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.

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.

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Full prescribing information available on request.