and corticosteroids, SSRIs.). • Dose of diclofenac to be reduced in patients receiving ciclosporin or tacrolimus. • Monitoring of serum potassium level if used concomitantly with drugs known to cause hyperkalemia (e.g. diuretics, ciclosporin, tacrolimus, trimethoprim. • Interactions with concomitant use of quinolone antibacterials, CYP2C9 inhibitors (e.g. voriconazole), and CYP2C9 inducers (e.g. rifampicin). • Monitoring recommended for patients receiving anticoagulants, anti-platelet agents as well as blood glucose level if used concomitantly with antidiabetics. • Cases of metabolic acidosis have been reported when diclofenac was co-administered with metformin, especially in patients with pre-existing renal impairment. • Monitoring of phenytoin plasma concentrations is recommended if used concomitantly. Packs: Voveran 50 GE: Box of 7x4x15 tablets. Voveran SR 100: Box of 25 X 15 tablets. Voveran SR 75: Box of 10 X 10 tablets. Voveran D: Box of 10 X 10 tablets. **Note:** For Further information, please write to Medical information cell, Branded Formulations, **Dr. Reddy's Laboratories Ltd.**, 7-1-27, Ameerpet Hyderabad-500 016. Toll free No.: 1800 425 0014, e-mail: customerservices@drreddys.com. Warning: Not for veterinary use.

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For the use only of a registered medical practitioner or a hospital or a laboratory only.

India BSS dtd 11 May 2022 based on international BSS dtd 5 Feb 2018.

Voveran® Plus

Diclofenac sodium 50 mg and paracetamol 325 mg

BASIC SUCCINCT STATEMENT: VOVERAN® PLUS

Presentation: Each tablet of Voveran® Plus contains: Diclofenac sodium 50 mg; Paracetamol 325 mg. Indications: Short-term treatment in the following acute conditions: Post-traumatic pain, inflammation and swelling, e.g. due to sprains; Post-operative pain, inflammation and swelling, e.g. following dental or orthopaedic surgery; Painful and/or inflammatory conditions in gynaecology, e.g. primary dysmenorrhoea or adnexitis; Painful syndromes of the vertebral column; Non-articular rheumatism; As an adjuvant in severe painful inflammatory infections of the ear, nose or throat, e.g. pharyngotonsillitis, otitis. In keeping with general therapeutic principles, the underlying disease should be treated with basic therapy, as appropriate. Fever alone is not an indication. **Dosage:** Adults: 1 tablet upto three times a day. **Contraindications:** Active gastric or intestinal ulcer, bleeding or perforation; known hypersensitivity to the active substances, to aspirin or other non-steroidal anti-inflammatory drugs (NSAIDs) and any of the excipients. Last trimester of pregnancy; severe hepatic, renal or cardiac failure. Acute hepatitis. Hereditary constitutional hyperbilirubinaemia (Gilbert's disease). **Precautions/warnings:** Avoid use with other systemic NSAIDs including COX-2 inhibitors. Risks of gastrointestinal (GI) bleeding, perforation or serious allergic reactions; to be discontinued if these conditions occur. Risk of allergic reactions. May mask signs and symptoms of infection. Extreme caution in renal and/or hepatic impairment (continuous medical monitoring indicated), haemolytic anaemia due to glucose-6-phosphate dehydrogenase deficiency and when used concomitantly with potentially hepatotoxic or liver enzyme-inducing drugs. Caution recommended in patients with symptoms/history of GI disease, asthma, seasonal allergic rhinitis, chronic pulmonary diseases, elderly or impaired hepatic function (including porphyria), ulcerative colitis or Crohn's disease. Caution when used concomitantly with corticosteroids, anticoagulants, anti-platelets agents or SSRIs . Caution when driving or using machines. Should not be used in the first and second trimester of pregnancy