

Mezzopram® 10mg, 20mg and 40mg Dispersible Gastro-resistant Tablets

Omeprazole 10mg, 20mg and 40mg Dispersible Gastro-resistant Tablets

(omeprazole magnesium)

Your medicine is known by above names but will be referred to as Mezzopram through this leaflet.

Patient Information Leaflet

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 signs of illness 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 Mezzopram is and what it is used for
- 2) What you need to know before you take Mezzopram
- 3) How to take Mezzopram
- 4) Possible side effects
- 5) How to store Mezzopram
- 6) Contents of the pack and other information

1) What Mezzopram is and what it is used for

Mezzopram Dispersible gastro-resistant tablets contain the active substance omeprazole. It belongs to a group of medicines called 'proton pump inhibitors'. They work by reducing the amount of acid that your stomach produces.

Mezzopram is used to treat the following conditions:

In adults:

- 'Gastro-oesophageal reflux disease' (GORD). This is where acid from the stomach escapes into the gullet (the tube which connects your throat to your stomach) causing pain, inflammation and heartburn.
- Ulcers in the upper part of the intestine (duodenal ulcer) or stomach (gastric ulcer).
- Ulcers which are infected with bacteria called '*Helicobacter pylori*'. If you have this condition, your doctor may also prescribe antibiotics to treat the infection and allow the ulcer to heal.
- Ulcers caused by medicines called NSAIDs (Non-Steroidal Anti-Inflammatory Drugs). Mezzopram can also be used to stop ulcers from forming if you are taking NSAIDs.
- Too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome).

In children:

Children over 1 year of age and ≥ 10 kg

- 'Gastro-oesophageal reflux disease' (GORD). This is where acid from the stomach escapes into the gullet (the tube which connects your throat to your stomach) causing pain, inflammation and heartburn. 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 and adolescents

- 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 Mezzopram

Do not take Mezzopram

- if you are allergic to omeprazole or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to medicines containing other proton pump inhibitors (e.g. pantoprazole, lansoprazole, rabeprazole, esomeprazole).
- if you are taking a medicine containing nelfinavir (for HIV infection).

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Mezzopram.

Serious skin reactions including Stevens Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS) and acute generalized exanthematous pustulosis (AGEP) have been reported in association with Omeprazole treatment. Stop using Omeprazole and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Mezzopram may hide the symptoms of other diseases. Therefore, if any of the following happen to you before you start taking Mezzopram or while you are taking 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).
- You experience severe or persistent diarrhoea, as omeprazole has been associated with a small increase in infectious diarrhoea.
- You have severe liver problems.
- You are due to have a specific blood test (Chromogranin A).
- You have ever had a skin reaction after treatment with a medicine similar to Mezzopram that reduces stomach acid.

If you take Mezzopram on a long-term basis (longer than 1 year) your doctor will probably keep you under regular surveillance. You should report any new and exceptional symptoms and circumstances whenever you see your doctor.

When taking omeprazole, inflammation in your kidney may occur. Signs and symptoms may include decreased volume of urine or blood in your urine and/or hypersensitivity reactions such as fever, rash, and joint stiffness. You should report such signs to the treating physician.

Taking a proton pump inhibitor like Mezzopram, 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 Mezzopram. Remember to also mention any other ill-effects like pain in your joints.

This medicine may affect the way that your body absorbs vitamin B₁₂, particularly if you need to take it for a long time. Please contact your doctor if you notice any of the following symptoms, which could indicate low levels of vitamin B₁₂:

- Extreme tiredness or lack of energy
- Pins and needles
- Sore or red tongue, mouth ulcers
- Muscle weakness

- Disturbed vision
- Problems with memory, confusion, depression

Children

Some children with chronic illnesses may require long-term treatment although it is not recommended. Do not give this medicine to children under 1 year of age or < 10 kg.

Other medicines and Mezzopram

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 Mezzopram can affect the way some medicines work and some medicines can have an effect on Mezzopram.

Do not take Mezzopram if you are taking a medicine containing **nelfinavir** (used to treat HIV infection).

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

- Ketoconazole, itraconazole, posaconazole or voriconazole (used to treat infections caused by a fungus).
- Digoxin (used to treat heart problems).
- 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 taking Mezzopram.
- Medicines that are used to thin your blood, such as warfarin or other vitamin K blockers. Your doctor may need to monitor you when you start or stop taking Mezzopram.
- Rifampicin (used to treat tuberculosis).
- Atazanavir (used to treat HIV infections).
- Tacrolimus (in cases of organ transplantation).
- St John's wort (*Hypericum perforatum*) (used to treat mild depression).
- Cilostazol (used to treat intermittent claudication).
- Saquinavir (used to treat HIV infection).
- Clopidogrel (used to prevent blood clots (thrombi)).
- Erlotinib (used to treat cancer).
- 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 Mezzopram treatment.

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

Mezzopram with food and drink

See section 3.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Omeprazole is excreted in breast milk but is not likely to influence the child when therapeutic doses are used. Your doctor will decide whether you can take Mezzopram if you are breast-feeding.

