

PACKAGE LEAFLET: INFORMATION FOR THE USER

[product name] 10 mg gastro-resistant tablets

[product name] 20 mg gastro-resistant tablets

Rabeprazole sodium

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What [product name] is and what it is used for
2. Before you take [product name]
3. How to take [product name]
4. Possible side effects
5. How to store [product name]
6. Further information

1. WHAT [PRODUCT NAME] IS AND WHAT IT IS USED FOR

[product name] tablets contain rabeprazole. It belongs to a class of medicines called proton pump inhibitors. They act by reducing the amount of acid made by the stomach.

[product name] tablets are used for:

- Active duodenal ulcer or active benign gastric/stomach ulcer (peptic ulcers).
- Symptomatic erosive or ulcerative gastro-oesophageal reflux disease (GORD) commonly referred to as inflammation of the gullet caused by acid and associated with heartburn, or for long-term treatment of GORD (GORD maintenance).
- The symptomatic treatment of moderate to very severe gastro-oesophageal reflux disease (symptomatic GORD) also associated with heartburn.
- Zollinger-Ellison Syndrome, a rare condition in patients whose stomachs make extremely high amounts of acid.
- In combination with two antibiotics (clarithromycin and amoxicillin) [product name] tablets are used for the eradication of *H. pylori* infection in patients with peptic ulcer disease.

2. BEFORE YOU TAKE [PRODUCT NAME]

Do not take [product name]

- If you are allergic (hypersensitive) to rabeprazole sodium, other proton pump inhibitors or any of the other ingredients of [product name] (see section 6)
- If you are pregnant, you think you might be pregnant or if you are breast-feeding (please see "Pregnancy and breast-feeding").

Take special care with [product name]

Tell your doctor or pharmacist:

- If you are allergic to other proton pump inhibitors.
- If you have been told you have a stomach tumour.
- If you have a history of liver disease.
- If you are taking atazanavir (a drug used to treat HIV).

If you are taking this medicine for a long time, your doctor will want to monitor you.

Blood and liver problems have been seen in some patients but often get better when rabeprazole treatment is stopped.

[product name] should not be used in children.

If you experience severe (watery or bloody) diarrhoea with symptoms such as fever, abdominal pain or tenderness, stop taking [product name] and see a doctor straight away.

Taking a proton pump inhibitor like [product name], 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).

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Tell your doctor or pharmacist:

- If you are taking ketoconazole or itraconazole (drugs used to treat fungal infections).
- If you are taking atazanavir (a drug used to treat HIV).

Pregnancy and breast-feeding

Do not take [product name] tablets if you are pregnant or think you may be pregnant.

Do not take [product name] tablets if you are breast-feeding or planning to breast-feed.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

You may feel sleepy while taking [product name]. If this happens, do not drive or use any tools or machines.

3. HOW TO TAKE [PRODUCT NAME]

Always take [product name] exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

YOU MUST SWALLOW THE [PRODUCT NAME] TABLET WHOLE.

DO NOT CRUSH OR CHEW IT.

The dosages below are those usually recommended for adults and the elderly. Do not change the dose or length of the treatment yourself. [product name] should not be used in children.

Active duodenal ulcer and active benign gastric ulcer

The usual dose is one [product name] 20 mg tablet once a day.

If you have an *active duodenal ulcer*, your treatment is expected to continue for four weeks; but after that time your doctor may decide to continue your treatment for a further four weeks.

If you have an *active benign gastric ulcer*, your treatment is expected to continue for six weeks; but after that time your doctor may decide to continue your treatment for a further six weeks.

Erosive or ulcerative gastro-oesophageal reflux disease

The usual dose is one [product name] 20 mg tablet once a day. Your treatment is expected to continue for four weeks; but after that time your doctor may decide to continue your treatment for a further four weeks.

GORD maintenance

The usual dose is one [product name] 10 mg or 20 mg tablet once a day. Your doctor will advise you on how long to take your tablets. You need to see your doctor at regular intervals for review of your tablets and symptoms.

