OMEZ
Omeprazole 20mg Capsules

Dr.Reddy's

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: January 30, 2020

OMEZ-D+ SR

Esomeprazole 40mg + Domperidone 30 mg sustained release Capsules

Dr.Reddy's

OMEZ-DSR+ (Esomeprazole and Domperidone capsule) Dosage Form and Strength: Each capsule contains Esomeprazole Magnesium Trihydrate IP 40 mg as enteric coated pellets and domperidone IP 30 mg as sustained release pellets and Excipient qs. Therapeutic Indications: Omez DSR+ is indicated for the treatment of adult patients with gastro esophageal reflux disease (GERD) not responding to esomeprazole alone. Dosage and Administration: One capsule of Esomeprazole 40mg + SR Domperidone 30mg orally once daily for upto 4 weeks. 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).

Adverse Effects: Common adverse events reported with Esomeprazole in clinical trials include headache, nausea, vomiting, diarrhoea, abdominal pain, flatulence, constipation, and dry mouth. The most frequent reactions to Domperidone are those related to elevated prolactin levels including breast tenderness, galactorrhoea, gynaecomastia and amenorrhoea. Warnings and Precautions: Carcinogenesis, Mutagenesis, Impairment of Fertility. Drug interactions: Drug interaction studies have shown that Esomeprazole does not have any clinically significant interactions with phenytoin, warfarin, quinidine, clarithromycin, amoxycillin, oral contraceptives or diazepam. Esomeprazole may interfere with the absorption of drugs where gastric pH is an important determinant of bioavailability (e.g., ketoconazole, iron salts and digoxin). Concomitant administration of anticholinergic drugs may antagonize the antidyspeptic effect of Domperidone. If administered prior to atropine, Domperidone reduces the relaxant eect of atropine upon the lower esophageal sphincter but has no reversing effect if atropine is administered first.

Further information available upon request.

Date: May 2023

Please refer to full prescribing information before usage.

Available on request from Dr. Reddy's. For further information please write to Dr. Reddy's Laboratories Ltd., 8-2-337, Banjara Hills, Hyderabad- 500 034. India

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

Nise
Nimesulide 100 mg Tablets

Dr.Reddy's

Nise (Abbreviated Prescribing Information) India

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 (di zziness, 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

Doxycycline hyclate 100 mg, lactic acid bacillus 5 billion spores Capsules

Dr.Reddy's

Composition: Each capsule contains Doxycycline 100mg + Lactic acid bacillus spores-5 billion. **Therapeutic Indications:** For adult patients prone to intra-abdominal bacterial infection & antibiotic associated diarrhoea. **Dosage and Administration:** In Adults for the treatment ofacute infections is two capsules per day (as a single dose or in divided doses) followed by a maintenance dose of one capsule/day. In themanagement of more severe infections, two capsules daily should be given throughout 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 (last half 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. Dosage adjustment required in patients with hepatic impairment. **Adverse reactions:** In patients receiving tetracyclines include anorexia, nausea, vomiting, diarrhoea, rash, photosensitivity, urticaria, and hemolytic anemia. **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 during nursing should be avoided if possible. Further information available upon request.

