Package leaflet: Information for the patient

Zosa Junior

10 mg gastro-resistant granules for oral suspension, sachet

Esomeprazole

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.

- If you have any further questions, ask your doctor or pharmacist.

- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Zosa Junior is and what it is used for

2. What you need to know before you take Zosa Junior

3. How to take Zosa Junior

4. Possible side effects

5. How to store Zosa Junior

6. Contents of the pack and other information

1. What Zosa Junior is and what it is used for

Zosa Junior contains a substance called esomeprazole. This belongs to a group of medicines called proton pump inhibitors. These work by reducing the amount of acid that your stomach produces.

Zosa Junior is used to treat the following conditions:

Children over 1 year of age

Zosa Junior is used to treat a condition called “gastroesophageal reflux disease” (GERD).

• This is where acid from the stomach escapes into the gullet (esophagus) causing pain, inflammation and heartburn. Heartburn is a burning feeling rising from the stomach or lower chest up towards the neck.

• In children, the symptoms of the condition can include the return of stomach contents into the mouth (regurgitation), being sick (vomiting) and poor weight gain.

Children over 4 years of age

• Ulcers which are infected with bacteria called '*Helicobacter pylori'*. If your child has this condition, your doctor may also prescribe antibiotics to treat the infection and allow the ulcer to heal.

2. What you need to know before you take Zosa Junior

Do not take Zosa Junior:

• If you are allergic to esomeprazole or other similar proton pump inhibitors (e.g. pantoprazole, lansoprazole, rabeprazole, omeprazole), or any other ingredients of this medicine (listed in section 6).

• If you are taking a medicine containing nelfinavir (used to treat HIV infection).

Do not take Zosa Junior if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Zosa Junior.

Warnings and precautions

Talk to your doctor or pharmacist before taking Zosa Junior:

• If you have severe liver problems.

• If you have severe kidney problems.

• If you have ever had a skin reaction after treatment with a medicine similar to Zosa Junior that reduces stomach acid.

• If you are due to have a specific blood test (Chromogranin A).

Zosa Junior may hide the symptoms of other diseases. **Therefore, if any of the following happen to you while you are taking Zosa Junior, you should talk to your doctor immediately:**

• You lose a lot of weight for no reason.

• You get stomach pain or indigestion.

• You begin to vomit repeatedly.

• You have problems swallowing.

• You vomit blood or pass black (blood-stained) motions (faeces).

If you have been prescribed Zosa Junior "on demand" you should contact your doctor if the symptoms are persistent or change character. "On demand" treatment has not been investigated in children and is therefore not recommended in this patient group.

Taking a proton pump inhibitor like Zosa Junior, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).

Rash and skin symptoms

If you get a rash on your skin, especially in areas exposed to the sun tell your doctor as soon as you can, as you may need to stop your treatment with Zosa Junior. Remember to also mention any other ill-effects like pain in your joints.

Serious skin rashes have occurred in patients taking esomeprazole (see also section 4). The rash can involve ulcers of the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). These serious skin rashes often come after flu-like symptoms such as fever, headache, body ache. The rash may cover large parts of the body with blistering and peeling of the skin.

If at any time during the treatment (even after several weeks) you develop a rash or any of these skin symptoms, stop taking this medicine and contact your doctor immediately.

Other medicines and Zosa Junior

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This includes medicines that you buy without a prescription. This is because Zosa Junior can affect the way some medicines work and some medicines can have an effect on Zosa Junior.

Do not take Zosa Junior if you are taking nelfinavir (used to treat HIV infection).

Tell your doctor or pharmacist if you are taking any of the following medicines:

• Atazanavir (used to treat HIV infection).

• Clopidogrel (used to prevent blood clots).

• Ketoconazole, itraconazole or voriconazole (used to treat infections caused by a fungus).

• Erlotinib (used to treat cancer).

• Diazepam (used to treat anxiety or relax muscles).

• Citalopram, imipramine or clomipramine (used to treat depression).

• Phenytoin (used in epilepsy).

• Warfarin or coumarin (medicines called anticoagulants that are used to thin your blood).

• Cilostazol (used to treat intermittent claudication – a pain in your legs when you walk which is caused by an insufficient blood supply).

• Cisapride (used for indigestion and heartburn).

• Digoxin (used for heart problems).

• Methotrexate (a chemotherapy medicine used in high doses to treat cancer) – if you are taking a high dose of methotrexate, your doctor may temporarily stop your Zosa Junior treatment.

• Tacrolimus (organ transplantation).

• Rifampicin (used for treatment of tuberculosis).

• St. John's wort (*Hypericum perforatum)* (used to treat depression).

If your doctor has prescribed the antibiotics amoxicillin and clarithromycin as well as Zosa Junior to treat ulcers caused by *Helicobacter pylori* infection, it is very important that you tell your doctor about any other medicines you are taking.

Zosa Junior gastro-resistant granules with food and drink

Zosa Junior gastro-resistant granules can be taken with or without food.

Pregnancy, breast-feeding and fertility

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Your doctor will decide whether you can take Zosa Junior during this time.

It is not known if Zosa Junior passes into breast milk. Therefore you should not take Zosa Junior if you are breast-feeding.

