Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about PERIACTIN. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

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

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

Keep this leaflet with the medicine.

You may need to read it again.

What PERIACTIN is used for

PERIACTIN contains cyproheptadine (as cyproheptadine hydrochloride) as the active ingredient. Cyproheptadine belongs to a group of medicines called antihistamines.

PERIACTIN is used to relieve the symptoms of allergy; such as hayfever, runny nose, sneezing, and itchy and watery eyes.

It also relieves the itchiness associated with some skin problems; such as rash, hives, dermatitis, eczema, mild reactions to insect bites, and chickenpox.

PERIACTIN is also used to treat migraines and other similar headaches in people whose symptoms have not been relieved by other medicines.

Migraine is an intense, throbbing headache, often affecting one side of the head. It often includes nausea, vomiting, sensitivity to light, and sensitivity to sound.

PERIACTIN works by blocking the action of histamine and other substances produced by the body, which are causing your allergy or itchiness.

Ask your doctor if you have any questions about why PERIACTIN has been prescribed for you.

Your doctor may have prescribed it for another

There is no evidence that it is addictive.

Before you take it

When you must not take it

Do not take PERIACTIN if you have ever had an allergic reaction to:

- cyproheptadine
- any of the tablet ingredients listed at the end of this leaflet.

Do not take PERIACTIN to treat an acute attack of asthma.

Do not take PERIACTIN if you have the following medical conditions:

- a type of glaucoma called angle-closure glaucoma
- a narrowing or blockage between the stomach and the small intestine which causes the vomiting of undigested food, such as in some stomach ulcers
- prostate problems
- · difficulty passing urine.

Check with your doctor if you are not sure whether you have any of these conditions.

Do not give PERIACTIN to newborn or premature babies or children under 2 years of age.

The safety and effectiveness in children below the age of 2 years has not been established.

Do not take PERIACTIN if you are breast-feeding or plan to breast-feed.

Like most antihistamine medicines, PERIACTIN is not recommended for use while breast-feeding.

Do not take PERIACTIN if you are being treated for depression with medicines called monoamine oxidase inhibitors (MAOIs).

MAOIs include moclobemide, phenelzine and tranylcypromine.

Do not take PERIACTIN if you are elderly and frail or weak.

Your doctor will advise you if this applies to you.

Do not take it if the packaging is torn or shows signs of tampering or if the expiry date on the pack has passed.

If you take this medicine after the expiry date has passed, it may not work as well.

If you are not sure whether you should start taking PERIACTIN, talk to your doctor.

Before you start to take it

Tell your doctor if you are allergic to any other medicines or any foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially the following:

- · lung problems, such as asthma or bronchitis
- · an overactive thyroid gland
- · raised eye pressure
- heart disease
- · high blood pressure.

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

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

Do not take PERIACTIN if you are breast-feeding or plan to breast-feed.

Like most antihistamine medicines, PERIACTIN is not recommended for use while breast-feeding.

If you have not told your doctor about any of the above, tell them before you take any PERIACTIN.

Taking other medicines

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

Some medicines should not be taken with PERIACTIN. These include antidepressant medicines such as moclobemide, phenelzine, tranylcypromine, fluvoxamine, paroxetine, fluoxetine and venlafaxine.

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

- medicines used to treat anxiety and to help you sleep
- alcohol

These medicines may be affected by PERIACTIN or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

If you take medicines used to treat anxiety or to help you sleep while you are taking PERIACTIN, you are likely to experience greater drowsiness, sleepiness, tiredness or dizziness. These are also likely to occur more quickly.

If you drink alcohol while you are taking PERIACTIN, you are likely to become more drowsy, sleepy, tired or dizzy. These effects are also likely to occur more quickly.

Your doctor or pharmacist has more information on medicines to avoid or be careful with while taking PERIACTIN.

How to take it

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet

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

How much to take

Take PERIACTIN only when prescribed by your doctor.

Your doctor will tell you how many tablets you need to take each day.

