1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

ACTINCYPRO 4 mg tablets

Cyproheptadine hydrochloride

Contains sugar: Lactose monohydrate 128,57 mg

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

ACTINCYPRO is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use ACTINCYPRO carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ACTINCYPRO with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

1. What ACTINCYPRO is and what it is used for
2. What you need to know before you take ACTINCYPRO
3. How to take ACTINCYPRO
4. Possible side effects
5. How to store ACTINCYPRO
6. Contents of the pack and other information

1. What ACTINCYPRO is and what it is used for

ACTINCYPRO belongs to a group of antihistamine medicines and is recommended for the symptomatic treatment of allergies and itchy skin conditions.

It is used in the symptomatic treatment of seasonal and chronic rhinitis (when a reaction occurs that causes nasal congestion, runny nose, sneezing and itching).

ACTINCYPRO is used for the symptomatic relief of itching of the skin as experienced in conditions such as but not limited to dermatitis, eczema and hives or wheals caused.

2. What you need to know before you take ACTINCYPRO

Do not take ACTINCYPRO:

- if you are hypersensitive (allergic) to cyproheptadine hydrochloride or any of the other ingredients of ACTINCYPRO (listed in section 6).
- if you are receiving monoamine oxidase inhibitor therapy, medicines used to treat depression.
- if you suffer from closed angle glaucoma, a condition where the pressure inside your eye becomes too high.
- if you suffer from obstruction in the stomach caused by a peptic ulcer (stenosing peptic ulcer).
- if you have symptoms of an enlarged prostate, or bladder neck obstruction for example decrease in urine flow, urinary frequency, excessive urination at night (symptomatic prostatic hypertrophy).
- if you suffer from an obstruction between the stomach and the small intestine (pyloroduodenal obstruction).
- if you are elderly and frail or weak.
- ACTINCYPRO should not be used for therapy of an acute asthmatic attack.
- ACTINCYPRO should not be used in newborn or premature infants and children younger than 2 years.

- if you are breastfeeding your baby.

Warnings and precautions

Take special care with ACTINCYPRO:

- ACTINCYPRO may lead to drowsiness and impaired concentration that may be aggravated by the simultaneous intake of alcohol or other central nervous system depressants. You should take care, particularly at the start of therapy when taking charge of vehicles or machinery or performing potentially hazardous tasks where loss of concentration could lead to accidents.
- if you suffer from acute asthma attacks or have a history of bronchial asthma. ACTINCYPRO should not be used to treat respiratory tract symptoms,
- if you use antihistamines such as ACTINCYPRO for prolonged periods it may cause blood disorders (blood dyscrasias),
- if you suffer from an overactive thyroid (hyperthyroidism),
- if you suffer from heart disease,
- if you suffer from high blood pressure (hypertension).
- if you are elderly, ACTINCYPRO is more likely to cause dizziness, sedation and low blood pressure (hypotension).
- if you suffer from increased intraocular pressure (ocular hypertension).

Children

There is no experience with ACTINCYPRO in children younger than 2 years.

Other medicines and ACTINCYPRO

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following:

- if you are taking Monoamine oxidase inhibitors (MAOIs) such as phenelzine, selegilline, tranylcypromin, medicines used to treat depression (see Do not take ACTINCYPRO). These medicines may intensify certain side effects of ACTINCYPRO.
- ACTINCYPRO may have additive effects with alcohol and other Central Nervous System (CNS) depressants, for example sleeping tablets, sedatives, anti-anxiety medicines and anti-depressants which may cause an increase in drowsiness.
- if you are taking selective serotonin reuptake inhibitors (SSRIs) medication used to treat depression (e.g. citalopram, fluoxetine, paroxetine), as ACTINCYPRO may interfere with the way your anti-depressant works.
- ACTINCYPRO may cause a false positive test result for tricyclic anti-depressant medicines when evaluating a urine drug screen.

Pregnancy, breastfeeding and fertility

You should not take ACTINCYPRO if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking ACTINCYPRO.

Driving and using machines

ACTINCYPRO may lead to drowsiness and impaired concentration, which may be aggravated by simultaneous intake of alcohol or other CNS depressant medicines which may influence your ability to drive and operate machinery. You should not drive, use machinery or perform any tasks that require concentration until you are certain that ACTINCYPRO does not adversely affect your ability to do so safely (see section 4).

It is not always possible to predict to what extent ACTINCYPRO may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which ACTINCYPRO affects you (see section 4).

ACTINCYPRO contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take ACTINCYPRO

Do not share medicines prescribed for you with any other person.

Always take ACTINCYPRO exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The usual dose of ACTINCYPRO is:

Adults and children over 14 years:

The dosage will range from 4 mg (one tablet) to 20 mg (five tablets) a day, the majority of patients requiring 12 mg (three tablets) to 16 mg (four tablets) a day.

