

559

RABEPRAZOLE SODIUM TEVA
10 mg GASTRO-RESISTANT TABLETS
RABEPRAZOLE SODIUM TEVA
20 mg GASTRO-RESISTANT TABLETS
Rabeprazole sodium

PACKAGE LEAFLET: INFORMATION FOR THE USER

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 Rabeprazole sodium Teva is and what it is used for**
- 2. Before you take Rabeprazole sodium Teva**
- 3. How to take Rabeprazole sodium Teva**
- 4. Possible side effects**
- 5. How to store Rabeprazole sodium Teva**
- 6. Further information**

1 WHAT RABEPRAZOLE SODIUM TEVA IS AND WHAT IT IS USED FOR

This medicine contains the active ingredient rabeprazole sodium. This belongs to a group of medicines called proton pump inhibitors (PPIs). They work by lowering the amount of acid that your stomach produces.

Rabeprazole sodium Teva Gastro-resistant Tablets are used to treat the following conditions:

- Gastro-oesophageal reflux disease (GORD), which can include heartburn. GORD is caused when acid and food from your stomach escape into your food pipe (oesophagus).
- Ulcers in your stomach or the upper part of your gut (intestine). If these ulcers are infected with bacteria called '*Helicobacter pylori*' (*H.Pylori*), you will also be given antibiotics. Using Rabeprazole sodium Teva and antibiotics together gets rid of the infection and makes the ulcer heal. It also stops the infection and ulcer from coming back.
- Zollinger-Ellison syndrome where your stomach produces too much acid.

2 BEFORE YOU TAKE RABEPRAZOLE SODIUM TEVA

Do NOT take Rabeprazole sodium Teva

- if you are **allergic** (hypersensitive) to **rabeprazole sodium** or any of the other ingredients of Rabeprazole sodium Teva (listed in section 6 below).
- if you are **pregnant** or think that you are pregnant.
- if you are **breast-feeding**.

Do not use Rabeprazole sodium Teva if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before using Rabeprazole sodium Teva.

Also see Pregnancy and breast-feeding section.

Children
Rabeprazole sodium Teva should not be used in children.

Take special care with Rabeprazole sodium Teva
Check with your doctor or pharmacist before taking Rabeprazole sodium Teva if:

- You are allergic to other proton pump inhibitor medicines or 'substituted benzimidazoles'.
- Blood and liver problems have been seen in some patients but often get better when Rabeprazole sodium Teva is stopped.
- You have a stomach tumour.
- You have ever had liver problems.
- If you are taking atazanavir for HIV infection.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using Rabeprazole sodium Teva.

Taking a proton pump inhibitor like Rabeprazole sodium Teva, 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).

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

Using other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines. In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Ketoconazole or itraconazole - used to treat infections caused by a fungus. Rabeprazole sodium Teva may lower the amount of this type of medicine in your blood. Your doctor may need to adjust your dose.
- Atazanavir - used to treat HIV infection. Rabeprazole sodium Teva may lower the amount of this type of medicine in your blood and they should not be used together.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using Rabeprazole sodium Teva.

Pregnancy and breast-feeding

- Do not use Rabeprazole sodium Teva if you are pregnant or think you may be pregnant.
- Do not use Rabeprazole sodium Teva if you are breast-feeding or planning to breast-feed.

Ask your doctor or pharmacist for advice before taking any medicine during pregnancy or while breast-feeding.

Driving and using machines
You may feel sleepy while taking Rabeprazole sodium Teva. If this happens, do not drive or use any tools or machines.

Important information about some of the ingredients of Rabeprazole sodium Teva
This medicinal product contains **lactose**. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3 HOW TO TAKE RABEPRAZOLE SODIUM TEVA

Always take Rabeprazole sodium Teva exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Only remove a tablet from the blister strip when it is time to take your medicine.
- Swallow your tablets whole with a drink of water. Do not chew or crush the tablets.
- Your doctor will tell you how many tablets to take and how long to take them for. This will depend on your condition.
- If you are taking this medicine for a long time, your doctor will want to monitor you.

Adults and the elderly
For gastro-oesophageal reflux disease (GORD)
Treatment of moderate to severe symptoms (symptomatic GORD)

- The usual dose is 1 Rabeprazole sodium Teva 10 mg Gastro-resistant Tablet once a day for up to 4 weeks.
- Take the tablet in the morning before eating.
- If your condition returns after 4 weeks' treatment, your doctor may tell you to take one Rabeprazole sodium Teva 10 mg Gastro-resistant Tablet as and when you require it.

Treatment of more severe symptoms (erosive or ulcerative GORD)

- The usual dose is one Rabeprazole sodium Teva 20 mg Gastro-resistant Tablet once a day for 4 to 8 weeks.
- Take the tablet in the morning before eating.