and by breast-feeding mothers. Not recommended to use in women attempting to conceive as it may impair female fertility. Combined use with protective agents to be considered in patients with history of ulcer, elderly, and those requiring low dose aspirin. Monitoring of liver function and blood counts recommended during prolonged treatment. Monitoring of renal function recommended in patients with history of hypertension, impaired cardiac or renal function, extracellular volume depletion, the elderly, patients treated with diuretics or drugs that impact renal function. Monitoring recommended in patients with defect of haemostasis. Beware of severe fluid retention and oedema Caution in patients with alcohol dependence. Analgesic headache with chronic use. Long-term use may result in analgesic nephropathy. As the cardiovascular risks of diclofenac may increase with dose and duration of exposure, the lowest effective daily dose should be used for the shortest duration possible. The patient's need for symptomatic relief and response to therapy should be re-evaluated periodically, especially when treatment continues for more than 4 weeks. **Interactions:** Caution with concomitant use of diuretics and antihypertensives (e.g. beta blockers, ACE inhibitors), methotrexate, other NSAIDs and corticosteroids, SSRIs. Monitoring recommended for patients receiving anticoagulants, anti-platelets agents as well as blood glucose level if used concomitantly with antidiabetics. Monitoring of serum lithium or digoxin levels recommended if used concomitantly. Dose to be reduced in patients receiving ciclosporin. Interactions with concomitant use of quinolone antibacterials, barbiturates, carbamazepine, hydantoin, isoniazide, rifampicin, sulfinpyrazone, chloramphenicol, salicylamide and chlorzoxazone. Metoclopramide & domperidone Cholestyramine and propantheline and zidovudine. **Undesirable effects:** Thrombocytopenia, leukopenia, anemia, agranulocytosis, Hypersensitivity, anaphylactic and anaphylactoid reactions, Angioedema, Disorientation, depression, insomnia, nightmare, irritability, psychotic disorder,Headache, dizziness, Somnolence, Paresthesia, memory impairment, convulsion, anxiety, tremor, meningitis aseptic, dysgeusia, cerebrovascular accident,Visual impairment, vision blurred, diplopia,Vertigo, Tinnitus, hearing impaired, Myocardial infarction, cardiac failure, palpitations, chest pain, Hypertension, vasculitis, Asthma, bronchospasm, Pneumonitis,Nausea, vomiting, diarrhea, dyspepsia, abdominal pain, flatulence, decreased appetite, Gastritis, gastrointestinal hemorrhage, hematemesis, diarrhea hemorrhagic, melena, gastrointestinal ulcer (with or without bleeding or perforation), Colitis (including hemorrhagic colitis and exacerbation of ulcerative colitis or Crohn's disease), constipation, stomatitis, glossitis, esophageal disorder, intestinal diaphragm disease, pancreatitis, Transaminases increased, Hepatitis, jaundice, liver disorder, Hepatitis fulminant, hepatic necrosis, hepatic failure, Rash, Urticaria, Dermatitis bullous, eczema, erythema, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis , dermatitis exfoliative, alopecia, photosensitivity reaction, purpura, Henoch-Schonlein purpura, pruritus, Renal failure acute, hematuria, proteinuria, nephrotic syndrome, tubulointerstitial nephritis, renal papillary necrosis, General disorders and administration site conditions, Edema. **Warning:** Not for veterinary use. **Packs:** Blister pack of 10 X 10 softlets. **Note:** For Further information, please write to Medical information cell, Branded Formulations, **Dr. Reddy's Laboratories Ltd.,** 7-1-27, Ameerpet Hyderabad-500 016. Toll free No.: 1800 425 0014, e-mail: customerservices@drreddys.com.