Your healthcare provider will most likely start your dosage 4 mg (one tablet) three times a day and adjust the dosage accordingly.

Children 7 to 14 years:

The usual dose is 1 tablet two or three times a day. This dosage may need to be adjusted according to the size and response of the patient. If an additional dose is needed it should be given at bedtime. Do not give more than 4 tablets (16 mg) a day.

Children 2 to 6 years:

The usual dose is half a tablet (2 mg) two or three times a day. Any additional dose should be given at bedtime. Do not give more than 2 tablets (4 mg) a day.

If you take more ACTINCYPRO than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Symptoms of overdose may include seeing things that are not really there (hallucinations), central nervous system depression (when the body's normal neurological functions slow down), interruptions in the normal connections between nerve cells in the brain, (stimulation to convulsions), unable to breath (respiratory arrest) and sudden stopping of your heartbeat (cardiac arrest) and death, especially in infants and children. Atropine-like signs and symptoms include dry mouth, fixed dilated pupils, flushing as well as gastrointestinal symptoms may occur.

If you forget to take ACTINCYPRO

Do not take a double dose to make up for forgotten individual doses.

If you have missed a dose of ACTINCYPRO, take the dose that you have missed as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. If you have forgotten to take several doses, contact your doctor without delay.

4. Possible side effects

ACTINCYPRO can have side effects.

Not all side effects reported for ACTINCYPRO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ACTINCYPRO, please consult your healthcare provider for advice.

If any of the following happens, stop taking ACTINCYPRO and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to ACTINCYPRO. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- A condition that occurs when there is an extremely low number of granulocytes in your blood (a type of white blood cell, agranulocytosis, leukopenia).
  This may cause an increase in infections.
- A sudden, violent, irregular movement of the body, caused by involuntary contraction of muscles (convulsions).
- yellow pigmentation of skin and eyes, yellowing of the skin or whites of the eyes caused by liver or blood problems (jaundice).

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

Tell your doctor if you notice any of the following:

Side effects with an unknown frequency:

- Inflammation of the inner ear (acute labyrinthitis),
- a disorder where red blood cells are destroyed faster than they can be made (haemolytic anaemia), deficiency of platelets in the blood which causes bleeding into the tissues, bruising and slow blood clotting after injury (thrombocytopenia),
- early menstruation,
- anorexia, increased appetite,
- weight gain,
- confusion, seeing or hearing things that are not really there (hallucinations),
- restlessness, inability to sleep (insomnia),
- irritability, nervousness, excitation, aggressive behaviour,
- unrealistic feeling of well-being (euphoria),
- emotional behaviour that seems excessive and out of control (hysteria),
- dizziness, headache, sedation, sleepiness (often transient),
- unintentional muscle movement involving to-and-fro movements of one or more parts of the body,
  shaking or quivering (tremor), disturbed coordination, feeling that you are about to become unconscious (faintness), pins-and-needles (paraesthesias),
- an inflammatory or degenerative lesion of a nerve marked by pain, sensory disturbances and impaired or lost reflexes (neuritis),
- sensation of feeling off balance (vertigo),
- blurred vision, seeing double (diplopia),
- ringing in the ear (tinnitus),
- increased heartbeat (tachycardia, palpitation), abnormal heartbeat (extrasystoles),
- low blood pressure (hypotension),

- nasal stuffiness, wheezing, thickening of bronchial secretions, nosebleed (epistaxis),
- dryness of the mouth, inability to pass stool (constipation), pain or discomfort in the upper abdomen (epigastric distress), nausea, vomiting, loose watery stool (diarrhoea),
- condition in which the flow of bile from the liver stops or slows (cholestasis), liver failure (hepatic failure), inflammation of the liver (hepatitis), abnormal liver function (hepatic function abnormality),
- condition where the skin becomes very sensitive to sunlight (photosensitivity), excessive sweating (perspiration),
- frequency of urinating (micturition), difficulty urinating, urinary retention,
- fatigue, dryness of nose and throat, tightness of chest.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to **SAHPRA** via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ACTINCYPRO.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

5. How to store ACTINCYPRO

Store all medicines out of reach of children.

Store at or below 25 °C.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ACTINCYPRO contains

The active substance is 4 mg of cyproheptadine hydrochloride.

The other ingredients are calcium hydrogen phosphate anhydrous, lactose monohydrate, magnesium stearate, maize starch and pregelatinised maize starch.

Contains sugar: Lactose monohydrate 128,57 mg

What ACTINCYPRO looks like and contents of the pack

ACTINCYPRO is a round, white to off-white, flat, bevelled edge bisected tablet, debossed with "F" in upper half and "43" on lower half on one side and plain on other side.

The tablet can be divided into equal halves.

10 tablets are packed in PVC/PVdC/aluminium foil blister strips. 30 tablets are packed into an outer cardboard carton.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912

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Registration number

57/5.7.1/0019

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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