Long-term treatment of symptoms (GORD maintenance)

- The usual dose is one Rabeprazole sodium Teva 10 mg or 20 mg Gastro-resistant Tablet once a day for as long as your doctor has told you.
- Take the tablet in the morning before eating.
- Your doctor will want to see you at regular intervals to check your symptoms and dosage.

For ulcers of the stomach (peptic ulcers)

- The usual dose is one Rabeprazole sodium Teva 20 mg Gastro-resistant Tablet once a day for 6 weeks.
- Take the tablet in the morning before eating.
- Your doctor may tell you to take Rabeprazole sodium Teva for another 6 weeks if your condition does not improve.

For ulcers of the intestine (duodenal ulcers)

- The usual dose is one Rabeprazole sodium Teva 20 mg Gastro-resistant Tablet once a day for 4 weeks.
- Take the tablet in the morning before eating.
- Your doctor may tell you to take Rabeprazole sodium Teva for another 4 weeks if your condition does not improve.

For ulcers caused by H. pylori infection and to stop them coming back

- The usual dose is one Rabeprazole sodium Teva 20 mg Gastro-resistant Tablet twice a day for seven days.
- Your doctor will also tell you to take antibiotics called amoxicillin and clarithromycin.

For further information on the other medicines used for the *H. pylori* treatment, see the individual product information leaflets.

Zollinger-Ellison syndrome where excess acid is produced in the stomach

- The usual dose is three Rabeprazole sodium Teva 20 mg Gastro-resistant Tablets once a day to start with.
- The dose may then be adjusted by your doctor depending on how you respond to the treatment.

If you are on long-term treatment you will need to see your doctor at regular intervals for review of your tablets and symptoms.

Children
The product should not be used in children.

Patients with liver problems
You should consult your doctor who will take special care when beginning treatment with Rabeprazole sodium Teva and while you continue to be treated with Rabeprazole sodium Teva.

If you take more Rabeprazole sodium Teva than you should
If you take more Rabeprazole sodium Teva than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

If you forget to take Rabeprazole sodium Teva

- If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose and continue as usual.
- If you forget to take your medicine for more than 5 days, talk to your doctor before taking any more medicine.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

659

TEVA Design Department Harlow	
PRODUCT: Rabeprazole Sodium Teva 10mg, 20mg Gastro-Resistant Tabs All TEI V6 (KS)	Colours: Cutter Guide ■ PMS Process Black ■ PMS Green ■
Job No: 27637 Art No: X	Fonts: (Artwork) Body: Univers 55 Roman/ 65 Bold/ 55 Oblique xxpts Subhead: Univers 65 Bld xxpts Header: Univers 65 Bld xxpts
Designer: MW Date: 22-3-13	Amends: Draft: 1 Rev date: 22-03-13 Reviser: WA
Component: Leaflet	Approval: Senior Artwork Co-ordinator Signed Date <input type="checkbox"/> Subject to Reg. Agency approval <input type="checkbox"/> Approved by Reg. Dept. for print Signed Date
Dimensions: 190x340mm	Software used: Indesign CS6
Supplier Instructions Artwork, text and content must NOT be altered. The only exceptions to this are: bleeds, chokes, spreads or other adjustments required for print reproduction purposes only. If you have any difficulties please contact the Teva Artwork Team. We must receive a copy of the 3rd Party Vendors Proof before final approval can be made.	
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If you stop taking Rabeprazole sodium Teva

Relief of symptoms will normally occur before the ulcer has completely healed. **It is important that you do not stop taking the gastro-resistant tablets until told to do so by your doctor.**

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

4 POSSIBLE SIDE EFFECTS

Like all medicines, Rabeprazole sodium Teva can cause side effects, although not everybody gets them. The side effects are usually mild and improve without you having to stop taking this medicine.

Stop taking Rabeprazole sodium Teva and see a doctor straight away if you notice any of the following side effects - you may need urgent medical treatment:

- Allergic reactions - the signs may appear include sudden swelling of your face, difficulty breathing or low blood pressure which may cause fainting or collapse.
- Frequent infections, such as a sore throat or high temperature (fever), or ulcers in your mouth or throat.
- Bruising or bleeding easily.

These side effects are rare (affect less than 1 in 1,000 people).

- Severe skin blistering, or soreness or ulcers in your mouth and throat.

These side effects are very rare (affect fewer than 1 in 10,000 people).

