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**PACKAGE LEAFLET**

**Package leaflet: Information for the patient**

**<Invented name> 120 mg film-coated tablets**
bismuth oxide

**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 <Invented name> is and what it is used for

Upper abdominal symptoms may be caused by an inflammation of the lining of the stomach or duodenum (the first section of the small intestine). <Invented name> heals ulcers, and mucosal inflammation by forming a protecting layer (a kind of patch) and helps stop further irritation caused by stomach acid. It also has antibacterial activity against *Helicobacter pylori*, a germ that is likely to cause mucosal inflammation and peptic ulcers.

For the ulcer to heal permanently the germ must be destroyed. <Invented name> helps clear up or reduce infections caused by this germ. Your doctor may give you <Invented name> in combination with other medications to help destroy *Helicobacter pylori*.

## 2. What you need to know before you take <Invented name>

**Do not take <Invented name>**
- if you are allergic to bismuth oxide or any of the other ingredients of this medicine (listed in section 6),

- if you have severe kidney problems (severe renal failure).

**Warnings and precautions**
Talk to your doctor or pharmacist before taking <Invented name>.

Do not use other bismuth containing medicines at the same time as <Invented name>.

Prolonged use of bismuth containing products is not recommended. Your doctor will usually not prescribe <Invented name> for more than two months.

**Children and adolescents**
<Invented name> is not intended for use in children and adolescents.

**Other medicines and <Invented name>**
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take other medicines, especially those reducing gastric acidity half an hour before or after you take <Invented name>, as they may interfere with its effect.

<Invented name> may diminsh the effect of antibiotics called tetracyclines when used concomitantly.

**<Invented name> with food and drink**
Do not eat or drink anything half an hour before or after taking <Invented name>. Milk, fruit or fruit juce in particular can prevent the medicine from working properly.

**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 any medicine.

Do not take <Invented name> during pregnancy or if you are breast-feeding, unless if clearly necessary.

**Driving and using machines**
It is unlikely that <Invented name> will affect your ability to drive or use machines.

**<Invented name> contains potassium**
This medicine contains 1.19 mmol (or 46.58 mg) potassium per tablet. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

## 3. How to take <Invented name>

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

The recommended dose for adults and elderly is 4 tablets. They can be taken in the following ways:
- 1 tablet four times a day on an empty stomach, half an hour before each of three main meals and before bedtime

*or*
- 2 tablets twice daily, half an hour before breakfast and half an hour before dinner or before bedtime.

<Invented name> tablets should be swallowed whole with a sufficient amount of water.

Do not eat or drink half an hour before or after taking the tablet. If you skip a meal, you must still take the tablet(s).

**Duration of treatment**
For the treatment of duodenal or gastric ulcers the duration of one course of treatment is 4 to 8 weeks.

For the eradication of *H. pylori* the selection of combination therapy and duration of treatment (7 to 14 days) should consider the individual patient's drug tolerance, and should be undertaken in accordance with regional resistance patterns and treatment guidelines.

The maximum duration of one course of treatment is two months; do not take <Invented name> or other bismuth containing products for a period longer than that. Do not take any bismuth containing medicines in the two months following treatment with <Invented name>.

**If you take more <Invented name> than you should**
Do not worry if you have taken one or two additional tablets once. However, if you take many more tablets concurrently or within a short period of time, consult your doctor immediately. He/she will take appropriate measures to ensure bismuth is not absorbed. In addition, your kidney function will be monitored for several weeks.

**If you forget to take <Invented name>**
Do not take a double dose to make up for a forgotten one.

If you forget to take a dose, take it as soon as you remember, if it is not the time for the next dose to be administered. If this is the case, omit the forgotten dose.

## 4. Possible side effects

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

Potentially life-threatening **allergic reaction** may occur while you are taking <Invented name>. Signs of allergy include sudden wheezing, swelling of your lips, tounge and throat, difficulties swallowing, rash or even fainting.
If you notice any of these symptoms, stop taking <Invented name> and contact a **doctor immediately.**
These effects are serious but very rare (may affect up to 1 in 10,000 people).

Other side effects include:

**Very common** (may affect more than 1 in 10 people):
- blackening of stools (faeces). This is nothing to worry about and will disappear soon after you stop treatment.

**Uncommon** (may affect up to 1 in 100 people):
- nausea, vomiting, constipation or diarrhoea;
- rash, pruritus.

**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. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store <Invented name>

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 carton and blister after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light and moisture.
This medicinal product does not require any special temperature storage conditions.

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 <Invented name> contains**

- The active substance is bismuth oxide. Each film-coated tablet contains 120 mg bismuth oxide (as tripotassium dicitratobismuthate (bismuth subcitrate)).
- The other ingredients (excipients) are maize starch, povidone K30, polacrillin potassium, macrogol 6000 and magnesium stearate (E470b) in the tablet core and polyvinyl alcohol, macrogol 4000, talc and titanium dioxide (E171) in the film coating.
  See section 2 "<Invented name> contains potassium".

**What <Invented name> looks like and contents of the pack**

Film-coated tablets (tablets) are white to almost white, round (diameter: 10 mm), film-coated, slightly biconvex with bevelled edges.

<Invented name> is available in packs containing 28, 30, 40, 42, 45, 56 and 60 film-coated tablets in blisters.
Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

**This medicinal product is authorised in the Member States of the EEA under the following names:**

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| [To be completed nationally] | |
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**This leaflet was last revised in**

[To be completed nationally]

Detailed information on this medicine is available on the website of {name of Member State Agency (link)}