

PACKAGE LEAFLET: INFORMATION FOR THE USER

URUTAL

URUTAL 8mg Tablets

URUTAL Forte 16mg Tablets

BETAHISTINE DIHYDROCHLORIDE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

1. What URUTAL is and what it is used for
2. Before you take URUTAL
3. How to take URUTAL
4. Possible side effects
5. How to store URUTAL

1. WHAT URUTAL IS AND WHAT IS IT USED FOR

URUTAL contains betahistine. This medicine is called a histamine analogue. It is used to treat:

- dizziness (vertigo)
- ringing in the ears (tinnitus)
- hearing loss suffered by people with Ménière's disease

This medicine works by improving blood flow in the inner ear. This lowers the build up of pressure.

2. BEFORE YOU TAKE URUTAL

Do not take URUTAL if:

- You are allergic to any of the ingredients in the tablets.
- You have high blood pressure due to an adrenal tumour (phaeochromocytoma).

If any of the above applies to you, do not take this medicine and talk to your doctor.

Take special care and tell your doctor if:

- you have a stomach ulcer
- you have asthma
- you are pregnant or planning to become pregnant
- you are breast-feeding

If any of the above applies to you, talk to your doctor before taking this medicine.

Your doctor will tell you whether it is safe for you to start taking this medicine.

Your doctor may also want to monitor your asthma while you take URUTAL.

Taking other medicines

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

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Anti-histamines - these may (in theory) lower the effect of URUTAL. Also, URUTAL may lower the effect of anti-histamines.
- Monoamine-oxidase inhibitors (MAOIs) - used to treat depression or Parkinson's disease. These may increase the exposure of URUTAL.

Taking URUTAL with food and drink

You can take URUTAL with or without food.

Pregnancy and breast-feeding

Do not take URUTAL if you are pregnant unless your doctor has decided that it is absolutely necessary. Ask your doctor for advice.

Do not breast-feed while using URUTAL unless instructed by your doctor. It is not known if URUTAL passes into breast milk.

Driving and using machines

URUTAL is not likely to affect your ability to drive or use tools or machinery. However, remember that diseases for which you are being treated with URUTAL (vertigo, tinnitus and hearing loss associated with Ménière's syndrome) can make you feel dizzy or be sick, and can affect your ability to drive or use machines.

3. HOW TO TAKE URUTAL

How to take URUTAL

- Swallow the tablets with water.
- Preferably take the tablet with a meal.

How much URUTAL to take

Always follow your doctor's instructions because your doctor might adjust your dose

- URUTAL is available in two strengths, an 8 mg tablet and a 16 mg tablet.
- The usual starting dose is 16 mg three times a day (48 mg).
- Your doctor may lower your dose to 8 mg three times a day (24 mg).

Keep taking your tablets. The tablets can take a while to start to work.

URUTAL is not recommended for those under 18 years old.

How to stop taking URUTAL

Keep taking your tablets until your doctor tells you to stop.

Even when you start feeling better, your doctor may want you to carry on taking the tablets for some time to make sure that the medicine has worked completely.

If you take more URUTAL than you should

If you or someone else takes too much URUTAL (an overdose), talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

If you forget to take URUTAL

If you miss a tablet, wait until the next dose is due. Do not try to make up for the dose you have missed.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, URUTAL can cause side effects (unwanted effects or reactions), but not everyone gets them.

The following serious side effects may occur during treatment with URUTAL:

Allergic reactions such as:

- swelling of your face, lips, tongue or neck. This may cause difficulty breathing.
- a red skin rash, inflamed itchy skin

If any of these side effects occur you should stop treatment immediately and contact your doctor.

Common side effects (at least 1 in 100 and less than 1 in 10 patients):

Nausea, indigestion, headaches.

Other side effects

Itching, rash, hives, mild gastric complaints such as vomiting, stomach pain and bloating. Taking URUTAL with food can help reduce any stomach problems.

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. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE URUTAL

- **Keep out of the reach and sight of children.**
- This medicine should preferably be locked in a cupboard or medicine cabinet.
- Do not use the tablets after the expiry date which is printed on the carton and blister pack.
- Do not store your tablets above 25°C and keep them in the original package.
- If your doctor stops your treatment, return any unused tablets to a pharmacist.

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.