

Periactin®

4 mg tablets
Cyproheptadine hydrochloride

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

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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 of 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 applies 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 applies 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 other medicines can affect the way Periactin® works.

Do not take Periactin® if you are taking a type of medicine called a 'monoamine oxidase inhibitor' (MAOI) 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 medicine that makes you sleepy - such as sedatives or tranquilizers.

If you are not sure if any of the above applies 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.

Do not take Periactin® if you are a nursing mother.

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 cannot tolerate or digest some sugars (have intolerance to some sugars), talk to your doctor before taking this medicine.

3. HOW TO TAKE PERIACTIN®

- Always take Periactin® exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

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.

Method of administration

- Take this medicine by mouth.

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
 - feeling like you have a missed heart beat
 - increased heart rate
 - low blood pressure
 - palpitations.
- Blood
 - nosebleeds.
- Nervous system
 - feeling sleepy is the most common side effect (in many patients it wears off after 3 to 4 days of treatment)
 - inflammation of your nerves - signs include being more sensitive to pain and feeling that you cannot move (paralysis), fits (convulsions)
 - an exaggerated feeling of wellbeing (euphoria), feeling restless, over excited, nervous, irritable, aggressive or trembling
 - feeling sleepy, dizzy, confused, problems with coordination or feeling tired
 - being unable to sleep, pins and needles or feeling numb
 - seeing, hearing, or feeling something that is not there (hallucinations), being very upset (hysteria), and feel-

ing faint

- headache
- 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
- 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.

- 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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE PERIACTIN®

Keep out of reach and sight of children.

Do not store above 30°C.

Store in the original package.

Do not use Periactin® tablets after the expiry date stated on the carton and the blisters. The expiry date refers to the last day of that month.

6. FURTHER INFORMATION

What Periactin® contains

Active ingredient:

Periactin® tablet contains 4 mg of anhydrous cyproheptadine hydrochloride.

Other ingredients:

Dibasic calcium phosphate dihydrate; lactose hydrous; corn starch and magnesium stearate.

What Periactin® looks like and contents of the pack

Periactin® are white flat round tablets, with bevelled edges, one side scored, the other engraved "ALG P4". Periactin® is available in packs of 20 tablets.

For more information about this medicinal product, please contact:

Algorithm SAL

Tel: +961-9-222050

To report any side effect:

Lebanon and all MENA countries

Algorithm SAL

Fax: +961-9-222141

Email: pharmacovigilance@blgx.net

Website: www.algorithm-lb.com

Also contact the relevant competent authority.

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.

- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold you the medicament.

- The doctor and the pharmacist are experts in medicine, its benefits and risks.

- Do not by yourself interrupt the period of treatment prescribed.

- Do not repeat the same prescription without consulting your doctor.

Manufactured by

ALGORITHM S.A.L. Zouk Mosbeh, Lebanon.

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