PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

ZYACTIN 4 mg tablets

Cyproheptadine (as hydrochloride)

Contains sugar (40 mg lactose monohydrate per tablet).

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- ZYACTIN has been prescribed for you or your child personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What ZYACTIN is and what it is used for

ZYACTIN contains cyproheptadine which belongs to a group of medicines known as sedating antihistamines. It is used to relieve allergies, such as hay fever and some allergic skin conditions.

2. What you need to know before you take ZYACTIN

Do not take or give ZYACTIN

- If you or your child is hypersensitive (allergic) to cyproheptadine or any of the other ingredients of ZYACTIN (see **What ZYACTIN contains**).

- If you or your child has a condition which causes increased pressure in your eyes, such as glaucoma.
- If you have prostate problems, or if you have been experiencing any difficulty passing urine.
- If you or your child is taking medicines called monoamine oxidase inhibitors (MAOIs).
- If you know you or your child has a stomach ulcer or a blockage in your small intestines.
- If you are an elderly adult or very weak.
- If you are a nursing mother.

Warnings and precautions

Take special care with ZYACTIN:

- If you or your child experiences dizziness, drowsiness or low blood pressure. This can be because of ZYACTIN treatment.
- If you or your child suffers from asthma, an underactive thyroid, high blood pressure, heart disease or respiratory disease.

If you or your child is scheduled for blood or urine testing, ask your doctor if you should stop taking or giving ZYACTIN for several days before testing. ZYACTIN may affect your test results.

ZYACTIN is not meant to treat acute asthma attacks. If an attack occurs, follow the instructions your doctor has given you. Always have your inhaled rescue medicine for asthma attacks with you.

Children

ZYACTIN should not be given to children under 2 years of age, as the safety and efficacy have not been established.

Other medicines and ZYACTIN

Always tell your health care provider if you or your child is taking any other medicine. (This includes all complementary or traditional medicines.)

It is especially important to tell your doctor or pharmacist if you or your child is taking the following medicines:

- Hypnotics, sedatives, tranquillisers (used to treat sleeping disorders or anxiety).
- Antidepressants (used to treat depression).

ZYACTIN with food, drink and alcohol

Do not take ZYACTIN with alcohol, as the simultaneous intake of alcohol may make you feel drowsier or cause additional reductions in alertness and impairment of performance.

Pregnancy, breastfeeding and fertility

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 health care provider for advice before taking ZYACTIN.

The safety of ZYACTIN during pregnancy has not been established.

Do not take ZYACTIN if you are breastfeeding.

Driving and using machines

ZYACTIN can cause side effects, such as drowsiness and impaired concentration. Do not drive a vehicle, operate machinery, or do anything else that requires your attention if you have taken ZYACTIN.

ZYACTIN contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, consult your doctor before taking ZYACTIN.

3. How to take ZYACTIN

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

Always take or give ZYACTIN exactly as described in this leaflet or as your doctor or pharmacist

has told you. Check with your doctor or pharmacist if you are not sure.

Adults:

The usual dose is 12 mg (3 tablets) to 16 mg (4 tablets) daily. The recommended starting dose is 4 mg (1 tablet) taken three times a day.

Do not take more than 20 mg (5 tablets) per day.

Children (7 to 14 years):

The usual dose is 4 mg (1 tablet) 2 or 3 times a day. If an additional dose needs to be taken, it should preferably be taken at bedtime. Do not give more than 16 mg (4 tablets) per day to your child.

Children (2 to 6 years):

The usual dose is 2 mg (½ tablet) 2 or 3 times a day. If an additional dose needs to be taken, it should preferably be taken at bedtime. Do not give more than 8 mg (2 tablets) per day to your child.

You can take ZYACTIN with or without food.

If you have the impression that the effect of ZYACTIN is too strong or too weak, tell your doctor or pharmacist.

If you take more ZYACTIN than you should

In the event of an overdosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison centre. Take this leaflet and the remaining ZYACTIN with you so the doctor will know what you or your child has taken.

If you forget to take ZYACTIN

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

4. Possible side effects

ZYACTIN can have side effects.

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

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

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you or your child has them, you may have had a serious allergic reaction to ZYACTIN. 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:

- frequent infections such as fever, severe chills, sore throat or mouth ulcers;
- bleeding or bruising more easily than normal;
- fits (seizures);
- changes in the way your heart beats (faster, slower or irregular);
- anaphylactic shock (a serious allergic response that can involve swelling, hives, rash and slow pulse);
- yellowing of your skin and eyes, dark urine and tiredness which may be symptoms of liver problems;
- painful or difficult urination, inability to completely empty your bladder, urinary frequency.

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

Tell your doctor if you notice any of the following:

Frequent side effects

- sleepiness or drowsiness (the drowsiness side effect might get less after 3 to 4 days of use).

Less frequent side effects

- feeling sedated, restless or confused;
- feeling excited, exaggerated or uncontrollable emotion
- nervousness, irritability, aggressive behaviour;
- anaemia (fatigue, loss of energy, pale skin, cramps in your legs, difficulty with concentration);
- increased appetite or weight gain;
- headaches or dizziness;
- coordination problems;
- tremors (involuntary trembling or shaking of hands and feet);
- tingling or numbness of your hands and feet (pins and needles);
- difficulty falling or staying asleep;
- unrealistic feeling of well-being;
- seeing or hearing things that do not exist (hallucinations);
- vertigo (sensation of spinning or swaying);
- blurred vision or double vision;
- ringing in your ears (tinnitus);
- sensation of rotation or movement;
- low blood pressure;
- coughing up thick mucus, chest tightness or wheezing;
- blocked nose, nose bleeds;
- dry mouth, nose or throat, upper abdominal pain or discomfort, nausea (feeling sick), vomiting (being sick), diarrhoea, constipation;
- loss of appetite (anorexia);
- abnormal liver function;

- increased sensitivity of your skin to the sun;
- urticaria (swelling, redness and itchiness of the skin);
- increased sweating;
- early start of a women's period;
- feeling tired;
- sudden feeling of coldness with shivering (chills) accompanied by a rise in your body temperature (rigors).

Frequency unknown side effects

- diminished mental alertness, confusion;
- hallucinations (seeing or hearing things that are not real);
- restlessness;
- excitation;
- aggressive behaviour;
- euphoria (a feeling of intense excitement and happiness).

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 or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8

By reporting side effects, you can help provide more information on the safety of ZYACTIN.

5. How to store ZYACTIN

- Store at or below 25 °C.
- Keep the blister strips in the outer carton until required for use.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the blister strip or carton.

- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ZYACTIN contains

Each tablet contains 4 mg cyproheptadine (as hydrochloride).

The other ingredients are lactose monohydrate, magnesium stearate (E572), microcrystalline cellulose (E460(i)) and sodium starch glycolate.

What ZYACTIN looks like and contents of the pack

White to off-white, round, flat faced, bevelled edge tablets, bisected on one side and debossed with "11 10" on the other side.

Aluminium/aluminium blister strips of 10 tablets packed in an outer carton containing 30 tablets.

Holder of certificate of registration

Zydus Healthcare SA (Pty) Ltd

Southdowns Office Park

Building B, Ground Floor

22 Karee Street

Centurion, Pretoria

0157

Tel: 012 748 6400

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