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For the use only of a registered medical practitioner or a hospital or a laboratory.

India BSS dtd 5 May 14 revised on 21 Nov 18 effective from 21 Nov 18.

VOLTAFLAM® TH4

Diclofenac Sodium 50mg + Thiocolchicoside 4 mg

BASIC SUCCINCT STATEMENT: VOLTAFLAM® TH4

Presentation: Each hard gelatin capsule contains Diclofenac Sodium IP 50 mg (as gastro-resistant tablets) and Thiocolchicoside IP 4 mg (as uncoated tablet). **Indications:** For treatment of acute inflammatory conditions associated with spasm in adults only. **Dosage:** The reccomended daily dosage is one capsule twice a day. The maximum reccomended dose of Thiocolchicoside is 16 mg daily in divided dose and for Diclofenac Sodium IP is 150 mg daily. The dose should not exceed maximum daily reccomended dose. The treatment duration is limited to 7 consecutive days. The dose should be adjusted individually as a general reccomendation. Adverse effects may be minimized by using the lowest effective dose for shortest duration necessary to control symptoms. Contraindications: Hypersensitivity to the active substances or any of the excipients •Active, gastric or intestinal ulcer, bleeding or perforation. • History of gastrointestinal bleeding or perforation, relating to previous NSAID therapy • Active, or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding) • Last trimester of pregnancy • Hepatic failure • Renal failure • Established congestive heart failure (NYHA11-1V), ischemic heart disease, peripheral arterial disease and/or cerebrovascular disease. • Like other non-steroidal anti-inflammatory drugs (NSAIDs), diclofenac is also contraindicated in patients in whom attacks of asthma, angioedema, urticaria or acute rhinitis are precipitated by ibuprofen, acetylsalicylic acid or other nonsteroidal anti- inflammatory drugs. **Warnings/Precautions:** The concomitant use of Diclofenac with systemic NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided due to the absence of any evidence demonstrating synergistic benefits and the potential for additive undesirable effects. • Caution is indicated in the elderly on basic medical grounds. In particular, it is recommended that the lowest effective dose be used in frail elderly patients or those with a low body weight. The elderly have increased frequency of adverse reactions to NSAIDs especially gastrointestinal bleeding and perforation which may be fatal. To reduce the risk of GI toxicity In patients with a history of ulcer, particularly if complicated with haemorrhage or perforation, and in the elderly, the treatment should be initiated and maintained at the lowest effective dose. Combination therapy with protective agents (e.g. misoprostol or proton pump inhibitors) should be considered for these patients, and also for patients requiring concomitant use of medicinal products containing low dose acetylsalicylic acid (ASA/aspirin or medicinal products likely to increase gastrointestinal risk. • Caution is recommended in patients receiving concomitant medications which could increase the risk of ulceration or bleeding, such as systemic corticosterolds, anticoagulants such as warfarin, selective serotonin-reuptake inhibitors (SSR1s) or anti-platelet agents such as acetylsalicylic acid. • Close medical surveillance and caution should be exercised in patients with ulcerative colitis, or with Crohn's disease as these conditions may be exacerbated. • Close medical surveillance is required when prescribing diclofenac to patients with impairment of hepatic function as their condition may be exacerbated. • **Renal affects:** As fluid retention and oedema have been reported in association with NSAIDs therapy, including diclofenac, particular caution is called for in patients with impaired cardiac or renal function. • **Cardiovascular and cerebrovascular affects:** Patients with significant risk factors for cardiovascular events (e.g. hypertension, hyperlipidemia, diabetes mellitus, and smoking) should only be treated with diclofenac after careful consideration. • **Haematological effects:** Use of diclofenac is recommended only for short-term treatment. Diclofenac may reversibly inhibit platelet aggregation. Patients with defects of haemostasis, bleeding diasthesis or haematological abnormalities should be carefully monitored. • **Female fertility:** The use of diclofenac may impair female fertility and is not recommended in women attempting to conceive. In women who may have difficulties conceiving or who are undergoing investigation of infertility, withdrawal of Diclofenac should be considered. **Drug Interactions:** • Caution with concomitant use of diuretics and antihypertensives (e.g. beta blockers, ACE inhibitors), methotrexate, other NSAIDs and corticosteroids, SSRIs. • Monitoring recommended for patients receiving anticoagulants, anti-platelets agents as well as blood glucose level if used concomitantly with antidiabetics. • Monitoring of serum lithium or digoxin levels recommended if used concomitantly. • Dose of diclofenac to be reduced in patients receiving ciclosporin. • Interactions with concomitant use of quinolone antibacterials, CYP2C9 inhibitors (e.g. sulfinpyrazone, voriconazole). • Monitoring of phenytoin plasma concentrations is recommended if used concomitantly. • **Salicylamide:** Salicylamide prolongs the elimination half-life of paracetamol and increases the accumulation of hepatotoxic metabolites. • **Chlorzoxazone:** Co-administration of paracetamol and chlorzoxazone enhances the hepatotoxlcity of bath substances. • **Zidovudine:** Concomitant use of zidovudine and paracetamol increases the tendency to neuropenia. Fertility, pregnancy and lactation: • **Pregnancy:** Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/ foetal development. Data from epidemiological studies suggest an increased risk of miscarriage and or cardiac malformation after use of a prostaglandin synthesis inhibitor in early pregnancy. The absolute risk for cardiovascular malformation was increased from less than 1% up to approximately 1.5%. The risk is believed to increase with dose and duration of therapy. In animals, administration of a prostaglandin synthesis inhibitor has shown to result in increased pre and post-implantation loss and embryo-foetal lethality. Voltaflam TH4 is contraindicated in pregnancy and in women of child bearing potential who are not using effective contraceptive. • **Lactation:** Like other NSAIDs, Diclofenac passes into breast milk in small amounts and Thiocolchicoside is contraindicated in breast-feeding. Hence, Voltaflam TH4 should not be administered in lactating mothers. • **Fertility:** Voltaflam TH4 may impair female fertility and is not reccomended in women attempting to conceive. **Effects on ability to drive and use machines:** Patients who experience visual disturbances, dizziness, vertigo, somnolence, central nervous system disturbances, drowsiness or fatigue while taking NSAIDs should refrain from driving or operating machinery. **Warning:** Not for veterinary use. **Packs:** Pack of 10X10 hard gelatin capsules. India BSS dated 28 Aug 20 based on the Pack insert dated 13th Aug 2019.

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India BSS dtd 20 Mar 2018 based on international BSS dtd 5 Feb 2018 effective from 10 Sep 18.

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