Package leaflet: Information for the user

Zolepant 40 mg gastro-resistant tablets
pantoprazole

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 Zolepant is and what it is used for

Zolepant is a selective "proton pump inhibitor", a medicine which reduces the amount of acid produced in your stomach. It is used for treating acid-related diseases of the stomach and intestine.

Zolepant is used for:

Adults and adolescents 12 years of age and above:

- Reflux oesophagitis. An inflammation of your oesophagus (the tube which connects your throat to your stomach) accompanied by the regurgitation of stomach acid.

Adults:

- An infection with a bacterium called *Helicobacter pylori* in patients with duodenal ulcers and stomach ulcers in combination with two antibiotics (Eradication therapy). The aim is to get rid of the bacteria and so reduce the likelihood of these ulcers returning.

- Stomach and duodenal ulcers.

- Zollinger-Ellison-Syndrome and other conditions producing too much acid in the stomach.

2. What you need to know before you take Zolepant

Do not take Zolepant
- If you are allergic to pantoprazole, sorbitol or any of the other ingredients of this medicine (listed in section 6).
- If you are allergic to medicines containing other proton pump inhibitors.

Warnings and precautions
Talk to your doctor or pharmacist or nurse before taking Zolepant
- If you have severe liver problems. Please tell your doctor if you have ever had problems with your liver. He will check your liver enzymes more frequently, especially when you are taking Zolepant as a long-term treatment. In the case of a rise of liver enzymes the treatment should be stopped.
- If you have reduced body stores or risk factors for reduced vitamin B12 and receive long-term treatment with pantoprazole. As with all acid reducing agents, pantoprazole may lead to a reduced absorption of vitamin B12.
- If you are taking HIV protease inhibitors such as atazanavir (for the treatment of HIV-infection) at the same time as pantoprazole, ask your doctor for specific advice.
- Taking a proton pump inhibitor like pantoprazole, 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 (reduced bone density) or if you have been told that you are at risk of getting osteoporosis (for example, if you are taking steroids).
- If you are on Zolepant 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.
- If you have ever had a skin reaction after treatment with a medicine similar to Zolepant that reduces stomach acid.
- 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 Zolepant. Remember to also mention any other ill-effects like pain in your joints.
- If you are due to have a specific blood test (Chromogranin A).

Tell your doctor immediately if you notice any of the following symptoms:
- an unintentional loss of weight
- vomiting, particularly if repeated
- vomiting blood; this may appear as dark coffee grounds in your vomit
- you notice blood in your stools; which may be black or tarry in appearance
- difficulty in swallowing or pain when swallowing
- chest pain
- stomach pain
- you look pale and feel weak (anaemia)
- severe and/or persistent diarrhoea, as Zolepant has been associated with a small increase in infectious diarrhoea.

Your doctor may decide that you need some tests to rule out malignant disease because pantoprazole also alleviates the symptoms of cancer and could cause delay in diagnosing it. If your symptoms continue in spite of your treatment, further investigations will be considered.

If you take Zolepant 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.

Children and adolescents
These tablets are not recommended for use in children below 12 years.

Other medicines and Zolepant
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Zolepant may influence the effectiveness of other medicines, so tell your doctor if you are taking

- Medicines such as ketoconazole, itraconazole and posaconazole (used to treat fungal infections) or erlotinib (used for certain types of cancer) because Zolepant may stop these and other medicines from working properly.
- Warfarin and phenprocoumon, which affect the thickening, or thinning of the blood. You may need further checks.
- Medicines used to treat HIV-infection, such as atazanavir.
- Methotrexate (used to treat rheumatoid arthritis, psoriasis, and cancer) – if you are taking methotrexate your doctor may temporarily stop your Zolepant treatment because pantoprazole can increase levels of methotrexate in the blood.
- Fluvoxamine (used to treat depression and other psychiatric diseases) – if you are taking fluvoxamine your doctor may reduce the dose.
- Rifampicin (used to treat infections).
- St John's wort (Hypericum perforatum) (used to treat mild depression).

Zolepant with food and drink
Take the tablets 1 hour before a meal without chewing or breaking them and swallow them whole with some water.

Pregnancy and breast-feeding

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.

There are no adequate data from the use of pantoprazole in pregnant women. Excretion into human milk has been reported. You should use this medicine, only if your doctor considers the benefit for you greater than the potential risk for your unborn child or baby.

