

**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.



**ZOLPAN**  
gastro-resistant tablets 20 mg  
*Pantoprazole*

## What is in this leaflet

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

### 1. What **Zolpan** is and what it is used for

**Zolpan** 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.

**Zolpan** is used to treat adults and adolescents 12 years of age and above for:

- Symptoms (e.g. heartburn, acid regurgitation, pain on swallowing) associated to gastro-oesophageal reflux disease caused by reflux of acid from the stomach.
- Long-term management of reflux oesophagitis (inflammation of the oesophagus accompanied by the regurgitation of stomach acid) and preventing its return.

**Zolpan** is used to treat adults for:

- Preventing duodenal and stomach ulcers caused by non-steroidal anti-inflammatory drugs (NSAIDs, for example, ibuprofen) in patients at risk who need to take NSAIDs continuously.

### 2. What you need to know before you take **Zolpan** Do not take **Zolpan**

- If you are allergic to pantoprazole or to any of the other ingredients of **Zolpan** (listed in section 6).
- If you are allergic to medicines containing other proton pump inhibitors.

### Warnings and precautions

Be especially careful with **Zolpan**

- 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 **Zolpan** as a long-term treatment. In the case of a rise of liver enzymes the treatment should be stopped.
- If you need to take medicines called NSAIDs continuously and receive **Zolpan** because you have an increased risk of developing stomach and intestinal complications. Any personal risk factors such as your age (65 years old or more), a history of stomach or duodenal ulcers or stomach or intestinal bleeding.
- If you have reduced body stores or risk factors for reduced vitamin B12 and receive long-term treatment with **Zolpan**. 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 **Zolpan**, ask your doctor for specific advice.

**Tell your doctor immediately if you notice any of the following symptoms:**

- An unintentional loss of weight
- Vomiting, particularly if repeated
- Vomiting blood

- You notice blood in your stools
- Difficulty in swallowing
- You look pale and feel weak (anaemia)
- Severe and/or persistent diarrhoea, because **Zolpan** 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 **Zolpan** 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. Taking proton pump inhibitors such as **Zolpan**, especially over a period longer than a year, can slightly increase the risk of hip, wrist or spine fractures. Get to know your doctor if you have osteoporosis or if you are taking corticosteroids (which may increase the risk of osteoporosis).

### Other medicines and **Zolpan**

This is because **Zolpan** 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 **Zolpan** 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.
- Atazanavir (used for the treatment of HIV-infection).
- Methotrexate (a chemotherapy medicine used in high doses for cancer treatment). Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

### Pregnancy and breast-feeding

There are no adequate data from the use of pantoprazole in pregnant women. Excretion into human milk has been reported. 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. 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

If you experience side effects like dizziness or disturbed vision, you should not drive or operate machines.

### Important informations about other substances in **Zolpan**

This medicine contains mannitol. Mannitol can have a gentle laxative effect.

### 3. How to take **Zolpan**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Take the tablets 1 hour before a meal without chewing or breaking them and swallow them whole with some water.

If the doctor has not decided otherwise, the usual doses are:

#### **Adults and adolescents 12 years of age and above**

- *To treat symptoms (e.g. heartburn, acid regurgitation, pain on swallowing) associated to gastro-oesophageal reflux disease.* The usual dose is one tablet a day. This dose usually brings relief within 2 - 4 weeks – at most after another 4 weeks. Your doctor will tell you how long to continue taking the medicine. After this, any recurring symptoms can be controlled by taking one tablet daily, when required.
- *For long-term management and for preventing the return of reflux oesophagitis.* The usual dose is one tablet a day. If the illness returns, your doctor can double the dose, in which case you can use **Zolpan** 40 mg tablets instead, one a day. After healing, you can reduce the dose back again to one tablet 20 mg a day.

#### **Adults**

- *To prevent duodenal and stomach ulcers in patients who need to take NSAIDs continuously.* The usual dose is one tablet a day.

#### **Special group of patients**

- If you suffer from severe liver problems, you should not take more than one 20 mg tablet a day.
- These tablets are not recommended for use in children below 12 years.

#### **If you take more Zolpan than you should**

Tell your doctor or pharmacist. There are no known symptoms of overdose.

#### **If you forget to take Zolpan**

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 Zolpan**

Do not stop taking these tablets without first talking to your doctor or pharmacist. If you have any further questions about the use of this medicine, ask your doctor, pharmacist or nurse.

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects. If you get any of the following side effects, stop taking these tablets and tell your doctor immediately, or contact your nearest hospital:

- **Serious allergic reactions (frequency rare):** 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):** blistering of the skin and rapid deterioration of your general condition, erosion (including slight bleeding) of eyes, nose, mouth/lips or genitals (Stevens-Johnson-Syndrome, Lyell-Syndrome, Erythema multiforme), and sensitivity to light.
- **Other serious conditions (frequency not known):** yellowing of the skin or whites of the eyes (severe damage to liver cells, jaundice) or fever, rash, and enlarged kidneys sometimes with painful urination, and lower back pain (serious inflammation of the kidneys).

