

Setear

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Setear?

Setear contains 24 mg of the active ingredient betahistine dihydrochloride. Setear is used to treat an inner ear disorder called Meniere's syndrome, which may cause ringing in the ears, hearing loss or balance problems and sometimes nausea, vomiting and headache.

For more information, see Section [1. Why am I using Setear?](#) in the full CMI.

2. What should I know before I use Setear?

Do not use if you have ever had an allergic reaction to Setear or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Setear?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Setear and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Setear?

- The usual adult starting dose is half to one 24 mg tablet taken twice a day. Your doctor may however prescribe a different dose. The maximum recommended daily dosage is 48 mg.
- Swallow Setear with a glass of water following food, and at about the same time each day.

More instructions can be found in Section [4. How do I use Setear?](#) in the full CMI.

5. What should I know while using Setear?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Setear.• Tell your doctor if you have or have had a peptic ulcer, suffer from asthma, have a history of allergic skin conditions or tumours of the adrenal gland, have or have had any other medical conditions including pregnancy or breastfeeding, or have any allergies to any other medicines or substances.
Things you should not do	<ul style="list-style-type: none">• 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.
Driving or using machines	<ul style="list-style-type: none">• If you have dizziness from your condition or this medication, do not drive or use machines until you are sure that the dizziness has eased.
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets in a cool, dry place where the temperature stays below 25°C.• Keep your tablets in the pack until it is time to take them.

For more information, see Section [5. What should I know while using Setear?](#) in the full CMI.

6. Are there any side effects?

Common side effects include skin irritations, stomach upsets, dizziness, fast heart-beat, headache, difficulty sleeping, tiredness, nausea, vomiting, bloating, swollen stomach and diarrhoea.

Serious side effects include skin reactions, difficulty breathing, convulsions, hallucinations, confusion, allergic reaction, low blood pressure and slow heart-beat.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Setear

Active ingredient: betahistine dihydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using Setear. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Setear.**

Where to find information in this leaflet:

- [1. Why am I using Setear?](#)
- [2. What should I know before I use Setear?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Setear?](#)
- [5. What should I know while using Setear?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Setear?

Setear contains the active ingredient betahistine dihydrochloride.

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.

Setear tablets contain the active ingredient betahistine dihydrochloride, which work 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 normalize 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.

2. What should I know before I use Setear?

Warnings

Do not use 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 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. Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.
- you have a rare abnormality of the adrenal gland known as pheochromocytoma.
- you have or have had a peptic ulcer.

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

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

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

Some medicines and Setear may interfere with each other.

These include:

- any antihistamine medications, which are used to treat allergies and allergic reactions
- monoamine oxidase inhibitors (MAOIs) (e.g. some antidepressants, selegiline)

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

4. How do I use Setear?

How much to take

- The usual adult starting dose is half to one 24mg Setear tablet, taken twice 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.
- Swallow Setear with a glass of water.
- Follow the instructions provided and use Setear until your doctor tells you to stop.
- 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.

When to take Setear

- 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.

If you forget to use Setear

Setear should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember.

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

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

If you use too much Setear

If you think that you have used too much Setear, you may need urgent medical attention.

The most common symptom of overdosing is nausea.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Setear?

Things you should do

Tell your doctor if you have allergies to any other medicines or 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 intend to become pregnant. Your doctor will discuss the possible risks and benefits of using Setear during pregnancy. If you become pregnant while taking Setear, tell your doctor immediately.

Tell your doctor if you are breastfeeding or plan to breast-feed. Your doctor will discuss the possible risks and benefits of using Setear during breastfeeding.

Remind any doctor, dentist or pharmacist you visit that you are using 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.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you should 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Setear affects you.

Your condition or Setear may cause dizziness in some people.

Looking after your medicine

- Keep your tablets in the pack until it is time to take them.
- Keep your tablets in a cool, dry place where the temperature stays below 25°C.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention. See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• skin irritations• stomach upsets• dizziness• fast heart-beat• headache• difficulty sleeping (insomnia)• tiredness• nausea, vomiting, bloating, or swollen stomach• diarrhoea	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• skin reactions• difficulty breathing• convulsions• hallucinations• confusion• allergic reaction• low blood pressure, slow heart beat	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription. Setear tablets contain 24 mg of the active ingredient betahistine dihydrochloride.

What Setear contains

Active ingredient (main ingredient)	betahistine dihydrochloride
Other ingredients (inactive ingredients)	lactose monohydrate maize starch microcrystalline cellulose citric acid povidone crospovidone hydrogenated vegetable oil
Potential allergens	lactose monohydrate

Contains sugars as lactose.

Do not take this medicine if you are allergic to any of these ingredients.

What Setear looks like

Setear tablets are white and flat with beveled edges. They have a breakline on one side. Available in blister packs of 60 tablets. (AUST R 261439)

Who distributes Setear

Southern XP Pty Ltd
Unit 5/118 Church Street
Hawthorn, 3122, Victoria
Australia

Sponsor:

Southern XP IP Pty Ltd
Unit 5/118 Church Street
Hawthorn, 3122, Victoria
Australia

This leaflet was prepared in December 2021.