Driving and using machines

Mezzopram is not likely to affect your ability to drive or use any tools or machines. Side effects such as dizziness and visual disturbances may occur (see section 4). If affected, you should not drive or operate machinery.

Mezzopram gastro-resistant tablets contain glucose and sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3) How to take Mezzopram

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

Your doctor will tell you how many tablets to take and how long to take them for. This will depend on your condition and how old you are.

The recommended dose is given below:

Adults:

To treat symptoms of GORD such as **heartburn and acid regurgitation:**

- If your doctor has found that your food pipe (gullet) has been slightly damaged, the recommended dose is 20 mg once a day for 4-8 weeks. Your doctor may tell you to take a dose of 40 mg for a further 8 weeks if your gullet has not yet healed.
- The recommended dose once the gullet has healed is 10 mg once a day.
- If your gullet has not been damaged, the usual dose is 10 mg once a day.

To treat **ulcers in the upper part of the intestine** (duodenal ulcer):

- The recommended dose is 20 mg once a day for 2 weeks. Your doctor may tell you to take the same dose for a further 2 weeks if your ulcer has not yet healed.
- If the ulcers does not fully heal, the dose can be increased to 40 mg once a day for 4 weeks.

To treat **ulcers in the stomach** (gastric ulcer):

- The recommended dose is 20 mg once a day for 4 weeks. Your doctor may tell you to take the same dose for a further 4 weeks if your ulcer has not yet healed.
- If the ulcers does not fully heal, the dose can be increased to 40 mg once a day for 8 weeks.

To **prevent the duodenal and stomach ulcers** from coming back:

- The recommended dose is 10 mg or 20 mg once a day. Your doctor may increase the dose to 40 mg once a day.

To treat duodenal and stomach **ulcers caused by NSAIDs** (Non-Steroidal Anti-Inflammatory Drugs):

- The recommended dose is 20 mg once a day for 4 to 8 weeks.

To **prevent duodenal and stomach ulcers** if you are taking **NSAIDs**:

- The recommended dose is 20 mg once a day.

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

- The recommended dose is 20 mg Mezzopram twice a day for one week.
- Your doctor will also tell you to take two antibiotics among amoxicillin, clarithromycin and metronidazole.

To treat too much acid in the stomach caused by a **growth in the pancreas (Zollinger-Ellison syndrome)**:

- The recommended dose is 60 mg daily.
- Your doctor will adjust the dose depending on your needs and will also decide how long you need to take the medicine for.

Use in Children and adolescents

To treat symptoms of GORD such as **heartburn and acid regurgitation:**

- Children over 1 year of age and with a body weight of more than 10 kg may take Mezzopram. The dose for children is based on the child's weight and the doctor will decide the correct dose.

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

- Children aged over 4 years may take Mezzopram. The dose for children is based on the child's weight and the doctor will decide the correct dose.
- Your doctor will also prescribe two antibiotics called amoxicillin and clarithromycin for your child.

Taking this medicine

It is recommended that you take your tablets in the morning.

You can take your tablets with food or on an empty stomach.

Swallow your tablets whole with half a glass of water. Do not chew or crush the tablets. This is because the tablets contain coated pellets which stop the medicine from being broken down by the acid in your stomach. It is important not to damage the pellets.

What to do if you or your child have trouble swallowing the tablets

If you or your child have trouble swallowing the tablets:

- Break the tablet and disperse it in a spoonful of water (non-fizzy), any acidic fruit juice (e.g. apple, orange or pineapple) or apple sauce.
- Always stir the mixture just before drinking (the mixture will not be clear). Then drink the mixture straight away or within 15 minutes.
- To make sure that you have drunk all of the medicine, rinse the glass very well with half a glass of water and drink it. **Do not use** milk or fizzy water. The solid pieces contain the medicine - do not chew or crush them.

If you take more Mezzopram than you should

If you take more Mezzopram than prescribed by your doctor, talk to your doctor or pharmacist straight away.

If you forget to take Mezzopram

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 stop taking Mezzopram

Do not stop taking Mezzopram without first talking to your doctor or pharmacist.

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

The 20 mg and 40 mg tablet can be divided into equal doses.

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 rare (may affect up to 1 in 1,000 people) or very rare (may affect up to 1 in 10,000 people) but serious side effects, stop taking Mezzopram 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). (rare)
- 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'. (very rare)
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome). (rare)
- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalized exanthematous pustulosis). (rare)
- Yellow skin, dark urine and tiredness which can be symptoms of liver problems.

Other side effects include:

Common side effects (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 side effects (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).
- Changes in blood tests that check how the liver is working.
- Skin rash, lumpy rash (hives) and itchy skin.
- Generally feeling unwell and lacking energy.
- Fracture in the hip, wrist or spine

Rare side effects (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).
- Dry mouth.
- An inflammation of the inside of the mouth.
- An infection called "thrush" which can affect the gut and is caused by a fungus.
- Hair loss (alopecia).
- Skin rash on exposure to sunshine.
- Joint pains (arthralgia) or muscle pains (myalgia).
- Severe kidney problems (interstitial nephritis).
- Increased sweating.

