

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S1

ZYNCET film coated tablets

Cetirizine hydrochloride.

Contains sugar: Each film coated tablet contains 65,3 mg lactose monohydrate.

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

ZYNCET is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use ZYNCET carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ZYNCET with any other person.
- Ask your health care 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 ZYNCET is and what it is used for.
2. What you need to know before you take ZYNCET.
3. How to take ZYNCET.
4. Possible side effects.
5. How to store ZYNCET.
6. Contents of the pack and other information.

1. What ZYNCET is and what it is used for

ZYNCET contains cetirizine hydrochloride which belongs to a group of medicines called antihistamines. ZYNCET helps to relieve the symptoms of some allergies such as hay fever or skin allergies such as rash or itching.

2. What you need to know before you take ZYNCET

Do not take ZYNCET:

- If you are hypersensitive (allergic) to cetirizine hydrochloride, hydroxyzine, piperazine (used to treat allergic conditions), or any of the other ingredients of ZYNCET (see section 6).
- If you suffer from severe kidney problems.
- If you have asthma and you have previously experienced side effects to antihistamines.
- If you are pregnant or breastfeeding (see Pregnancy, breastfeeding and fertility).
- Safety and efficacy have not been established in children under the age of 2 years.

Warnings and precautions

Take special care with ZYNCET:

- ZYNCET is a non-sedating medicine, however some patients may become drowsy after taking ZYNCET (see Driving and using machines).
- If you suffer from any condition that may cause difficulty in emptying your bladder (urinary retention), including spinal cord lesions or an enlarged prostate if you are a male.
- If you suffer from epilepsy, or you are at risk of convulsions (fits).
- If you are scheduled for an allergy test, you must stop taking ZYNCET at least 3 days before testing, since it may affect your allergy test results.
- If you have porphyria (a disorder that can cause nerve or skin problems).

Children and adolescents

Children under the age of two years should not be given ZYNCET as safety and efficacy have not been established.

ZYNCET is not recommended in children under the age of 6 years as the formulation does not allow for proper dose adaptation. A paediatric formulation of cetirizine is recommended.

Other medicines and ZYNCET

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

The following medicines may cause an interaction when used in combination with ZYNCET:

- Alcohol.

- Sedating medicines (such as tranquillisers).

ZYNCET with food, drink and alcohol

The use of alcohol is not recommended with ZYNCET.

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 ZYNCET.

Do not use ZYNCET if you are pregnant or breastfeeding your baby.

ZYNCET is excreted into breast milk.

Driving and using machines

ZYNCET may cause side effects such as drowsiness and may impair your ability to drive a vehicle and use machinery. Do not drive a vehicle, operate machinery, or do anything else that require your attention until you know how ZYNCET affects you.

ZYNCET contains lactose monohydrate

ZYNCET contains lactose monohydrate, which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars (cannot digest some sugars), contact your doctor before taking ZYNCET.

3. How to take ZYNCET

Always take ZYNCET exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Adults or children 12 years of age or older:

The usual dose is one 10 mg tablet daily.

Children 6 to 12 years of age:

The usual dose is one 10 mg tablet daily, or half a tablet (5 mg) twice daily.

If you have a liver or kidney disorder you should take half a tablet (5 mg).

ZYNCET can be taken with or without food.

Do not exceed the recommended dosage. Always take ZYNCET exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

If you have the impression that the effect of ZYNCET is too strong or too weak, talk to your doctor or pharmacist.

If you take more ZYNCET than you should

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

Take this leaflet and the rest of the remaining tablets with you so the doctor will know what you have taken.

If you forget to take ZYNCET

If you have missed your dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take ZYNCET at the next regularly scheduled time.

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

4. Possible side effects

ZYNCET can have side effects.

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

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

- Swelling of your hands, feet, ankles, face, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash, hives or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ZYNCET. 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:

- Unexplained bruising or bleeding, causing pinpoint bleeds on your skin or nosebleeds.
- Signs of recurrent infections, such as fever or sore throat.
- Thoughts of harming or killing yourself (suicidal ideation).
- Convulsions (fits).
- Changes in the way your heart beats, such as beating faster than normal or skipping beats.
- Yellowing of your skin and eyes, also called jaundice or hepatitis. Changes in liver function test results.
- Severe pustular skin rash (acute generalised exanthematous pustulosis (AGEP)).
- Painful urination, involuntary urination, inability to empty your bladder completely.

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

Tell your doctor as soon as possible if you notice any of the following:

Side effects occurring frequently:

- Sore throat, runny nose.

Side effects occurring less frequently:

- Haemolytic anaemia (pale skin, tiredness, fever, weakness, dizziness, confusion).
- Drowsiness.
- Feeling depressed, confused, agitated or aggressive.
- Hallucinations (seeing or hearing things that are not real).

- Insomnia (difficulty sleeping).
- Tics.
- Problems with your eyesight, including blurred vision, difficulty focussing, involuntary eye movements.
- Ringing in your ears.
- Vertigo (unbalanced, spinning feeling in your head).
- Low blood pressure.
- Thick mucous (phlegm).
- Wheezing sound when breathing and coughing (bronchospasm).
- Nausea or stomach discomfort.
- Increased appetite.
- Dry mouth.
- Constipation or diarrhoea.
- Fixed drug eruption (red patches on your skin, itching, fever).
- Sensitivity to light.
- Loss of hair.
- Increased sweating.
- Muscle pain.
- Tiredness, general feeling of discomfort or weakness.
- Water retention (swelling of your hands, feet, arms or legs).
- Increased weight.

The following side effects may occur, but the frequency is not known:

- Dizziness or headache.
- Feeling anxious or nervous.
- Nightmares (bad dreams).
- Paraesthesia (tingling, pins and needles or burning sensation of your skin).
- Movement disorders, uncontrolled shaking (tremor), involuntary muscle contractions or movements.

- Changes in your taste perception.
- Loss of memory or memory impairment.
- Joint pain.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA's website. By reporting side effects, you can help provide more information on the safety of ZYNCET.

5. How to store ZYNCET

- Store at or below 25 °C.
- Store in a cool dry place.
- Protect from light.
- Do not remove from outer carton until required for use.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Do not use after the expiry date printed on the label 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 ZYNCET contains

The active ingredient is 10 mg cetirizine hydrochloride.

The other ingredients are Eudragit E-100, lactose monohydrate, macrogol, magnesium stearate, maize starch, povidone, talcum and titanium dioxide.

What ZYNCET looks like and contents of the pack

Oblong, biconvex, white, film coated tablet with score on one side.

PVC/aluminium foil blister strips containing 10 tablets per strip. Each carton contains 10 or 30 tablets.

Holder of certificate of registration

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