

PACKAGE LEAFLET: INFORMATION FOR THE USER

PERIACTIN® 4MG TABLETS

(Cyproheptadine Hydrochloride)

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to take Periactin carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Periactin is and what it is used for
2. Before you take Periactin
3. How to take Periactin
4. Possible side effects
5. How to store Periactin
6. Further Information

1. What Periactin is and what it is used for

Periactin contains a medicine called cyproheptadine. This belongs to a group of medicines called 'antihistamines'. In some illnesses too much 'histamine' and 'serotonin' are produced in the body. These occur naturally in your body. Periactin helps in these illnesses by stopping the unwanted effects of histamine and serotonin.

Periactin is used for:

- skin allergies with itchiness, swelling, or red skin, eczema or nettle rash
- itchiness of chicken pox and reactions to insect bites and stings
- sneezing, watery eyes and blocked or runny nose caused by an allergy (allergic rhinitis)
- conjunctivitis caused by an allergy- with red, watery, inflamed eyes
- migraine and other similar headaches.

2. Before you take Periactin

Do not take Periactin if:

- you are allergic (hypersensitive) to cyproheptadine or any of the other ingredients of Periactin (listed in section 6 below)
- you are taking a type of medicine called a monoamine oxidase inhibitor (MAOI) for depression, such as meclobemide, phenelzine, tranylcypamine, linezolid or pargyline.
- you have a narrowing of the opening from the stomach ('stricture')
- you have an eye problem called 'glaucoma'
- you are being treated for an asthmatic attack
- you are elderly and not very mobile
- you have problems passing urine
- you have a stomach ulcer.

Do not take Periactin if any of the above apply to you. If you are not sure talk to your doctor or pharmacist before taking Periactin .

Take special care with Periactin

Check with your doctor before taking your medicine if:

- you have ever been told that you have high pressure inside your eye (high intra-ocular pressure)
- you have an over-active thyroid gland
- you have high blood pressure
- you have heart problems
- you have asthma.

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

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This includes herbal medicines. This is because Periactin can affect the way some other medicines work.

Also some medicines can affect the way Periactin works.

Do not take Periactin if you are taking a type of medicine called a 'monoamine oxidase inhibitor' (MAO inhibitor) such as meclobemide, phenelzine, tranylcypamine, linezolid or pargyline.

Also, it is important to tell your doctor or pharmacist if you take:

- sleeping pills - such as temazepam, nitrazepam, zopiclone, zaleplon or zolpidem
- medicines for worry or anxiety - such as diazepam, alprazolam, chlordiazepoxide, clorazepate
- medicines for depression- such as fluoxetine, paroxetine, amitriptyline or imipramine
- any medicines that make you sleepy - such as sedatives or tranquillisers.

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

Taking Periactin with food and drink

Do not drink alcohol while you are taking Periactin. This is because Periactin can make you sleepy and drinking alcohol at the same time can make you even more sleepy.

Pregnancy and breast-feeding

Do not take Periactin if you are or think you may be pregnant. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Do not drive or use any tools or machines while taking this medicine. This is because Periactin can make you sleepy.

Important information about some of the ingredients of Periactin

Periactin contains lactose, which is a type of sugar. If you have been told by your doctor that you can not tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before taking this medicine.

3. How to take Periactin

If this medicine is from your doctor or pharmacist, do exactly as they have told you. Otherwise follow the instructions below.

Taking this medicine

- Take this medicine by mouth.
- If you do not understand the instructions, or you are not sure, ask your doctor or pharmacist.

The usual doses of Periactin are

For allergies

Adults and children over 14 years

- Start with 1 tablet three times a day.
- Most patients need 3-4 tablets a day.
- Do not take more than 8 tablets a day.

Children aged 7-14 years

- The usual dose is 1 tablet two or three times a day as needed.
- If you need to give an extra dose, give it at bedtime.
- Do not give more than 4 tablets a day.

Children aged 2-6 years

- The usual dose is half a tablet two or three times a day.
- If you need to give an extra dose, give it at bedtime.
- Do not give more than 3 tablets a day.

For migraine

- Take 1 tablet when you are getting the migraine
- Take another one, if needed, after 30 minutes.
- Then take 1 tablet every 4-6 hours to maintain relief.
- Do not take more than 2 tablets in any 4-6 hour period.

Children under 2 years

- Do not give Periactin to children under 2 years of age.

If you take more Periactin than you should

If you take too much Periactin by mistake, contact your doctor immediately or seek medical help as soon as possible.

If you forget to take Periactin

- If you forget to take a tablet, skip the missed dose.
- Take the next dose as usual.
- Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Periactin can cause side effects, although not everybody gets them.

Stop taking Periactin and tell your doctor straight away, if you notice any of the following serious side effects- you may need urgent medical treatment:

- allergic skin rash and hives
- severe allergic reaction which causes difficulty in breathing or dizziness

Other side effects include:

Heart and circulation

- increased heart rate
- low blood pressure
- palpitations
- feeling like you have a missed heart beat

Blood

- nosebleeds

Nervous system

- feeling sleepy, dizzy, problems with co-ordination, or feeling tired
- feeling confused, restless, over excited, nervous, irritable or trembling
- being unable to sleep, pins and needles or feeling numb
- inflammation of your nerves - signs include being more sensitive to pain and feeling that you can not move (paralysis), fits (convulsions)
- feeling aggressive
- seeing, hearing, or feeling something that is not there (hallucinations)
- feeling faint
- headache
- an exaggerated feeling of well being (euphoria)
- being very upset (hysteria)
- anti-histamine medicines such as this medicine can sometimes make young children over excited

Eyes or ears

- Inflammation inside the ear, ringing in the ears
- blurred or double vision
- vertigo

Chest

- dry throat and nose
- presence of phlegm
- blocked nose
- feeling wheezy
- tight chest

Stomach and gut

- dry mouth
- stomach ache, loss of appetite
- feeling sick (nausea), being sick (vomiting)
- increase in your appetite and weight gain
- diarrhoea or constipation

Urinary

- passing urine more often
- difficulty passing urine
- being unable to empty your bladder of urine

Skin and hair

- your skin being sensitive to sunlight
- you may sweat more than usual
- severe shivering
- swelling of your skin

Liver

- liver problems, including jaundice, hepatitis and hepatic failure - signs include yellowing of your skin and eyes, sometimes with a fever, pale stools and dark urine

Sexual

- menstrual problems

If any of the side effects get serious, or if you notice any side effects 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme (Tel: Freephone 0800 100 3352 or Website: www.mhra.gov.uk/yellowcard).

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Periactin

Keep out of the reach and sight of children.

Do not store above 25°C. Store in the original package in order to protect from light.

Do not transfer your medicines into another box or container - they might get mixed up.

Do not use Periactin after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further Information

What Periactin contains

Active ingredient:

The active substance is cyproheptadine hydrochloride. Each Periactin contains 4 mg anhydrous cyproheptadine hydrochloride.

Other ingredients:

The other ingredients are calcium hydrogen phosphate E341, lactose, magnesium stearate E572, potato starch, pregelatinised maize starch.

What Periactin looks like and contents of the pack

Periactin tablets are white round bevel-edged tablets marked 'MSD 62' on one side with a single scoreline on the other.

Periactin are supplied in blister packs of 30 tablets.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation is held by Auden Mckenzie (Pharma Division) Ltd, Mckenzie House, Bury Street, Ruislip, Middlesex, HA4 7TL, UK.

Periactin tablets are made by Tiofarma BV, Benjamin Franklinstraat 7-9, 3261 LW Oud-Beijerland, Netherlands.

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