Symptomatic GORD

The usual dose is one [product name] 10 mg tablet once a day. Your once daily treatment is expected to continue for up to four weeks. If your symptoms do not resolve within four weeks consult your doctor. Following this initial four week treatment, if your symptoms return, your doctor may then tell you to take one [product name] 10 mg tablet as and when you require it in order to control your symptoms.

Zollinger-Ellison Syndrome:

The usual recommended dose is three [product name] 20 mg tablets once a day to start with. The dose may then be adjusted by your doctor depending on how you respond to the treatment. Your doctor will tell you how many tablets to take and when to take them. You need to see your doctor at regular intervals for review of your tablets and symptoms.

Eradication of *H. pylori*

The usual recommended dose is [product name] 20 mg to be taken (in combination with two antibiotics - clarithromycin 500 mg and amoxicillin 1 g) twice each day and normally for 7 days. Relief of symptoms will normally occur before the ulcer has completely healed. Therefore it is important that you do not stop taking the tablets until told to do so by your doctor. For further information on the other components of the *H. pylori* eradication therapy see the individual product information leaflets.

If you take more [product name] than you should

Do not take more tablets each day than you are prescribed. If you accidentally take more tablets than the prescribed dose, please consult your doctor or go to the hospital straight away. Always take the tablets and the carton with you to the hospital so that the doctor knows what has been taken.

If you forget to take [product name]

If you forget to take a dose, just take it immediately when you remember, and then continue as usual. If you forget to take your medicine for more than 5 days, call your doctor before taking any more medicine.

Do not take a double dose to make up for a forgotten gastro-resistant tablet.

If you stop taking [product name]

Do not change the dosage or stop the medication without discussing it with your doctor first.

If you have any further questions on the use of this product, ask your doctor or pharmacist.
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4. POSSIBLE SIDE EFFECTS

Like all medicines, [product name] can cause side effects, although not everybody gets them.

Very common:	Affects more than 1 user in 10
Common:	Affects 1 to 10 users in 100
Uncommon:	Affects 1 to 10 users in 1,000
Rare:	Affects 1 to 10 users in 10,000
Very rare:	Affects less than 1 user in 10,000
Not known:	Frequency cannot be estimated from available data

Stop taking [product name] and see a doctor straight away if you notice 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'.

Other possible side effects:

Common:

- Infection
- Insomnia (difficult sleeping)
- Headaches, dizziness
- Cough, pharyngitis (sore throat), rhinitis (runny nose)
- Diarrhoea, vomiting, nausea, abdominal pain, constipation (costiveness), flatulence (wind)
- Pain without any known cause, back pain
- Asthenia (weakness), flu like syndrome

Uncommon:

- Nervousness or drowsiness
- Bronchitis, sinusitis
- Dyspepsia (indigestion), dry mouth, eructation (belching)
- Skin rash, redness of the skin
- Muscle or joint pain, leg cramps
- Urinary tract infection
- Chest pain
- Chills, fever
- Changes in liver function test values

Rare:

- Anorexia (loss of appetite)
- Depression
- Hypersensitivity - a severe immediate allergic reaction for example facial swelling, low blood pressure and shortness of breath which resolve after stopping the treatment.
- Vision disturbances
- Gastritis (upset stomach or stomach pain), stomatitis (sore mouth), taste disturbances
- Liver problems such as hepatitis (inflammation of the liver) and jaundice (yellowing of your skin and whites of your eyes), hepatic encephalopathy (brain damage due to liver disease)
- Itching, sweating, skin blisters (these reactions have usually resolved after discontinuation of therapy)
- Kidney problems such as interstitial nephritis (disorders of the connective tissue within the kidney)
- Weight gain
- Changes in white blood cells:
 - Neutropenia (decrease of neutrophils, a type of white blood cell) or leucopenia (decrease of white blood cells) - reductions in white blood cells resulting in frequent infections, such as sore throat or high temperature (fever), or ulcers in your mouth or throat.

- Leucocytosis (increase in white blood cells)
- Thrombocytopenia (decrease of blood platelets) - reduction in blood platelets resulting in bleeding or bruising more easily than normal.