KETOROL SP
Serratiopeptidase 15mg, Paracetamol 325mg, Aceclofenac 100mg Tablets

Dr.Reddy's

Ketorol SP (Aceclofenac, Paracetamol & Serratiopeptidase Tablet)
Composition: Each film coated tablet contains: Aceclofenac 100 mg, Paracetamol 325 mg, Serratiopeptidase 15 mg (As enteric coated tablet eq. to 30000 enzyme activity units of Serratiopeptidase). Indications: Resolution of inflammation and pain due to bone and soft tissue injury & Resolution of post-operative inflammation, oedema and pain. Dosage & administration: 1 tablet twice daily to be taken orally, not to be chewed or crushed and swallowed as whole along with sufficient amount of liquid. Contraindications: It is contraindicated when there is known sensitivity to aceclofenac, paracetamol, serratiopeptidase or to any of the excipients; history of or active, recurrent peptic ulcer/haemorrhage; previous episodes of hypersensitivity reactions (e.g. asthma, rhinitis, angio-oedema or urticaria) in response to NSAIDs; history of anaphylactic reactions; severe heart failure, hypertension, and hepatic or renal impairment; pregnancy (last trimester), unless there are compelling reasons for using it. The lowest effective dosage should be used. Special Warnings and Precautions for use: It should not be combined with other analgesic medications that contain paracetamol and should be given with care to patients with impaired kidney or liver function. Patients at the greatest risk of this reaction are those with impaired renal function, cardiac impairment, liver dysfunction, those taking diuretics and the elderly. Renal function should be monitored in these patients. Use in specific populations: In Pregnancy and lactation- use in the last trimester of pregnancy is contraindicated and is not recommended in breastfeeding women. In Geriatric patients- caution is advised in elderly patients who are more likely to have concomitant renal, hepatic or cardiovascular impairment or receiving concurrent medication. Adverse Reactions: Commonly-observed are:- GI Effects: Peptic ulcers, perforation or GI bleeding, nausea, vomiting, diarrhoea, flatulence, constipation, dyspepsia, abdominal pain, melaena, haematemesis, ulcerative stomatitis, exacerbation of colitis and Crohn's disease have been reported following administration. Hypersensitivity reactions have been reported following treatment with NSAIDs. Cardiovascular: Oedema, hypertension and cardiac failure have been reported in association with NSAID treatment. Over dosage: Liver damage is possible in adults who have taken 10 g or more of paracetamol. Ingestion of 5 g or more of paracetamol may lead to liver damage if the patient has risk factors.
Dated: 13th July, 2021
Further information is available on request.

Atarax Tab
Hydroxyzine HCL 10 and 25 mg Tablets/Syrup/Drops

Dr.Reddy's

ATARAX® Injection, Tablets, Syrup and Drops (Hydroxyzine)
Abbreviated Prescribing Information

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 up to 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. **Contra-Indications:** 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.

ZEDEX

Dextromethorphan 10mg + Chlorpheniramine Maleate 2mg/5ml Syrup

Dr.Reddy's

Abridged Prescribing Information: ZEDEX®

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 2 years, have not been established. **ADVERSE REACTIONS:** 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: Adults-5ml 4 times a day, Children above 6 years 2.5ml 4 times a day, Children 4-6 years 1.25ml 4 times a day

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

ZEDEX -P

Chlorpheniramine Maleate 0.5mg + Phenylephrine 5mg + Paracetamol 125mg + Sodium Citrate 60mg + Menthol 1mg/5ml Syrup

Dr.Reddy's

Abridged Prescribing Information: ZEDEX-P®

COMPOSITION: Each 5ml of Zedex P syrup consists of Chlorpheniramine maleate IP: 0.5 mg Paracetamol: 125mg Phenylephrine hydrochloride IP: 5mg, Sodium Citrate: 60mg Menthol IP :1mg Flavoured syrup base as **INDICATIONS:** For the treatment of common cold and cough associated with fever **CONTRAINDICATIONS:** Hypersensitivity to any of the ingredients. Also contraindicated in patients with hyperthyroidism. Moderate to severe hypertension, ventricular tachycardia, severe coronary artery disease, narrow-angle glaucoma, urinary retention and prostatic hypertrophy, peptic ulcer, emphysema, chronic bronchitis: It should not be used as treatment for lower respiratory tract conditions including asthma and during an asthma attack. It should not be used in patients on MAO inhibitor therapy (or for 14 days after stopping MAOI therapy). **WARNINGS:** Use with caution in the presence of cardiac disorders, diabetes or peripheral vascular disease. 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 P Syrup can cause fetal harm or is excreted in human milk.

Therefore, Zedex-P Syrup should be given to a pregnant or lactating woman only if clearly need.

Pediatric Use: Safety and effectiveness in the pediatric population under 2 years have not been established. Others: Caution against driving and operating machinery is advised while taking Zedex P syrup. ADVERSE REACTIONS: The components of Zedex-P are well tolerated and adverse effects are very rare. These may include hypertension, palpitations, sedations, dizziness, drowsiness, headache, sleep disturbances, pallor, rashes, pruritis, Gl disturbance, dry mouth, urinary difficulty and change in blood cell counts.

DOSAGE AND ADMINISTRATION: Children (4-12 yrs)-5ml thrice daily, (2-4 yrs)-2.5ml thrice daily

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

BRO-ZEDEX

Terbutaline Sulphate 1.25mg + Bromhexine HCl 4mg + Guaiphenesin 50mg + Menthol 2.5mg/5ml

Dr.Reddy's

Abridged Prescribing Information: BROZEDEX SF SYRUP

COMPOSITION: Each 5 ml syrup contains: Bromhexine IP 4 mg, Terbutaline IP:1.25mg, Guaiphenesin IP- 50 mg, Mentholated sugar-free syrup base with sorbitol as. **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. Sugar-free base decreases the effect of added sugar in diabetes and patient with other cardiac risk factors. **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. Guaiphenesin is possibly porphyrogenic and should be used with caution 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 ADMINISTARTION:** Adults: 2 teaspoon, thrice daily, Children: 6-12 years: 1 teaspoon 3-4 times/day, 2-6 years: 1/4 - 1 teaspoon 3-4 times a day. Adapted from Brozedex SF PI latest version.