Driving and using machines
Zolepant has no or negligible influence on the ability to drive and use machines.
If you experience side effects like dizziness or disturbed vision, you should not drive or operate machines.

Zolepant contains sorbitol and sodium
This medicine contains 36 mg sorbitol in each tablet**.**
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Zolepant

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

When and how should you take Zolepant
Take the tablets 1 hour before a meal without chewing or breaking them and swallow them whole with some water.

Unless told otherwise by your doctor, the recommended dose is:

Adults and adolescents 12 years of age and above:

To treat reflux oesophagitis
The recommended dose is one tablet a day. Your doctor may tell you to increase to 2 tablets daily. The treatment period for reflux oesophagitis is usually between 4 and 8 weeks. Your doctor will tell you how long to take your medicine.

Adults:

For the treatment of an infection with a bacterium called *Helicobacter pylori* in patients with duodenal ulcers and stomach ulcers in combination with two antibiotics (Eradication therapy)
One tablet, two times a day plus two antibiotic tablets of either amoxicillin, clarithromycin and metronidazole (or tinidazole), each to be taken two times a day with your pantoprazole tablet. Take the first pantoprazole tablet 1 hour before breakfast and the second pantoprazole tablet 1 hour before your evening meal. Follow your doctor's instructions and make sure you read the package leaflets for these antibiotics. The usual treatment period is one to two weeks.

For the treatment of stomach and duodenal ulcers
The recommended dose is one tablet a day. After consultation with your doctor, the dose may be doubled.
Your doctor will tell you how long to take your medicine. The treatment period for stomach ulcers is usually between 4 and 8 weeks. The treatment period for duodenal ulcers is usually between 2 and 4 weeks.

For the long-term treatment of Zollinger-Ellison-Syndrome and of other conditions in which too much stomach acid is produced
The recommended starting dose is usually two tablets a day.
Take the two tablets 1 hour before a meal. Your doctor may later adjust the dose, depending on the amount of stomach acid you produce. If prescribed more than two tablets a day, the tablets should be taken twice daily.
If your doctor prescribes a daily dose of more than four tablets a day, you will be told exactly when to stop taking the medicine.

Special patient groups:
- If you have kidney problems, moderate or severe liver problems, you should not take Zolepant for eradication of *Helicobacter pylori*.

- If you suffer from severe liver problems, you should not take more than one tablet 20 mg pantoprazole a day (for this purpose tablets containing 20 mg pantoprazole are available).

Use in children and adolescents
Children below 12 years.
These tablets are not recommended for use in children below 12 years.

If you take more Zolepant than you should
Tell your doctor or pharmacist. There are no known symptoms of overdose.

If you forget to take Zolepant
Do not take a double dose to make up for a forgotten dose. Take your next, normal dose at the usual time.

If you stop taking Zolepant
Do not stop taking these tablets 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.

4. Possible side effects

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

If you get any of the following side effects, stop taking these tablets and tell your doctor immediately, **or contact the casualty department at your nearest hospital:**

Serious allergic reactions (frequency rare (may affect up to 1 in 1,000 people)):
- swelling of the tongue and/or throat,
- difficulty in swallowing,
- hives (nettle rash),
- difficulties in breathing,
- allergic facial swelling (Quincke's oedema / angioedema),
- severe dizziness with very fast heartbeat and heavy sweating.

Serious skin conditions (frequency not known (frequency cannot be estimated from the available data)): you may notice one or more of the following:
- blistering of the skin and rapid deterioration of your general condition,
- erosion (including slight bleeding) of eyes, nose, mouth/lips or genitals or skin sensitivity/rash, particularly in areas of skin exposed to light/the sun,
- you may also have joint pain or flu-like symptoms, a fever, swollen glands (e.g. in the armpit) and blood tests may show changes in certain white blood cells or liver enzymes (Stevens-Johnson-Syndrome, Lyell Syndrome, Erythema multiforme, Subacute cutaneous lupus erythematosus, Drug reaction with eosinophilia and systemic symptoms (DRESS), Photosensitivity).

Other serious conditions (frequency not known (frequency cannot be estimated from the available data)):
- yellowing of the skin or whites of the eyes (severe damage to liver cells, jaundice)
- fever
- rash
- enlarged kidneys sometimes with painful urination and lower back pain (serious inflammation of the kidneys).

