

Betahecon®
8mg tablets/16mg tablets

betahistine dihydrochloride

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 becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Betahecon is and what it is used for

Betahecon contains betahistine dihydrochloride. Betahecon is a type of medicine called a “histamine analogue”.

Betahecon is used for:

Ménière’s disease – the signs of this include:

- feeling dizzy (vertigo),
- ringing in the ears (tinnitus)
- hearing loss or hearing difficulty

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

Before you take Betahecon

Do not take Betahecon if:

- you are allergic (hypersensitive) to betahistine or any of the other ingredients in the tablets (see section 6 for further details)
- You have high blood pressure due to an adrenal gland 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 ever had 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 or pharmacist before taking Betahecon.

Your doctor may want to monitor you more closely while you take Betahecon. Your doctor will tell you whether it is safe for you to start taking this medicine.

Children

Betahecon is not recommended for those under 18 years old.

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 and herbal medicines.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:
Anti-histamines - This is because in theory Betahecon may not work properly. Also, Betahecon 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 Betahecon.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Betahecon.

Taking Betahecon with food and drink

Betahecon can be taken with or without food. However, Betahecon can cause mild stomach problems (listed in Section 4). Taking Betahecon with food can help reduce stomach problems.

Pregnancy and breast-feeding

It is not known if Betahecon affects an unborn baby:

Stop taking Betahecon and tell your doctor if you become pregnant or think you might be pregnant.

Do not take Betahecon if you are pregnant unless your doctor has decided that it is necessary.

It is not known if Betahecon passes into breast milk:

Do not breast-feed while using Betahecon unless instructed by your doctor.

Ask your doctor for advice.

Driving and using machines

Betahecon 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 Betahecon (Ménière's disease) can make you feel dizzy or sick, and can affect your ability to drive and use machines.

3. How to take Betahecon

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

- Your doctor will adjust your dose, depending on your progress.
- Keep taking your medicine. The medicine can take a while to start to work.

How to take Betahecon

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

How much Betahecon to take

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

- Betahecon is available in two strengths – 8mg tablets and 16mg tablets.

- The usual dose is 24mg to 48mg per day:

8mg tablets – one or two tablets three times a day

16 mg tablets – half or one tablet three times a day.

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. Betahecon is not recommended for use in children.

How to stop taking Betahecon

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 Betahecon than you should

If you or someone else takes too many Betahecon tablets (an overdose), you may feel sick (nauseous), sleepy or have stomach pain. Talk to a doctor or go to a hospital immediately. Take the Betahecon pack with you.

If you forget to take Betahecon

If you miss a dose, take it when you remember. If it's nearly time for your next dose, ignore the missed dose and carry on as normal.

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 Betahecon can cause side effects (unwanted effects or reactions), but not everyone gets them. Very few side effects have been reported with Betahecon.

Allergic reactions

If you have an allergic reaction, stop taking Betahecon and see a doctor or go to a hospital straight away. The signs may include:

- 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

Stop taking Betahecon and see a doctor or go to a hospital straight away, if you notice any of the signs above

Other side effects include:

Common (affects less than 1 in 10 people)

- feeling sick (nausea)
- indigestion (dyspepsia)
- headache

Other side effects that have been reported with the use of Betahecon

Mild stomach problems such as being sick (vomiting), stomach pain, stomach swelling (abdominal distension) and bloating. Taking Betahecon with food can help reduce stomach problems.

If any of the side effects become serious, or if you notice any side effects that are not listed in this leaflet, please tell your doctor or pharmacist.

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 HPRAs Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store these tablets

- **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 printed on the carton and blister strip. The expiry date refers to the last day of that month.
 - This medicinal product does not require any special temperature storage conditions. Store in the original package.
 - If the 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.

6. Further Information

What Betahecon contains

Each tablet contains 8 or 16 mg of betahistine dihydrochloride.
The tablets also contain microcrystalline cellulose, mannitol (E421), citric acid monohydrate, colloidal anhydrous silica and talc.

What Betahecon looks like and contents of the pack

Betahecon 8mg tablets are white, flat and round, imprinted '256' on one face.
Betahecon 16 mg tablets are white, biconvex, scored and round, imprinted '267' on one face. The score line can be used to split the tablet in half.
Betahecon 8 mg packs contain 120 tablets.
Betahecon 16 mg packs contain 84 tablets.

The Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder is

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