IZRA

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

Abbreviated prescribing information for IZRA (Esomeprazole Magnesium Tablets I.P.) [Please refer the complete prescribing information available at www.torrentpharma.com]

MECHANISM OF ACTION: Esomeprazole is a weak base and is concentrated and converted to the active form in the highly acidic environment of the secretory canaliculi of the parietal cell, where it inhibits the enzyme H +K + -ATPase – the acid pump and inhibits both basal and stimulated acid secretion.

INDICATION: It is indicated for GERD, erosive reflux esophagitis, prevention of relapse of esophagitis & helps in eradication of H.Pylori associated peptic ulcer.

DOSAGE AND ADMINISTRATION: The dose of IZAR must be taken as prescribe by Physician. Administration: The tablets should be swallowed orally with liquid. The tablets should not be chewed or crushed.

CONTRAINDICATION: Hypersensitivity to the active substance, to substituted benzimidazoles or to any of the excipients. Esomeprazole should not be used concomitantly with nelfinavir.

WARNINGS & PRECAUTIONS*:* Long term use, Helicobacter pylori eradication, Gastrointestinal infections, Absorption of vitamin B12, Hypomagnesaemia, Risk of fracture, Subacute cutaneous lupus erythematosus (SCLE), Co-administration of esomeprazole with atazanavir is not recommended and Increased Chromogranin A (CgA) level may interfere with investigations for neuroendocrine tumours. To avoid this interference, esomeprazole treatment should be stopped for at least 5 days before CgA measurements.

DRUG INTERACTIONS: Effects of esomeprazole on the pharmacokinetics of other drugs like Protease inhibitors, Methotrexate, Tacrolimus, Medicinal products metabolised by CYP2C19, Diazepam, Phenytoin, Voriconazole, Cilostazol, Cisapride, Warfarin, Clopidogrel, Amoxicillin and quinidine, Naproxen or rofecoxib, Medicinal products which inhibit CYP2C19 and/or CYP3A4 and Medicinal products which induce CYP2C19 and/or CYP3A4.

ADVERSE REACTIONS:

These effects are rare and may affect up to 1 in 1,000 people.

Common (may affect up to 1 in 10 people): Headache, Effects on your stomach or gut: diarrhoea, stomach pain, constipation, wind (flatulence), Feeling sick (nausea) or being sick (vomiting), Benign polyps in the stomach. *Uncommon (may affect up to 1 in 100 people):* Swelling of the feet and ankles, Disturbed sleep (insomnia), Dizziness, tingling feelings such as “pins and needles”, feeling sleepy, Spinning feeling (vertigo), Dry mouth, Changes in blood tests that check how the liver is working. Skin rash, lumpy rash (hives) and itchy skin, Fracture of the hip, wrist or spine (if IZRA is used in high doses and over long duration). *Rare (may affect up to 1 in 1,000 people):* Blood problems such as a reduced number of white cells or platelets. This can cause weakness, bruising or make infections more likely, Low levels of sodium in the blood. This may cause weakness, being sick (vomiting) and cramps. Feeling agitated, confused or depressed, Taste changes, Eyesight problems such as blurred vision, Suddenly feeling wheezy or short of breath (bronchospasm), An inflammation of the inside of the mouth, An infection called “thrush” which can affect the gut and is caused by a fungus, Liver problems, including jaundice which can cause yellow skin, dark urine, and tiredness, Hair loss (alopecia), Skin rash on exposure to sunshine, Joint pains (arthralgia) or muscle pains (myalgia), Generally feeling unwell and lacking energy.

Increased sweating *Very rare (may affect up to 1 in 10,000 people):* Changes in blood count including agranulocytosis (lack of white blood cells) Aggression, seeing,feeling or hearing things that are not there (hallucinations). Severe liver problems leading to liver failure and inflammation

of the brain. Sudden onset of a severe rash or blistering or peeling skin. This may be associated with a high fever and joint pains (Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis), Muscle weakness, Severe kidney problems, Enlarged breasts in men, Acute kidney injury *Not known (frequency cannot be estimated from the available data):* If you are on IZRA for more than three months it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness or increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium. Inflammation in the gut (leading to diarrhoea) and Rash, possibly with pain in the joints. IZRA may in very rare cases affect the white blood cells leading to immune deficiency. If you have an infection with symptoms such as fever with a severely reduced general condition or fever with symptoms of a local infection such as pain in the neck, throat or mouth or difficulties in urinating, you must consult your doctor as soon as possible so that a lack of white blood cells (agranulocytosis) can be ruled out by a blood test. It is important for you to give information about your medication at this time.

MARKETED BY:

TORRENT PHARMACEUTICALS LTD.

IN/ IZRA 20,40mg/Apr-20/01/PI

(Additional information is available on request)