Other side effects are:
Common (may affect up to 1 in 10 people)
- Benign polyps in the stomach.

Uncommon (may affect up to 1 in 100 people)
- Headache;
- dizziness;
- diarrhoea;
- feeling sick;
- vomiting;
- bloating and flatulence (wind);
- constipation;
- dry mouth;
- abdominal pain and discomfort;
- skin rash, exanthema, eruption;
- itching;
- fracture of the hip, wrist or spine;
- feeling weak, exhausted or generally unwell;
- sleep disorders.

Rare (may affect up to 1 in 1,000 people)
- Disturbances in vision such as blurred vision;
- hives;
- pain in the joints;
- muscle pains;
- weight changes;
- raised body temperature;
- high fever;
- swelling of the extremities (peripheral oedema);
- allergic reactions;
- depression;
- breast enlargement in males;
- distortion or complete lack of the sense of taste.

Very rare (may affect up to 1 in 10,000 people)
- Disorientation.

Not known (frequency cannot be estimated from the available data)
- Hallucination, confusion (especially in patients with a history of these symptoms);
- feeling of tingling, prickling, pins and needles, burning sensation or numbness;
- inflammation in the large bowel, that causes persistent watery diarrhoea;
- rash, possibly with pain in the joints.

Side effects identified through blood tests:
Uncommon (may affect up to 1 in 100 people)
- An increase in liver enzymes.

Rare (may affect up to 1 in 1,000 people)
- An increase in bilirubin;
- increased fats in the blood;
- sharp drop in circulating granular white blood cells, associated with high fever.

Very rare (may affect up to 1 in 10,000 people)
- A reduction in the number of blood platelets, which may cause you to bleed or bruise more than normal;

- a reduction in the number of white blood cells, which may lead to more frequent infections;
- Coexisting abnormal reduction in the number of red and white blood cells, as well as platelets.

Not known (frequency cannot be estimated from the available data)
- Decreased level of sodium, magnesium, calcium or potassium in blood (see section 2).

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 HPRA Pharmacovigilance, Website: www.hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zolepant

Keep this medicine out of the sight and reach of children.

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

This medicine does not require any special temperature storage conditions.

Blister pack: Store in the original package in order to protect from moisture.

Container: Keep the container tightly closed in order to protect from moisture.
After first opening of the container, the product should be used within 3 months.

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 Zolepant contains

- The active substance is pantoprazole. Each gastro-resistant tablet contains 40 mg pantoprazole (as pantoprazole sodium sesquihydrate).
- The other ingredients are mannitol, crospovidone (type A, type B), sodium carbonate, sorbitol (E420), calcium stearate in the tablet core and hypromellose, povidone (K25), titanium dioxide (E171), yellow iron oxide (E172), propylene glycol, methacrylic acid - ethyl acrylate copolymer, sodium laurilsulfate, polysorbate 80, macrogol 6000 and talc in the film-coating.

What Zolepant looks like and contents of the pack
The 40 mg gastro-resistant tablets are light brownish yellow, oval, slightly biconvex tablets.

Pack sizes:
Cartons of 7, 14, 15, 20, 28, 30, 50, 50 x 1, 56, 60, 84, 90, 98, 100, 100 x 1, 112 and 140 gastro-resistant tablets in blister packs.

A plastic container of 100 and 250 gastro-resistant tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland.
Manufacturer
KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto, Slovenia.

Product Authorisation Number
PA 281/140/2

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

AT	PANTOPRAZOL TEVA
BE	PANTOPRATEVA
DK	PANTOPRAZOL KRKA
FI	PANTOPRAZOLE KRKA
FR	PANTOPRAZOLE TEVA
DE	PANTOPRAZOL TAD
IE	ZOLEPANT
IT	PANTOPRAZOLO KRKA
UK (NI)	PANTOPRAZOLE
NL	PANTOPRAZOL
NO	PANTOPRAZOL KRKA
SE	PANTOPRAZOL KRKA
ES	PANTOPRAZOL TEVA
PT	PANTOPRAZOLE KRKA
PL	NOLPAZA
SK	NOLPAZA
LV	NOLPAZA
EE	NOLPAZA
LT	NOLPAZA
CZ	NOLPAZA

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