Very rare side effects (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
- Erythema multiforme
- Muscle weakness.
- Enlarged breasts in men.

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

- Inflammation in the gut (leading to diarrhoea).
- If you are on Mezzopram 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.

- Rash, possibly with pain in the joints.

Mezzopram 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 medicine at this time.

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 via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects you can help provide more information on the safety of this medicine.

5) How to store Mezzopram

- **Keep out of the sight and reach of children.**
- Do not use after the expiry date printed on the carton and blister label after 'EXP'. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- If the medicine becomes discoloured or show any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- Medicines should not be disposed of 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 Mezzopram contains:

The active substance is omeprazole (as omeprazole magnesium).

- Each Mezzopram 10mg gastro-resistant tablet contains 10mg omeprazole (as omeprazole magnesium).
- Each Mezzopram 20mg gastro-resistant tablet contains 20mg omeprazole (as omeprazole magnesium).
- Each Mezzopram 40mg gastro-resistant tablet contains 40mg omeprazole (as omeprazole magnesium).

The other ingredients are:

Tablet core: sucrose, maize starch, d-glucose, copovidone, povidone K 22,5-27, talc, titanium dioxide (E171), methacrylic acid-ethyl acrylate copolymer (1:1), glycerol monostearate, propylene glycol, stearic acid, polysorbate 80, simeticone, cellulose microcrystalline, macrogol 6000, crospovidone (type A), silica colloidal anhydrous, magnesium stearate.

Tablet coating: hypromellose, macrogol 6000, titanium dioxide (E171), talc, red iron oxide red (E172).

Mezzopram 10mg and 40mg also contain yellow iron oxide (E172).

What Mezzopram looks like and contents of the pack

- **Mezzopram 10mg Dispersible Gastro-resistant Tablets:** Light pink oval film-coated tablet (11.2 x 5.8mm).
- **Mezzopram 20mg Dispersible Gastro-resistant Tablets:** Pink, oval film-coated tablet with a breaking notch on both sides. The tablet can be divided into equal doses (14.2 x 7.2mm).
- **Mezzopram 40mg Dispersible Gastro-resistant Tablets:** Reddish oval film-coated tablet with a score line on both sides. The tablet can be divided into equal doses (18.2 x 9.0mm).

Mezzopram 10mg Dispersible Gastro-resistant Tablets are available in blister packs containing 14, 28 and 49 tablets.

Mezzopram 20mg Dispersible Gastro-resistant Tablets are available in blister packs containing 14, 28, 49 and 90 tablets.

Mezzopram 40mg Dispersible Gastro-resistant Tablets are available in blister packs containing 7, 14, 28, 49 and 90 tablets.

PL 46420/0068 Mezzopram 10mg Dispersible Gastro-resistant Tablets Omeprazole 10mg Dispersible Gastro-resistant Tablets **POM**

PL 46420/0069 Mezzopram 20mg Dispersible Gastro-resistant Tablets Omeprazole 20mg Dispersible Gastro-resistant Tablets **POM**

PL 46420/0070 Mezzopram 40mg Dispersible Gastro-resistant Tablets Omeprazole 40mg Dispersible Gastro-resistant Tablets **POM**

Who makes and repackages your medicine?

Your medicine is manufactured by Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany. Procured from within the EU and repackaged by the Product Licence holder: Suerte Pharma Ltd, 4/5 Northolt Trading Estate, Belvue Road, Northolt, Middlesex, UB5 5QS.

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Mezzopram is a registered trademark of Sandoz AG, Switzerland.

For any information about this medicine or to request a copy of this leaflet in Braille, large print or audio, please call the PL holder: Suerte Pharma Limited on 020 8839 3000.

The following information is intended for healthcare professionals only:

Stomach tube administration for doctors:

If the patient is unable to swallow, the tablets can be dissolved in still water and administered via a stomach tube. It is important to ensure that the suitability of the selected syringe and tube is carefully verified.

Administration via a stomach tube

1. Put the tablet into an appropriate syringe and fill the syringe with approximately 25 ml water and approximately 5 ml air. For some tubes, dispersion in 50 ml water is needed to prevent the pellets from clogging the tube.
2. Immediately shake the syringe for approximately 2 minutes to disperse the tablet.
3. Hold the syringe with the tip up and check that the tip has not clogged.
4. Attach the syringe to the tube whilst maintaining the above position.
5. Shake the syringe and position it with the tip pointing down. Immediately inject 5-10 ml into the tube. Invert the syringe after injection and shake it. Keep the syringe tip pointed upward as this will avoid clogging.
6. Turn the syringe with the tip down and immediately inject another 5-10 ml into the tube. Repeat this procedure until the syringe is empty.
7. Fill the syringe with 25 ml water and 5 ml air and repeat step 5 if necessary to wash down any sediment left in the syringe. Some tubes will require 50 ml water.