

## **Package leaflet: Information for the user**

### **Gastrolief 20 mg gastro-resistant Tablets**

Pantoprazole

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 2 weeks.
- You should not take Gastrolief for more than 4 weeks without consulting a doctor.

#### **What is in this leaflet**

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

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

Gastrolief contains the active substance pantoprazole, which blocks the 'pump' that produces stomach acid. Hence it reduces the amount of acid in your stomach.

Gastrolief is used for the short-term treatment of reflux symptoms (for example heartburn, acid regurgitation) in adults.

Reflux is the backflow of acid from the stomach into the gullet ("foodpipe"), which may become inflamed and painful. This may cause you symptoms such as a painful burning sensation in the chest rising up to the throat (heartburn) and a sour taste in the mouth (acid regurgitation).

You may experience relief from your acid reflux and heartburn symptoms after just one day of treatment with Gastrolief, but this medicine is not meant to bring immediate relief. It may be necessary to take the tablets for 2-3 consecutive days to relieve the symptoms.

You must talk to a doctor if you do not feel better or if you feel worse after 2 weeks.

#### **2. What you need to know before you take Gastrolief**

##### **DO NOT take Gastrolief**

- if you are allergic to pantoprazole, soya lecithin or any of the other ingredients of this medicine (listed in section 6.)
- if you are taking a medicine containing atazanavir (for the treatment of HIV-infection). See 'Other medicines and Gastrolief'.

#### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Gastrolief

- if you have been treated for heartburn or indigestion continuously for 4 or more weeks
- if you are over 55 years old and taking non-prescription indigestion treatment on a daily basis
- if you are over 55 years old with any new or recently changed reflux symptoms
- if you have previously had a gastric ulcer or stomach surgery
- if you have liver problems or jaundice (yellowing of skin or eyes)
- if you regularly see your doctor for serious complaints or conditions
- if you are due to have an endoscopy or a breath test called a C-urea test

- if you have ever had a skin reaction after treatment with a medicine similar to Gastrolief 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 Gastrolief. 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**, before or after taking this medicine, if you notice any of the following symptoms, which could be a sign of another, more serious, disease:

- an unintentional loss of weight (not related to a diet or an exercise programme)
- 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
- you look pale and feel weak (anaemia)
- chest pain
- stomach pain
- severe and/or persistent diarrhoea, because pantoprazole has been associated with a small increase in infectious diarrhoea.

Your doctor may decide that you need some tests.

If you are due to have a blood test, tell your doctor that you are taking this medicine.

You may experience relief from your acid reflux and heartburn symptoms after just one day of treatment with Gastrolief, but this medicine is not meant to bring immediate relief. You should not take it as a preventive measure.

If you have been suffering from repetitive heartburn or indigestion symptoms for some time, remember to see your doctor regularly.

### **Children and adolescents**

Gastrolief should not be used by children and adolescents under 18 years of age due to a lack of safety information in this younger age group.

### **Other medicines and Gastrolief**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Gastrolief may stop certain other medicines from working properly. Especially medicines containing one of the following active substances:

- atazanavir (used to treat HIV-infection). You must not use Gastrolief if you are taking atazanavir. See 'DO NOT take Gastrolief'
- ketoconazole (used for fungal infections)
- warfarin and phenprocoumon (used to thin blood and prevent clots). You may need further blood tests
- methotrexate (used to treat rheumatoid arthritis, psoriasis, and cancer) – if you are taking methotrexate your doctor may temporarily stop your Gastrolief treatment because pantoprazole can increase levels of methotrexate in the blood

Do not take Gastrolief with other medicines which limit the amount of acid produced in your stomach, such as another proton pump inhibitor (omeprazole, lansoprazole or rabeprazole) or an H<sub>2</sub> antagonist (e.g. ranitidine, famotidine).

However, you may take Gastrolief with antacids (e.g. magaldrate, alginic acid, sodium bicarbonate, aluminium hydroxide, magnesium carbonate, or combinations thereof), if needed.

### **Pregnancy and breast-feeding**

You should not take this medicine if you are pregnant or while 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.

**Driving and using machines**

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

**Gastrolief contains maltitol**

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

**Gastrolief contains soya lecithin**

If you are allergic to peanut or soya, do not use this medicinal product.

**3. How to take Gastrolief**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one tablet a day. Do not exceed this recommended dose of 20 mg pantoprazole daily.

You should take this medicine for at least 2-3 consecutive days. Stop taking Gastrolief when you are completely symptom-free. You may experience relief from your acid reflux and heartburn symptoms after just one day of treatment with Gastrolief, but this medicine is not meant to bring immediate relief.

If you have no symptom-relief after taking this medicine for 2 weeks continuously, consult your doctor. Do not take Gastrolief tablets for more than 4 weeks without consulting your doctor.

Take the tablet before a meal, at the same time every day. You should swallow the tablet whole with some water. Do not chew or break the tablet.

**If you take more Gastrolief than you should**

Tell your doctor or pharmacist if you have taken more than the recommended dose. If possible take your medicine and this leaflet with you.

**If you forget to take Gastrolief**

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

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.