Other side effects are:

- **Uncommon** (may affect more than 1 in 1000 people): headache; dizziness; diarrhoea; feeling sick, vomiting; bloating and flatulence (wind); constipation; dry mouth; abdominal pain and discomfort; skin rash, exanthema, eruption; itching; feeling weak, exhausted or generally unwell; sleep disorders.
- **Rare** (may affect up to 1 in 1,000 people): distortion or complete lack of the sense of taste; 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.
- **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); decreased sodium level in blood.

If you take **Zolpan** for more than three months, you may experience a decrease in blood magnesium levels. Low levels of magnesium can be manifested as fatigue, involuntary muscle contraction, disorientation, convulsions, dizziness, increased heart rate. If you notice any of these symptoms, immediately inform your doctor. A low level of magnesium can also lead to a decrease in calcium or potassium levels in blood. Your doctor may decide that regular blood tests should be performed to monitor the level of magnesium in the blood.

#### **Side effects identified through blood tests:**

- **Uncommon** (may affect more than 1 in 1000 people): an increase in liver enzymes.
- **Rare** (may affect up to 1 in 1,000 people): an increase in bilirubin; increased fat levels in 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.

#### **Reporting of side effect**

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

#### **5. How to store Zolpan**

Keep all medicines out of the sight and reach of children. Store below 30°C in a dry place.

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

#### **6. Contents of the pack and other information**

##### **What Zolpan contains**

**ZOLPAN 20 mg:** 1 gastro-resistant tablet contains 20 mg pantoprazole, in the form of pantoprazole sodium sesquihydrate as an active substance.

The other ingredients are: mannitol, povidone, crospovidone, disodium carbonate anhydrate, calcium stearate, colloidal silicon dioxide, purified water.

Film: Opadry II white, povidone, methacrylic acid, triethyl citrate, ammonium hydroxide, talc, yellow iron oxide, titanium dioxide, purified water.

##### **What Zolpan looks like and contents of the pack**

Card box with 14 gastro-resistant tablets (round shaped tablets, yellow color) of 20 mg pantoprazole in plastic bottle.  
Card box with 28 gastro-resistant tablets (round shaped tablets, yellow color) of 20 mg pantoprazole in plastic bottle.

##### **Marketing Authorisation Holder and manufacturer**

ZADA Pharmaceuticals Ltd.

Donji Bistak bb

75300 Lukavac, Bosnia and Herzegovina.

**This leaflet was last revised in:** 11. 2015.

##### **Data of first authorisation / renewal of the authorisation in Bosnia and Herzegovina:**

Zolpan, gastro-resistant tablets, 14x20 mg

**Date:** 13.11.2015.

**Number:** 04-07.3-2-5047/15

Zolpan, gastro-resistant tablets, 28x20 mg

**Date:** 13.11.2015.

**Number:** 04-07.3-2-5048/15

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.



**ZOLPAN**  
gastro-resistant tablets 40 mg  
*Pantoprazole*

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#### 1. What **Zolpan** is and what it is used for

**Zolpan** 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.

**Zolpan** is used to treat adults and adolescents 12 years of age and above for:

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

**Zolpan** is used to treat adults for:

- 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 **Zolpan**

##### Do not take **Zolpan**

- If you are allergic to pantoprazole or to 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

Be especially careful with **Zolpan**

- If you have severe liver problems. Please tell your doctor if you ever had problems with your liver in the past. He will check your liver enzymes more frequently, especially when you are taking **Zolpan** 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 **Zolpan**. 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 **Zolpan**, ask your doctor for specific advice.

**Tell your doctor immediately if you notice any of the following symptoms:**

- An unintentional loss of weight
- Vomiting, particularly if repeated
- Vomiting blood
- You notice blood in your stools
- Difficulty in swallowing
- You look pale and feel weak (anaemia)
- Severe and/or persistent diarrhoea, because **Zolpan** 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 **Zolpan** 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. Taking proton pump inhibitors such as **Zolpan**, especially over a period longer than a year, can slightly increase the risk of hip, wrist or spine fractures. Get to know your doctor if you have osteoporosis or if you are taking corticosteroids (which may increase the risk of osteoporosis).

##### Other medicines and **Zolpan**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This is because **Zolpan** 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 **Zolpan** 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.
- Atazanavir (used for the treatment of HIV-infection).

##### Pregnancy and breast-feeding

There are no adequate data from the use of pantoprazole in pregnant women. Excretion into human milk has been reported. 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. 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

If you experience side effects like dizziness or disturbed vision, you should not drive or operate machines.