Very rare:

- Severe skin reactions such are:
 - Erythema multiforme (reddening of the skin with blisters)
 - Toxic epidermal necrolysis (severe skin damage with the detachment of the top layer of skin from the lower layers of the skin over the body)
 - Steven-Johnson syndrome (severe blisters, peeling and bleeding in the skin and also in the lips, eyes, mouth and nose)

Frequency not known:

- Confusion
- Swelling of the feet or ankles
- Breast swelling in men
- Hyponatremia (low levels of sodium in the blood) - the symptoms are feeling sick and unwell with weak muscles or confused.
- If you are on [product name] 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, 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE [PRODUCT NAME]

Keep out of the reach and sight of children.

Do not use [product name] 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.

Do not store above 30 °C. Store in the original package in order to protect from moisture.

Do not use any [product name] pack that is damaged or shows signs of tampering.

Medicine should not be disposed of in waste-water or with household garbage. Ask your pharmacist what you should do with medications you no longer need. These measures will help to protect the environment.

6. FURTHER INFORMATION

What [product name] contains

The active substance is: rabeprazole sodium.

One gastro-resistant tablet contains 10 mg rabeprazole sodium, equivalent to 9.42 mg rabeprazole.

One gastro-resistant tablet contains 20 mg rabeprazole sodium, equivalent to 18.85 mg rabeprazole.

The other ingredients are:

[product name] 10 mg gastro-resistant tablets:

Tablet Core: Magnesium oxide, mannitol, sodium starch glycollate (Type A), povidone (K-30), magnesium stearate

Intermediate layer: Ethyl cellulose, magnesium oxide, diethyl phthalate,

Coating: Hypromellose phthalate, titanium dioxide (E 171), talc, diethyl phthalate, iron oxide red (E 172)

[product name] 20 mg gastro-resistant tablets:

Tablet Core: Magnesium oxide, mannitol, sodium starch glycollate (Type A), povidone (K-30), magnesium stearate

Intermediate layer: Ethyl cellulose, magnesium oxide, diethyl phthalate

Coating: Hypromellose phthalate, titanium dioxide (E 171), talc, diethyl phthalate, iron oxide yellow (E 172)

What [product name] looks like and contents of the pack

[product name] 10 mg gastro-resistant tablets are pink, round biconvex, coated tablets, plain on both sides.

[product name] 20 mg gastro-resistant tablets are yellow, round biconvex, coated tablets, plain on both sides.

Pack sizes:

DK/H/1821/001/DC

7, 14, 28, 30, 56, 98 gastro-resistant tablets.

DK/H/1821/002/DC

7, 14, 28, 30, 56, 98, 120 gastro-resistant tablets.

DK/H/1822/001-002/DC

14, 28, 56, 98 gastro-resistant tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

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

DK/H/1821/001-002/DC

DK: Rabeprazolnatrium STADA 10 (20) mg enterotabletter

AT: Rabeprazol STADA 10 (20) mg Filmtabletten

BE: Rabeprazole EG 10 (20) mg maagsapresistente tabletten

DE: Rabeprazol STADA 10 (20) mg magensaftresistente Tabletten

ES: Rabeprazol STADA 10 (20) mg comprimidos gastrorresistentes EFG

FR: RABEPRAZOLE EG 10 (20) mg, comprimé gastro-résistant

HU: RabeStad

IE: Rabiclon 10 (20) mg gastro-resistant tablets

IT: RABEPRAZOLO EG 10 (20) mg compresse gastroresistenti

LU: Rabeprazole EG 10 (20) mg comprimés gastro-résistants

NL: Rabeprazolnatrium **CF-Centrafarm** 10 (20) mg, maagsapresistente tabletten

PT: Rabeprazol Stada

SE: Rabestad 10 (20) mg enterotablett

DK/H/1822/001-002/DC

DK: Rabenidda 10 (20) mg enterotabletter

DE: Rabeprazol AL 10 (20) mg magensaftresistente Tabletten

This leaflet was last approved in {MM/YYYY}.
[To be completed nationally]