Other possible side effects:

Common side effects (affect 1 to 10 users in 100):

- Infections
- Difficulty sleeping
- Headache or feeling dizzy
- Cough, runny nose or sore throat (pharyngitis)
- Effects on your stomach or gut such as stomach pain, diarrhoea, wind (flatulence), feeling sick (nausea), being sick (vomiting) or constipation
- Aches or back pain
- Weakness or 'flu-like' symptoms

Uncommon side effects (affect 1 to 10 users in 1,000):

- Feeling nervous or drowsy
- Chest infection (bronchitis)
- Painful and blocked sinuses (sinusitis)
- Dry mouth
- Indigestion or belching
- Skin rash or redness
- Muscle, leg or joint pain
- Bladder infection (urinary tract infection)
- Chest pain
- Chills or fever
- Changes in how your liver is working (shown in blood tests)
- Slight increase in the risk of hip, wrist or spine fractures if you take Rabeprazole sodium Teva over a period of more than one year

Rare side effects (affect 1 to 10 users in 10,000):

- Loss of appetite (anorexia)
- Depression
- Hypersensitivity (includes allergic reactions)
- Visual disturbance
- Sore mouth (stomatitis) or taste disturbance
- Upset stomach or stomach pain
- Liver problems including yellowing of your skin and whites or your eyes (jaundice)
- Itchy rash or blistering
- Sweating
- Kidney problems
- Weight gain
- Changes in white blood cells (shown in blood tests) which may result in frequent infection.
- Reduction in blood platelets resulting in bleeding or bruising more easily than normal.

Other possible side effects (unknown frequency):

- Breast swelling in men
- Fluid retention
- Low blood levels of sodium which can cause tiredness and confusion, muscle twitching, fits and coma
- Patients who have previously had liver problems may very rarely get encephalopathy (a brain disease).

If you are on Rabeprazole sodium Teva 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.

Do not be concerned by this list of side effects. You may not get any of them. 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 RABEPRAZOLE SODIUM TEVA

Keep out of the reach and sight of children.

Store below 25°C.

Store in original package in order to protect from moisture.

Do not use Rabeprazole sodium Teva after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 FURTHER INFORMATION**What Rabeprazole sodium Teva contains**

The active substance is rabeprazole sodium.

Each 10 mg gastro-resistant tablet contains 10 mg rabeprazole sodium.

Each 20 mg gastro-resistant tablet contains 20 mg rabeprazole sodium.

The other ingredients are:

Core:

Mannitol, low substituted hydroxypropylcellulose, magnesium oxide, heavy, hydroxypropylcellulose, magnesium stearate.

Coating - 10 mg tablets:

Hypromellose (E464), cellulose, microcrystalline, stearic acid, titanium dioxide (E171), hypromellose phthalate, triethyl citrate, lactose, monohydrate, macrogol 4000, red iron oxide (E172), yellow iron oxide (E172).

Coating - 20 mg tablets:

Hypromellose (E464), cellulose, microcrystalline, stearic acid, titanium dioxide (E171), hypromellose phthalate, triethyl citrate, lactose, monohydrate, macrogol 4000, red iron oxide (E172), yellow iron oxide (E172), black iron oxide (E172).

Printing ink:

Shellac, black iron oxide (E172), ammonium hydroxide, propylene glycol

What Rabeprazole sodium looks like and contents of the pack

- Rabeprazole sodium Teva 10 mg Gastro-Resistant Tablets are pink, round tablets, imprinted on one side of the tablet with black ink "N" and "10".
- Rabeprazole sodium Teva 20 mg Gastro-Resistant Tablets are yellow, round tablets, imprinted on one side of the tablet with black ink "93" "64". Plain on the other side.
- Rabeprazole sodium Teva Gastro-resistant Tablets are available in pack sizes of 1, 7, 14, 15, 20, 25, 28, 30, 50, 56, 57, 60, 75, 98, 100 and 120 gastro-resistant tablets. Hospital packs of 50 and 98 gastro-resistant tablets.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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This medicinal product is authorised in the member states of the EEA under the following names:

United Kingdom: Rabeprazole Sodium 10 & 20 mg Gastro-resistant Tablets

Austria: Rabeprazol Teva 10 & 20 mg magensaftresistente Tabletten

Belgium: Rabeprazole Teva 10 & 20 mg maagsapresentente tabletten

Bulgaria: Rabezol 10 & 20 mg gastro-resistant tablet

Germany: Rabeprazol Natrium Teva 10 & 20 mg magensaftresistente Tabletten

Denmark: Rabeprazolnatrium Teva 10 & 20 mg

Greece: Rabeprazole Sodium Teva 10 & 20 mg Γαστροανθεκτικά δισκία

Spain: Rabeprazol Sódico Teva 10 & 20 mg comprimidos gastrorresistentes EFG

France: Rabeprazole Teva 10 & 20 mg comprimé gastro-résistant

Hungary: Rabeprazol-nátrium Teva 10 & 20 mg gyomornedv-ellenálló tableta

Ireland: Rabeprazole sodium Teva 10 & 20 mg Gastro-resistant Tablet

Italy: Rabeprazolo Teva 10 & 20 mg compresse gastroresistenti

Luxembourg: Rabeprazole Teva 10 & 20 mg comprimés gastro-résistants

The Netherlands: Rabeprazolnatrium 10 & 20 mg - Gastro-resistant Film-coated Tablets

Poland: Rabeprol

Romania: Rabeprazol Teva 10 & 20 mg comprimate gastrorezistente

Slovenia: Rabeprazol Teva 10 & 20 mg gastrorezistentne tablete

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