

Package leaflet: Information for the user

ZOSA DSR® 40/30 mg Capsule

Esomeprazole gastro-resistant tablet 40 mg IP

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 or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What ZOSA DSR® is and what it is used for
2. What you need to know before you take ZOSA DSR®
3. How to take ZOSA DSR®
4. Possible side effects
5. How to store ZOSA DSR®
6. Contents of the pack and other information

1. What ZOSA DSR® is and what it is used for

ZOSA DSR® contains medicines called esomeprazole and domperidone.

Esomeprazole belongs to a group of medicines called proton pump inhibitors. They work by reducing the amount of acid that your stomach produces.

Domperidone belongs to a group of medicines called dopamine antagonists.

ZOSA DSR® is used for the treatment of adult patients with gastroesophageal reflux disease (GERD) not responding to esomeprazole alone. Gastroesophageal reflux disease (GERD) is a condition where acid from the stomach escapes into the food pipe (the tube which connects your throat to your stomach) causing pain, inflammation, and heartburn.

Children and adolescents aged 1-18 years

Safety and effectiveness of ZOSA DSR® have not been established in pediatric patients.

2. What you need to know before you take ZOSA DSR®

Do not take ZOSA DSR®

- If you are allergic to esomeprazole or domperidone or any of the other ingredients of this medicine. Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- If you are allergic to other proton pump inhibitor medicines (e.g. pantoprazole, lansoprazole, rabeprazole, omeprazole).
- If you are taking a medicine containing nelfinavir (used to treat HIV infection).
- If you have a tumour of the pituitary gland (prolactinoma)
- If you have a blockage or tear in your intestines
- If you have black, tarry bowel motions (stools) or notice blood in your bowel motions. This could be a sign of bleeding in the stomach or intestines.
- If you have a moderate or severe liver disease.
- If your ECG (electrocardiogram) shows a heart problem called “prolonged QT corrected interval”.
- If you have or had a problem where your heart cannot pump the blood round your body as well as it should (condition called heart failure).
- If you have a problem that gives you a low level of potassium or magnesium, or a high level of potassium in your blood.
- If you are taking certain medicines

You must not take ZOSA DSR® if any of the above apply to you. If you are not sure, talk to your doctor or nurse before you are given this medicine.

Warnings and precautions

Talk to your doctor or pharmacist or nurse before using ZOSA DSR®:

- You have severe liver problems.
- You have severe kidney problems.
- You have ever had a skin reaction after treatment with a medicine similar to esomeprazole that reduces stomach acid.
- You are due to have a specific blood test (Chromogranin A).
- If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking ZOSA DSR®. Do this even if they have applied in the past.

Esomeprazole may hide the symptoms of other diseases. Therefore, if any of the following happen to you before you take esomeprazole or after you are given it, talk to your doctor straight away:

- You lose a lot of weight for no reason and have problems swallowing.
- You get stomach pain or indigestion.
- You begin to vomit food or blood.
- You pass black stools (blood-stained faeces).

If you have been prescribed esomeprazole “on demand” you should contact your doctor if your symptoms continue or change in character.

Taking a proton pump inhibitor like esomeprazole, 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).

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 DSR®. Remember to also mention any other ill effects like pain in your joints.

Domperidone may be associated with an increased risk of heart rhythm disorder and cardiac arrest. This risk may be more likely in those over 60 years old or taking doses higher than 30 mg per day. The risk also increases when domperidone is given together with some drugs. Tell your doctor or pharmacist if you are taking drugs to treat infection (fungal infections or bacterial infection) and/or if you have heart problems or AIDS/HIV.

Domperidone should be used at the lowest effective dose in adults and adolescents 12 years of age and older and a body weight of 35kg or more.

While taking ZOSA DSR®, contact your doctor if you experience heart rhythm disorders such as palpitations, trouble breathing, loss of consciousness. Treatment with domperidone should be stopped.

Other medicines and ZOSA DSR®

Tell your doctor or nurse 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 DSR[®] can affect the way some medicines work, and some medicines can have an effect on ZOSA DSR[®].

You must not be given ZOSA DSR[®] if you are taking a medicine containing nelfinavir (used to treat HIV infection).

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

- Protease inhibitors like atazanavir (used to treat HIV infection).
- Clopidogrel (used to prevent blood clots).
- Ketoconazole, itraconazole, fluconazole, or voriconazole (used to treat infections caused by a fungus).
- Erlotinib (used to treat cancer).
- Citalopram, imipramine or clomipramine (used to treat depression).
- Diazepam (used to treat anxiety, relax muscles or in epilepsy).
- Phenytoin (used in epilepsy). If you are taking phenytoin, your doctor will need to monitor you when you start or stop having ZOSA DSR[®].
- Medicines that are used to thin your blood, such as warfarin. Your doctor may need to monitor you when you start or stop having ZOSA DSR[®].
- Cilostazol (used to treat intermittent claudication – a pain in your legs when you walk which is caused by an insufficient blood supply).
- Cisapride, dolasetron, prucalopride (used for gastro-intestinal disorders including 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 DSR[®] treatment.
- Tacrolimus (organ transplantation).
- Rifampicin (used for treatment of tuberculosis).
- St. John's wort (*Hypericum perforatum*) (used to treat depression).
- Erythromycin, clarithromycin, telithromycin, moxifloxacin, pentamidine (antibiotics to treat bacterial infections).
- Amiodarone, dronedarone, quinidine, disopyramide, dofetilide, sotalol, diltiazem, verapamil (used to treat heart problems or high blood pressure)
- Haloperidol, pimozide, sertindole (for treating psychoses)
- Citalopram, escitalopram (to treat depression)
 - Mequitazine, mizolastine (for treating allergy)

- Halofantrine (for malaria)
- Toremifene, vandetanib, vincamine (for treating cancer).

