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 they have the same symptoms as you.
- 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 Betahistine is and what it is used for
2. What you need to know before you take Betahistine
3. How to take Betahistine
4. Possible side effects
5. How to store Betahistine
6. Contents of the pack and other information

1. What Betahistine is and what it is used for
Betahistine is a type of medicine called a "histamine analogue". Betahistine is used for:
- Menière's disease – the signs of this include:
  • feeling dizzy (vertigo)
  • ringing in the ears (tinnitus)
  • hearing loss or hearing difficulty
How this medicine works
This medicine works by improving blood flow in the inner ear. This lowers the build up of pressure.

2. What you need to know before you take Betahistine
Do not take Betahistine
- if you are allergic to betahistine or to any of the other ingredients of this medicine (listed in section 6)
- if you have a pheochromocytoma, a rare tumour of the adrenal gland

Warnings and precautions
Talk to your doctor or pharmacist before taking Betahistine.
- if you have or have had a stomach ulcer (peptic ulcer)
- if you have asthma
- if you have nettle rash, skin rash or a cold in the nose caused by an allergy, since these complaints may be exacerbated.
- if you have low blood pressure
- Betahistine dihydrochloride is not the appropriate treatment for the following forms of vertigo:
  • attacks of benign positional vertigo
  • dizziness related to a disease of the central nervous system
- if you are pregnant or planning to become pregnant
- do not breast-feed while using betahistine dihydrochloride tablets unless instructed by your doctor. It is not known if betahistine passes into breast milk.

Driving and using machines
Betahistine is not likely to affect your ability to drive or use tools or machinery.
However, remember that the disease for which you are being treated with Betahistine (Ménière's disease) can make you feel dizzy or sick, and can affect your ability to drive and use machines.

3. How to take Betahistine
Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- Your doctor may adjust your dose.
- Keep taking your medicine. The medicine can take a while to start to work.

How to take Betahistine
- Swallow the tablets with water.
- Take the tablet with or after a meal. However, Betahistine can cause mild stomach problems (listed in Section 4). Taking Betahistine with food can help reduce stomach problems.

How much Betahistine to take
Always follow your doctor's instructions because your doctor might adjust your dose.

The recommended dose is:
- Adults
  The recommended dose is 24 mg to 48 mg per day. 8 mg tablets: one or two tablets three times a day.
  16 mg tablets: half or one tablet three times a day. 24 mg tablets: 1 tablet two times per day. This form of the medication is used when you need 48 mg of betahistine per day.
- Dosage
  Daily dose should not exceed 48 mg.

In some cases, improvement does not begin to become apparent until two weeks after starting treatment. The optimal result is obtained after several months of treatment.

If you take more than one tablet each day, spread your tablets evenly over the day. For example, take one tablet in the morning, one at midday and one in the evening.

Try to take your tablet at the same time each day. This will make sure that there is a steady amount of the medicine in your body. Taking at the same time will also help you remember to take your tablets. Betahistine is not recommended for use in children.

If you take more Betahistine than you should
If you or someone else takes too many Betahistine tablets (an overdose), you may feel sick (nauseous),...
### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Very few adverse effects have been reported with betahistine.

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

- **Allergic reactions:**
  - a red or lumpy skin rash or inflamed itchy skin
  - swelling of your face, lips, tongue or neck
  - a drop in your blood pressure
  - loss of consciousness
  - difficulty breathing

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

Other side effects include:

**Common (may affect up to 1 in 10 people):**
- feeling sick (nausea)
- indigestion (dyspepsia)
- headache.

**Possible side effects**

- difficulty swallowing
- passage of wind
- diarrhoea
- constipation
- dry mouth
- tiredness
- anxiety
- communicating problems
- racing heart
- dizziness
- a drop in blood pressure
- facial swelling (oedema)
- facial swelling after taking tablets
- abdominal distension
- bloating
- feeling sick or vomiting
- rash, and pruritus.

**Not known:** cutaneous and subcutaneous hypersensitivity reactions, e.g. anaphylaxis.

Other side effects that have been reported with the use of betahistine:

- Mild stomach problems such as being sick (gastralgia, vomiting), stomach pain, dry mouth, diarrhoea, stomach swelling (abdominal distension) and bloating. Taking betahistine with food can help reduce stomach swelling (abdominal distension) and bloating.
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