##### Important informations about other substances in **Zolpan**

**Zolpan** contains mannitol. Mannitol can have a laxative effect.

#### 3. How to take **Zolpan**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Take the tablets 1 hour before a meal without chewing or breaking them and swallow them whole with some water.

##### Adults and adolescents 12 years of age and above

- *To treat reflux oesophagitis*

The usual 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.

Following common combinations are taken twice a day:

- ZOLPAN 40 mg + 500 mg clarithromycin + 1000 mg amoxicillin

- ZOLPAN 40 mg + 250-500 mg clarithromycin + 400-500 mg metronidazole (or 500 mg tinidazole)
- ZOLPAN 40 mg + 400-500 mg metronidazole (or 500 mg tinidazole) + 1000 mg amoxicillin

The usual treatment period is one to two weeks.

- *For the treatment of stomach and duodenal ulcers.* The treatment 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 group of patients

- If you have kidney problems or moderate to severe liver problems, you should not take **Zolpan** 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).
- These tablets are not recommended for use in children below 12 years.

### If you take more Zolpan than you should

Consult your doctor or pharmacist. There are no known symptoms of overdose.

### If you forget to take Zolpan

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 Zolpan

Do not stop taking these tablets without first talking to your doctor or pharmacist. If you have any further questions about the use of this medicine, ask your doctor, pharmacist or nurse.

### 4. Possible side effects

Like all medicines, this medicine can cause side effects.

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

- **Serious allergic reactions (frequency rare):** 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):** blistering of the skin and rapid deterioration of your general condition, erosion (including slight bleeding) of eyes, nose, mouth/lips or genitals (Stevens-Johnson-Syndrome, Lyell-Syndrome, Erythema multiforme), and sensitivity to light.
- **Other serious conditions (frequency not known):** yellowing of the skin or whites of the eyes (severe damage to liver cells, jaundice) or fever, rash, and enlarged kidneys sometimes with painful urination, and lower back pain (serious inflammation of the kidneys), possibly leading to kidney failure.

Other side effects are:

- **Uncommon** (may affect more than 1 in 1000 people): headache; dizziness; diarrhoea; feeling sick, vomiting; bloating and flatulence (wind); constipation; dry mouth;

abdominal pain and discomfort; skin rash, exanthema, eruption; itching; feeling weak, exhausted or generally unwell; sleep disorders.

- **Rare** (may affect up to 1 in 1,000 people): distortion or complete lack of the sense of taste; 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.
- **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); decreased sodium level in blood.

If you take **Zolpan** for more than three months, you may experience a decrease in blood magnesium levels. Low levels of magnesium can be manifested as fatigue, involuntary muscle contraction, disorientation, convulsions, dizziness, increased heart rate. If you notice any of these symptoms, immediately inform your doctor. A low level of magnesium can also lead to a decrease in calcium or potassium levels in blood. Your doctor may decide that regular blood tests should be performed to monitor the level of magnesium in the blood.

### Side effects identified through blood tests:

- **Uncommon** (may more than 1 in 1000 people) an increase in liver enzymes.
- **Rare** (may affect up to 1 in 1,000 people) an increase in bilirubin; increased fat levels in 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.

### Reporting of side effects

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

### 5. How to store Zolpan

Keep all medicines out of the sight and reach of children. Store below 30°C in a dry place. Do not take this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

### 6. Contents of the pack and other information

#### What Zolpan contains

**ZOLPAN 40 mg:** 1 gastro-resistant tablet contains 40 mg pantoprazole, in the form of pantoprazole sodium sesquihydrate as an active substance. The other ingredients are: mannitol, povidone, crospovidone, disodium carbonate anhydride, calcium stearate, colloidal silicon dioxide, purified water. Film: Opadry II white, povidone, methacrylic acid, triethyl citrate, ammonium hydroxide, talc, yellow iron oxide, titanium dioxide, purified water.

#### What Zolpan looks like and contents of the pack

Card box with 14 gastro-resistant tablets (round shaped tablets, yellow color) of 40 mg pantoprazole in plastic bottle. Card box with 28 gastro-resistant tablets (round shaped tablets, yellow color) of 40 mg pantoprazole in plastic bottle.

#### Marketing Authorisation Holder and manufacturer

ZADA Pharmaceuticals Ltd.  
Donji Bistarac bb  
75300 Lukavac, Bosnia and Herzegovina.

This leaflet was last revised in: 11. 2015.

#### Data of first authorisation / renewal of the authorisation in Bosnia and Herzegovina:

Zolpan, gastro-resistant tablets, 14x40 mg  
**Date:** 13.11.2015. **Number:** 04-07.3-2-5049/15