Esomeprazole with food and drink

ZOSA DSR® should be taken at least 1 hour before meals.

Pregnancy and breast-feeding

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

It is not known if esomeprazole passes into breast milk. Small amounts of domperidone have been detected in breast-milk. Domperidone may cause unwanted side effects affecting the heart in a breast-fed baby. Therefore, you should not be given ZOSA DSR® if you are breastfeeding.

Driving and using machines

Esomeprazole is not likely to affect you being able to drive or use any tools or machines. Domperidone does not affect your ability to drive or use machines. However, side effects such as dizziness and blurred vision may uncommonly occur. If affected, you should not drive or use machines.

3. How to use ZOSA DSR®

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

- If you are taking this medicine for a long time, your doctor will want to monitor you (particularly if you are taking it for more than a year).
- If your doctor has told you to take this medicine as and when you need it, tell your doctor if your symptoms change.

How much to take

Your doctor will tell you how many capsules to take and how long to take them for.

The usual dose is one capsule once daily.

Taking this medicine

- You should take your capsules at least one hour before taking a meal.
- Swallow your capsules whole with a drink of water. Do not open or chew or crush the capsules.

Elderly

Dose adjustment is not required in the elderly.

People with kidney problems

Your doctor may tell you to take a lower dose or to take the medicine less often.

If you take more Esomeprazole than you should

- If you take more this medicine than prescribed by your doctor, talk to your doctor or pharmacist straight away. Take the carton and any capsules left with you. This is so the doctors know what you have taken.
- In the event of overdose, symptomatic treatment could be implemented. An ECG monitoring could be undertaken, because of the possibility of a heart problem called prolonged QT interval.
- The signs of taking more than you should include feeling sleepy, confused, uncontrolled movements which include unusual eye movements, unusual movements of the tongue or abnormal posture (such as a twisted neck).

If you forget to take Esomeprazole

- If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, 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 this medicine and contact a doctor immediately.

- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties in swallowing (severe allergic reaction).
- Reddening of the skin with blisters or peeling. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. This could be ‘Stevens-Johnson syndrome’ or ‘toxic epidermal necrolysis’.
- 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.

Additionally, stop taking this medicine and see your doctor or go to a hospital straightaway if:

- You have swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria). This may mean you are having an allergic reaction to domperidone.

- You have any uncontrolled movements. These include irregular eye movements, unusual movements of the tongue, and abnormal posture such as a twisted neck, trembling and muscle stiffness. This is more likely to happen in children. These symptoms should stop once you stop taking ZOSA DSR®.
- You have a very fast or unusual heartbeat. This could be a sign of a life-threatening heart problem.
- You have a fit (seizure).

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 esomeprazole is used in high doses and over long duration).
- Lowering of sexual drive (libido) in men
- Feeling anxious
- Feeling drowsy
- Headaches
- Diarrhoea
- Unusual production of breast milk in men and women
- Painful or tender breasts
- A general feeling of weakness

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.
- Eyesight problems such as blurred vision.
- Taste changes.
- 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.

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

- If you are on esomeprazole 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.

Inflammation of the pancreas (pancreatitis)

Systemic lupus erythematosus

Excessive sweating (hyperhidrosis)

Kidney damage (acute kidney injury)

Disorders of the cardiovascular system: heart rhythm disorders (rapid or irregular heart beat) have been reported; if this happens, you should stop the treatment immediately. Domperidone may be associated with an increased risk of heart rhythm disorder and cardiac arrest. This risk may be more likely in those over 60 years old or taking doses higher than 30 mg per day.

Feeling agitated or irritable

Feeling more nervous than usual

Abnormal eye movements

Inability to urinate

Breast enlargement in men

In women, menstrual periods may be irregular or stop

A blood test shows changes in the way your liver is working.

Esomeprazole 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.

Some patients who have used domperidone for conditions and dosages requiring longer term medical supervision have experienced the following unwanted effects: Restlessness; swollen or enlarged breasts, unusual discharge from breasts, irregular menstrual periods in women, difficulty breastfeeding, depression, hypersensitivity.

Side effects such as feeling drowsy, nervous, agitated or irritable or having a fit are more likely to happen in children.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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.

You can also report the side effect with the help of your treating physician.

5. How to store ZOSA DSR®

Keep this medicine out of the sight and reach of children

Store below 25°C. Protect from light and moisture.

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

Store this medicine in the original package (blister).

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

6. Contents of the pack and other information

What ZOSA DSR® contains

Each hard gelatine capsule contains:

Esomeprazole Magnesium Trihydrate IP

equivalent to Esomeprazole..... 40 mg

(as enteric coated pellets)

Domperidone IP 30 mg

(As prolonged release pellets)

Excipients..... q.s.