

SETEAR

Betahistine dihydrochloride

Consumer Medicine Information

Please read this leaflet carefully before you start SETEAR

What is in this leaflet

This leaflet answers some common questions about SETEAR tablets. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking SETEAR against the benefits they expect it will have for you.

Keep this leaflet with your medicine.

You may need to read it again.

What SETEAR is used for

SETEAR is used to treat a disorder of the working of your inner ear. This disorder may include one or more of the following symptoms, in one or both ears:

- Ringing in the ears (tinnitus)
- Loss of clear hearing
- Problems with balance (vertigo)

These symptoms may also be associated with nausea, vomiting and headache. Often these symptoms together are referred to as Ménière's Syndrome.

Based on animal studies, the active ingredient of SETEAR tablets, betahistine dihydrochloride, works

by improving the blood flow of the inner ear and restoring it to normal. It also acts on the nerve endings in the inner ear to normalise the way in which the nerves respond to outside influences.

Your doctor may have prescribed SETEAR for another reason. Ask your doctor if you have any questions about why SETEAR has been prescribed for you.

There is no evidence that SETEAR is addictive.

This medicine is available only with a doctor's prescription.

Before you take SETEAR

When you must not take it

Do not take SETEAR if:

- you are pregnant or intend to become pregnant. SETEAR may affect your developing baby if taken during pregnancy.
- you are breast-feeding or plan to breast-feed. SETEAR may pass into breast milk and therefore there is a possibility that the breast-fed baby may be affected.
- you are allergic to betahistine dihydrochloride or any of the ingredients listed at the end of this leaflet.
- you have a rare abnormality of the adrenal gland known as pheochromocytoma.
- you have or have had a peptic ulcer.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, wheezing or shortness of breath (**or as per PI**)

Do not give SETEAR to children under 18 years of age.

Do not take SETEAR after the expiry date (EXP) printed on the pack.

Do not take SETEAR if the packaging is torn or shows signs of tampering, or if the tablets do not look quite right.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking SETEAR, talk to your doctor or pharmacist.

Before you start to take it

You must tell your doctor if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

Tell your doctor if:

- you have or have had a peptic ulcer,
- you suffer from asthma
- you have a history of allergic skin conditions or if you have or have had any other medical conditions.

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor will discuss the possible risks and benefits of using SETEAR during pregnancy.

Tell your doctor if you are breastfeeding or plan to breastfeed.

Your doctor will discuss the possible risks and benefits of using SETEAR during breastfeeding.

If you have not told your doctor about any of the above, tell them before you start taking SETEAR.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and SETEAR may interfere with each other. These include:

- any antihistamine medications
- These medicines may be affected by SETEAR or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking SETEAR.

How to take SETEAR

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

Your doctor or pharmacist will tell you how many tablets you will need to take each day. This depends on your condition and whether or not you are taking any other medicines.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

The usual adult dose is one tablet taken two times a day. However your doctor may prescribe a different dose

depending on the severity of your condition.

The maximum recommended daily dosage is 48 mg.

How to take SETEAR

Swallow SETEAR tablets with a glass of water.

When to take it

Take SETEAR at about the same time each day.

Taking your tablets at the same time each day will have the best effect. It will also help you remember when to take the tablets.

Take SETEAR during or immediately after a meal, at about the same time each day.

If you take SETEAR on an empty stomach, it may cause stomach upsets.

How long to take it for

If you follow your doctor's instructions SETEAR should start working within a few days, although in some cases it may take a few weeks. The length of time that you should take SETEAR tablets varies from patient to patient. Some people respond rapidly to treatment and others may take some time. Please be patient with your treatment and take your tablets regularly. Do not stop taking your medicine unless your doctor tells you to - even if you feel better. Include this section if applicable.

If you forget to take you tablets

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much SETEAR. Do this even if there are no signs of discomfort or poisoning.

The most common symptoms of overdosing is nausea.

While you are taking SETEAR

Things you must do

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking SETEAR.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking SETEAR.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking SETEAR.

If you become pregnant while taking SETEAR, tell your doctor.

Things you must not do

Do not give SETEAR to anyone else, even if they have the same condition as you.

Do not take SETEAR to treat any other complaints unless your doctor tells you to.

Do not stop taking SETEAR, or lower the dosage without checking with your doctor.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking SETEAR. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Following is a list of possible side effects. Do not be alarmed by this list.

You may not experience any of them.

If you get any side effects, do not stop taking SETEAR without first talking with your doctor.

Tell your doctor if you notice any of the following and they worry you:

- skin irritations
- stomach upsets
- dizziness
- fast heart beat
- headache
- difficulty sleeping (insomnia)

These side effects are usually mild and some may also be present as part of your disorder. Stomach upsets can be overcome by taking SETEAR during meals.

Tell your doctor as soon as possible if you notice any of the following:

- skin reactions
- difficulty breathing

These may be serious side effects. You may need medical attention. Serious side effects are very rare.

Other side effects not listed above may also occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

After using SETEAR

Storage

Keep your tablets in the pack until it is time to take them. If you take the tablets out of the pack they will not keep well.

Keep your tablets in a cool, dry place where the temperature stays below 25°C. Do not store SETEAR or any other medicine in the bathroom or near a sink.

Do not leave it on a windowsill or in the car on hot days.

Heat and dampness can destroy some medicines.

Keep SETEAR tablets where children cannot reach them. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking SETEAR, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets left over.

Product description

What the tablets looks like

SETEAR tablets are white and flat with beveled edges. They have a breakline on one side. Available in packs of 60 tablets.

Ingredients

Each SETEAR tablet contains 24 mg of the active ingredient betahistine dihydrochloride. The tablets also contain lactose, maize starch, microcrystalline cellulose, anhydrous citric acid, povidone, crospovidone and hydrogenated vegetable oil.

Manufacturer

Registration Number
AUST R 261439

Sponsor

Southern Cross Pharma Pty Ltd
Suite 5/118 Church Street
Hawthorn, VIC, 3122

ABN 47 094 447 677

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