Driving and using machines

Zosa Junior is not likely to affect you being able to drive or use tools or machines. However, side effects such as dizziness and blurred vision may uncommonly or rarely occur (see section 4). If affected, you should not drive or use machines.

Zosa Junior contains sucrose and glucose

Zosa Junior contains sucrose and glucose which are both types of sugars. Careful oral hygiene and regular tooth brushing are therefore important. If you have been told by your doctor, that you have an intolerance to some sugars, contact your doctor before taking Zosa Junior

3. How to take Zosa Junior

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Your medicine comes as granules in individual sachets. Each sachet contains 10 mg of esomeprazole. Your doctor will tell you how many sachets to take each day. He or she will also tell you how long you should take them for.

• Empty the contents of the sachet or sachets into a glass containing some water. Do not use fizzy (carbonated) water. The amount of water depends on the number of sachets that your doctor has told you to take at one time.

• Use 15 millilitres (ml) of water (3 teaspoonfuls) for each sachet. This means that you will need 15 ml for one sachet and 30 ml for two sachets.

• Stir the granules in the water.

• Leave the mixture for a few minutes until it has thickened.

• Stir again and drink the mixture. The granules must not be chewed or crushed. Do not leave the mixture to stand for more than 30 minutes before you drink it.

• If anything remains in the glass, add some more water, stir and drink it immediately.

Zosa Junior gastro-resistant granules can be taken with or without food.

If you are being fed using a feeding (gastric) tube, your doctor or nurse can give you Zosa Junior through your tube. Information for your doctor or nurse is provided at the end of this leaflet.

The recommended doses are given below:

Use in children aged 1 to 11 years

• Zosa Junior is not recommended for children younger than 1 year.

To treat gastroesophageal reflux disease (GERD)

• The recommended dose is one sachet (10 mg) or two sachets (20 mg) once daily. The dose for children is based on the child's weight and the doctor will decide the correct dose.

Use in children aged 4 years and older

To treat ulcers caused by Helicobacter pylori infection and to stop them coming back.

• The dose for children is based on the child's weight and your doctor will decide the correct dose. The doctor will also prescribe two antibiotics for your child.

Use in adults and adolescents

Zosa Junior oral suspension may also be used by patients having difficulty swallowing dispersed Zosa Junior gastro-resistant tablets. Information on dosing for patients from the age of 12 years is in gastro-resistant tablet product information (ask your doctor or pharmacist if you require further information).

Elderly

There is no need to alter the dose if you are elderly.

People with liver problems

• For people with severe liver problems, the maximum daily dose of Zosa Junior is two sachets (20 mg). For children 1-11 years with severe liver problems, a maximum dose of 10 mg should not be exceeded.

People with kidney problems

• There are no special dosage restrictions for people with kidney problems. However, if you have severe kidney problems your doctor may decide to carry out regular tests.

If you take more Zosa Junior than you should

If you have taken more Zosa Junior than prescribed by your doctor, seek medical advice.

If you forget to take Zosa Junior

If you forget to take a dose, take it as soon as you remember. If it is almost time to take the next dose, wait until then. Do not take a double dose to make up for the forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you notice any of the following serious side effects, stop taking Zosa Junior and contact a doctor immediately:

• Yellow skin, dark urine and tiredness which can be symptoms of liver problems. These effects are rare, and may affect up to 1 in 1,000 people.

• Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties in swallowing (severe allergic reaction). These effects are rare, and may affect up to 1 in 1,000 people.

• Sudden onset of a severe rash or reddening of the skin with blisters or peeling may occur even after several weeks of treatment. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. The skin rashes may develop into serious widespread skin damage (peeling of the epidermis and superficial mucous membranes) with life threatening consequences. This could be 'erythema multiforme', 'Stevens-Johnson syndrome', 'toxic epidermal necrolysis' or 'drug reaction with eosinophilia and systemic symptoms'. These effects are very rare, and might affect up to 1 in 10,000 people.

Other side effects include:

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 Zosa Junior 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, , drug reaction with eosinophilia and systemic symptoms).

• Muscle weakness.

• Severe kidney problems.

• Enlarged breasts in men.

Not known (frequency cannot be estimated from the available data)

• If you are on Zosa Junior 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).

• Rash, possibly with pain in the joints.

Zosa Junior 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.

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly: Website: www.zuventus.co.in and click the tab “Safety Reporting” located on the top right end of the home page.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Zosa Junior

This medicinal product does not require any special storage conditions.

• Keep out of the sight and reach of children.

• Do not use this medicine after the expiry date which is stated on the carton and sachet after EXP. The expiry date refers to the last day of that month.

• The reconstituted suspension should be used within 30 minutes.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Zosa Junior gastro-resistant granules for oral suspension contains

Each sachet contains :

Esomeprazole Magnesium Trihydrate IP

equivalent to Esomeprazole -10 mg

(As Gastro-resistant form)

Colour : Sunset Yellow FC

7.Marketing Authorisation Holder

Zuventus Healthcare Limited
Zuventus House Plot No. Y2, CTS No: 358/A2,
near Nahur Railway Station, off Raycon IT Park Road,
Nahur West, Mumbai, Maharashtra 400078

8.Date of revision

This leaflet was last revised in 06/2023.