**Tell your doctor immediately** or contact the casualty department at your nearest hospital, if you get any of the following **serious side effects**. Stop taking this medicine straight away, but take this leaflet and/or the tablets with you.

- **Serious allergic reactions (rare: may affect up to 1 in 1,000 people):** Hypersensitivity reactions, so-called anaphylactic reactions, anaphylactic shock and angioedema. Typical symptoms are: swelling of the face, lips, mouth, tongue and/or throat, which may cause difficulty in swallowing or breathing, hives (nettle rash), severe dizziness with very fast heartbeat and heavy sweating
- **Serious skin reactions (frequency not known: frequency cannot be estimated from the available data):** rash with swelling, blistering or peeling of the skin, losing skin and bleeding around eyes, nose, mouth or genitals and rapid deterioration of your general health, or rash when exposed to the sun
- **Other serious reactions (frequency not known):** yellowing of the skin and eyes (due to severe liver damage), or kidney problems such as painful urination and lower back pain with fever

Other side effects include:

**Common (may affect up to 1 in 10 people):**

benign polyps in the stomach

**Uncommon side effects (may affect up to 1 in 100 people):**

headache; dizziness; diarrhoea; feeling sick, vomiting; bloating and flatulence (wind); constipation; dry mouth; bellyache and discomfort; skin rash or hives; itching; feeling weak exhausted or generally unwell; sleep disorders; increase in liver enzymes in blood test

**Rare side effects (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; pain in the joints; muscle pains; weight changes; raised body temperature; swelling of the extremities; depression; increased bilirubin and fat levels in blood (seen in blood tests); breast enlargement in males; high fever and a sharp drop in circulating granular white blood cells (seen in blood tests)

**Very rare side effects (may affect up to 1 in 10,000 people):**

disorientation; reduction in the number of blood platelets, which may cause you to bleed or bruise more than normal; 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 (seen in blood tests)

**Frequency not known (frequency cannot be estimated from the available data):**

rash, possibly with pain in the joints (subacute cutaneous lupus erythematosus), hallucination, confusion (especially in patients with a history of these symptoms); decreased level of sodium in blood; decreased level of magnesium in blood

**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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Gastrolief**

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 blister or bottle and carton. The expiry date refers to the last day of that month.

For tablets packed in plastic bottles: Gastrolief must be used within three months after first opening of the container.

Do not store above 25°C.

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 Gastrolief contains**

- The active substance is pantoprazole. Each tablet contains 20 mg pantoprazole (as sodium sesquihydrate).
- The other ingredients are:

*Tablet core*

Maltitol (E965), crospovidone type B, carmellose sodium, sodium carbonate anhydrous, calcium stearate.

*Tablet coating*

Poly(vinyl alcohol), talc, titanium dioxide (E171), macrogol 3350, soya lecithin, iron oxide yellow

(E172), sodium carbonate anhydrous, methacrylic acid-ethyl acrylate copolymer (1:1), sodium laurilsulfate, polysorbate 80, triethyl citrate.

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

The gastro-resistant tablets are oval, yellow, gastro-resistant tablets.  
Gastrolief is available in Alu/Alu blisters or HDPE bottles.

Packs containing 7 or 14 gastro-resistant tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

### **Manufacturer**

Sofarimex – Ind. Quimica e Farmaceutica, S.A., Av. das Indústrias – Alto do Colaride, 2735-213 Cacém, Portugal

Advance Pharma GmbH, Wallenroder Straße 12-14, 13435 Berlin, Germany

STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany

Centrafarm Services B.V., Nieuwe Donk 9, 4879 AC Etten-Leur, The Netherlands

Eurogenerics N.V., Heizel Esplanade B22, 1020 Brussels, Belgium

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

PharmaCoDane Aps, Marielundvej 46 A, 2750 Herlev, Denmark

STADA Arzneimittel GmbH, Muthgasse 36/2, A-1190 Vienna, Austria

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

Austria:	Refluxin 20 mg magensaftresistente Tabletten
Belgium:	Refluxine Control 20 mg maagsapresistente tabletten
France:	Pantoprazole EG Labo Conseil 20 mg, comprimé gastro-résistant
Ireland:	Gastrolief 20 mg gastro-resistant tablets
Italy:	Zolemer Reflusso 20 mg compresse gastroresistenti
Luxembourg:	Refluxine Control 20 mg comprimés gastro-résistants
The Netherlands:	Maagzuurtabletten HTP Pantoprazol 20 mg maagsapresistente tabletten

**This leaflet was last revised in January 2017.**

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The following recommendations for lifestyle and dietary changes may also help to relieve heartburn or acid related symptoms.

- Avoid large meals
- Eat slowly
- Stop smoking
- Reduce alcohol and caffeine consumption
- Reduce weight (if overweight)
- Avoid tight-fitting clothing or belts
- Avoid eating less than three hours before bedtime
- Elevate bedhead (if you suffer from nocturnal symptoms)
- Reduce intake of food that can cause heartburn. These might include: Chocolate, peppermint, spearmint, fatty and fried food, acidic food, spicy food, citrus fruits and fruit juices, tomatoes.