For allergies and itching:

• Adults:

the usual starting dose is 1 tablet three times a day. The dose may need to be adjusted depending on your response. **Do not take more than 8 tablets a day.**

Children:

- 2 to 6 years old, the usual starting dose is half a tablet two to three times a day. The dose may need to be adjusted depending on the response to this medicine. If an extra dose is needed, it should be given at bedtime. **Do not give more than 3 tablets a day.**

- 7 to 14 years old, the usual starting dose is 1 tablet three times a day. The dose may need to be adjusted depending on the response to this medicine. If an extra dose is needed, it should be given at bedtime. **Do not give more than 4 tablets a day.**

For migraine and vascular types of headaches:

The recommended dose is 1 tablet initially.
 This can be repeated in half an hour if necessary. Do not take more than 2 tablets in a 4 to 6 hour period.

Relief from migraine usually occurs with 2 tablets and is maintained with one tablet every 4 to 6 hours.

How to take it

Swallow the tablet with a glass of water.

If you forget to take it

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 dose as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

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

If you have trouble remembering to take your tablets, 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) for advice, or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much PERIACTIN. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose include a dry mouth, dilated pupils, flushing and stomach upsets. Other more serious symptoms, especially in infants and children, include hallucinations (seeing, feeling or hearing things that are not there), convulsions, heart attack, and a stop in breathing.

While you are taking it

Things you must do

Tell your doctor if you become pregnant while taking PERIACTIN.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking PERIACTIN.

Things you must not do

Do not drive a car or operate machinery if you feel drowsy, sleepy, tired or dizzy.

As with some other antihistamine medicines, PERIACTIN can cause drowsiness, sleepiness, tiredness or dizziness. If you drink alcohol, these symptoms could be worse.

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

Things to be careful of

Be careful drinking alcohol while taking this medicine.

The effects of alcohol can be increased by some antihistamine medicines, including PERIACTIN.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking PERIACTIN.

PERIACTIN helps most people with allergies and migraine, but it may have unwanted side effects in a few people. 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. If you are over 65 years of age you may have an increased chance of getting side effects.

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

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

- difficulty thinking or working because of:
 - drowsiness, sleepiness, tiredness, sedation
 - dizziness, headache
 - restlessness, nervousness, irritability
 - excitation (particularly in children)
 - buzzing or ringing in the ears
 - confusion
 - inability to sleep
 - aggressive behaviour.
- stomach or bowel problems
 - nausea, vomiting
 - upset stomach
 - increased or loss of appetite, weight gain
 - diarrhoea, constipation.
- changes in your sight or taste such as:
 - blurred vision
 - dry mouth, nose and throat.

- disturbed co-ordination, tremor or shaking
- excessive perspiration or sweating
- · early periods in women.

These are usually mild side effects of PERIACTIN. Drowsiness and sleepiness often disappear after the first three or four days of taking PERIACTIN. If you are over 65 years of age you are more likely to feel dizzy, drowsy and lightheaded.

Tell your doctor immediately if you notice any of the following:

- fast or irregular heart beats, also called palpitations
- skin rash, pinkish, itchy swellings on the skin, also called hives or nettlerash
- jaundice, a yellowing of the skin and/or eyes
- seeing, feeling or hearing things that are not there
- frequent and/or severe infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal, nose bleeds
- signs of anaemia, such as tiredness, being short of breath, looking pale
- passing urine frequently, difficulty passing urine
- · vertigo, a spinning sensation
- · tingling or numbness of the hands or feet.

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

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- · convulsions or fits
- wheezing, chest tightness
- fainting
- swelling of the face, lips, throat and tongue, which may cause difficulty breathing or swallowing.

These are very serious side effects. You may need urgent medical attention. Very serious side effects are rare.

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

Some people may get other side effects while taking PERIACTIN.

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

You may not experience any of them.

After taking it

Storage

Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out the blister pack they may not keep well.

Keep it in a cool dry place where the temperature stays below 30°C. Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

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 the tablets, or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

PERIACTIN tablets are white, scored, round and flat with 'P4' marked on one side.

Available in packs of 100 tablets.

Ingredients

Active ingredient:

Each tablet contains 4 mg of cyproheptadine hydrochloride.

Inactive ingredients:

- starch maize
- · starch pregelatinised maize
- calcium phosphate
- lactose
- · magnesium stearate.

PERIACTIN tablets do not contain gluten, sucrose, tartrazine or any other azo dyes.

Sponsor

Aspen Pharmacare Australia Pty Ltd

34-36 Chandos St

St Leonards NSW 2065

Australia

Australian Register Number:

AUST R 62384

This leaflet was prepared in April 2010.