PERIACTIN®

Active ingredient(s): Cyproheptadine hydrochloride (as sesquihydrate)

Consumer Medicine Information (CMI)

This leaflet provides important information about using PERIACTIN. 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 PERIACTIN.

Where to find information in this leaflet:

- 1. Why am I using PERIACTIN?
- 2. What should I know before I use PERIACTIN?
- 3. What if I am taking other medicines?
- 4. How do I use PERIACTIN?
- 5. What should I know while using PERIACTIN?
- 6. Are there any side effects?
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1. Why am I using PERIACTIN?

PERIACTIN is used to:

- Treat allergies and pruritus
- Relieve migraines and vascular types of headaches.

PERIACTIN belongs to a group of medicines called antihistamines. It works by acting in competition with serotonin and histamine at receptor sites.

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

There is not enough information to recommend the use of this medicine for children under the age of 2 years.

2. What should I know before I use PERIACTIN?

Warnings

Do not use PERIACTIN if:

 you are allergic to cyproheptadine, any of the ingredients listed at the end of this leaflet or any other similar medicines.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor or pharmacist if you:

 have allergies to any other medicines, foods, preservatives or dyes.

- have had any of the following medical conditions:
 - lower respiratory tract symptoms including those of acute asthma
 - o blood dyscrasias
 - o bronchial asthma
 - o hyperthyroidism
 - o cardiovascular disease
 - o hypertension
- 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 or pharmacist if you are pregnant or intend to become pregnant.

Do not breast-feed if you are taking this medicine. The active ingredient in PERIACTIN may pass into breast milk and there is a possibility that your baby may be affected.

Children and infants

Do not give this medicine to a child under the age of 2 years. Safety and effectiveness in children younger than 2 years have not been established.

Do not give this drug to newborn or premature infants. Use in infants has been associated with apnoea, cyanosis, and respiratory difficulty. This drug should not be used in newborn or premature infants.

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 may interfere with PERIACTIN and affect how it works.

- Monoamine oxidase inhibitors used to treat depression such as phenelzine and tranylcypromine.
- Central nervous system depressants used to treat anxiety, panic and sleep disorders such as hypnotics, sedatives, tranquilisers and anti-depressant drugs.

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

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

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4. How do I use PERIACTIN?

How much to take

- Allergies and pruritus
 - Adults: Take 1 tablet, 3 times a day, as required. Do not take more than 8 tablets in 24 hours.
 - Children (7 14 years): Take 1 tablet, 3 times a day as required. Do not take more than 4 tablets in 24 hours.
 - Children (2 6 years): Give half tablet, two to three times a day. Do not give more than 3 tablets in 24 hours
- Migraine and vascular types of headaches
 - Adults: Take 1 tablet initially. If required, take a second tablet after 30 minutes. Do not take more than 2 tablets every 4-6 hours.
- Follow the instructions provided with the medicine.
- Do not exceed the recommended dosage.
- Your doctor may adjust the dose according to your response.

How long to take PERIACTIN

Continue taking your medicine for as long as your doctor tells you.

How to take PERIACTIN

Swallow the tablets whole with a full glass of water.

If you forget to take it

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 use too much PERIACTIN

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

Symptoms of an overdose may vary from central nervous system depression or stimulation to convulsions respiratory and cardiac arrest, and death especially in infants and children. Also, atropine-like signs and symptoms (dry mouth; fixed, dilated pupils; flushing, etc.) as well as gastrointestinal symptoms may occur.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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 PERIACTIN?

Things you should do

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

- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking PERIACTIN as it may affect other medicines used during surgery.
- If you become pregnant while taking this medicine, tell your doctor immediately.
- If you are about to have any blood tests, tell your doctor that you are taking PERIACTIN as it may interfere with the results of some tests.

Things you should not do

- Do not take PERIACTIN to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.

Driving or using machines

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

PERIACTIN may cause dizziness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous. Drowsiness may continue the following day. Children should be careful when riding bicycles or climbing tree.

Drinking alcohol

Tell your doctor or pharmacist if you drink alcohol.

Be careful when drinking alcohol while you are taking this medicine. PERIACTIN may increase the effects of alcohol. Alcohol should be avoided whilst using this medicine.

Looking after your medicine

- Keep your tablets in the pack until it is time to take them.
 If you take the tablets out of the pack, they may not keep well.
- Keep your tablets in a cool dry place where the temperature stays below 30°C. Heat and dampness can destroy some medicines.

Follow the instructions in the carton on how to take care of your medicine properly.

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.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

When to discard your medicine

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

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?

This medicine helps most people with allergies, pruritus, migraines and vascular types of headaches, but it may have unwanted side effects in a few people.

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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.

If you are over 65 years of age you may have an increased chance of getting side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist if you have any further questions.

Common side effects

Common side effects	What to do
 Skin rash, excessive perspiration or photosensitivity Sedation, sleepiness, dizziness, confusion Restlessness, excitement, insomnia, irritability or aggressive behaviour Dryness of nose, mouth and throat Nausea, vomiting, diarrhoea or constipation 	Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
urinary retention issuesjaundiceblurred vision	Tell your doctor as soon as possible if you notice any of these serious side effects.

Very Serious side effects

Very serious side effects	What to do
 anaphylactic shock convulsions hallucinations issues breathing increased or unusual heartrate, such as palpitations 	Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of these very serious side effects.

Drowsiness and somnolence symptoms are usually mild and short-lived. Many patients do not experience these symptoms after the first three - four days of continuous administration.

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/

<u>reporting-problems</u> By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is available over-the-counter without a doctor's prescription.

What PERIACTIN contains

Active ingredient (main ingredient)	4 mg of cyproheptadine hydrochloride
Other ingredients	maize starch
(inactive	pregelatinised maize starch
ingredients)	calcium hydrogen phosphate dihydrate
	lactose monohydrate
	magnesium stearate
Potential allergens	lactose

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

What PERIACTIN looks like

PERIACTIN is a white, flat circular bevel edged tablet. Marked 'P4' on one side, scored on the other. (AUST R 62384).

Who distributes PERIACTIN

Viatris Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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