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

Dr. Reddy's Laboratories Ltd. 7-1-27, Ameerpret, Hyderabad-500 016
Toll-free No: 1800 425 0014: Website: https://www.drreddys.com
Email: customerservices@drreddys.com

Full prescribing information available on request.

BRO-ZEDEX LS

Dr.Reddy's

Abridged Prescribing Information: BROZEDEX LS

COMPOSITIONS: COMPOSITIONS Each 5ml syrup contains: Levosalbutamol Sulphate IP: 1mg/0.25 mg Ambroxol hydrochloride IP: 30 mg/ 7.5 mg, Guaiphenesin IP: 50 mg /12.5 mg, Mentholated Flavoured syrup base q.s. **INDICATIONS:** For the symptomatic relief of bronchospasm in bronchial asthma & chronic bronchitis **COCONTRAINDICATION:** Hypersensitivity to any of the ingredient of the formulation. **PRECAUTIONS AND WARNING:** General Potentially serious hypokalemia may result from beta 2- agonist therapy. Levosalbutamol like all other beta adrenergic agonists can produce clinically significant cardiovascular effect in some patients, as measured by pulse rate, blood pressure and/ or symptoms. Although such effects are uncommon after administration of Levosaloutamol at recommended doses, if they occur, the drug may need to discontinue.

Oral Levosalbutamol should be used with caution in patient with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias or hypertension. Guaiphenesin is possibly porphyrogenic and should be used with caution in patient with porphyria. Pregnancy & Lactation The component of the medication may cross the placental barrier or may get excreted in breast milk therefore this medication should be used only when clearly needed during pregnancy and lactation. **ADVERSE REACTION:** Potentially serious hypokalemia as a result from Beta 2 agonist therapy may rarely occurs. This effect may be potentiated by hypoxia. Particular cautions is advised in severe asthma, with monitoring off serum potassium levels. Other side effect such as palpitation, fine tremors of the skeletal muscle (particularly the hand) and muscle cramps may occur. The other likely side effects are gastrointestinal disturbances such as nausea, vomiting, burning substernal or epigastric pain and diarrhoea. In some cases nervousness, headache, dizziness, fatigue and sleeplessness may occur.

DOSAGE AND ADMINISTRATION: 2-6yrs: 2.5ml twice daily, 6-12 years: Start with 2.5 ml thrice daily and increased to 5ml of syrup 2-3 times daily. Adults (>12 yrs): 5ml three times daily. This may be increases to 10ml syrup twice daily. Adapted from Brozedex LS KID PI latest version.

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

Voveran® SR 100

Diclofenac Sodium Sustained Release with wax matrix

Dr.Reddy's

BASIC SUCCINCT STATEMENT:

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.

Marketed by: (Under agreement with Novartis India Limited)

Dr. Reddy's Laboratories Ltd., Global Distribution Centre, Survey No. 41, Bachupally (V), Bachupally (M), Medchal - Malkajgiri (Dist.), Hyderabad - 500 090, Telangana, India.

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.

In Back Pain & Sprains

Voveran® Emulgel®

Diclofenac Diethylamine Gel 1.16%

Dr.Reddy's

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 sucient to treat an area of about 400 to 800 cm2. 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 eects 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 eective from 19 Nov 18.

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India BSS dtd 11 May 2022 based on international BSS dtd 5 Feb 2018.
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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 eects may be minimized by using the lowest eective 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 buering 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 eects 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.
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India BSS dated 16 Jan 19 updated on 14 Nov 19.

In Back, Neck & Joint Pain

℞ **Voveran-D®**

Diclofenac Free Acid (Dispersible)

Dr.Reddy's

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 eective 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 eects 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 eects 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 eects 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 eects 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 eects: 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.

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

In Acute Pain and Inflammation

Voveran® Plus

Diclofenac sodium 50mg and paracetamol 325mg

Dr.Reddy's

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 eective 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 eects: 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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