ZYNOR 10 mg FILM-COATED TABLETS

Cetirizine dihydrochloride

PACKAGE LEAFLET:
INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

WHAT IS IN THIS LEAFLET

1 WHAT ZYNOR IS AND WHAT IT IS USED FOR

Cetirizine dihydrochloride is the active ingredient of Zynor. Zynor is an antiallergic medication.

In adults and children aged 6 year and above, Zynor is indicated

- for the relief of nasal and ocular symptoms of seasonal and perennial allergic rhinitis.
- for the relief of urticaria.

You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

2 WHAT YOU NEED TO KNOW BEFORE YOU TAKE ZYNOR

Do NOT take Zynor

- if you are allergic (hypersensitive) to the active substance of Zynor or any of the other ingredients of Zynor (listed in section 6), to hydroxyzine or to piperazine derivatives (closely related active substances of other medicines).
- if you have a severe kidney disease (severe renal failure with creatinine clearance below 10 ml/min).

Warnings and precautions
If you are a patient with renal insufficiency, please ask your doctor for advice; if necessary, you will take a lower dose. The new dose will be determined by your doctor.

If you have problems passing urine (like spinal cord problems or prostate or bladder problems), please ask your doctor for advice.

If you are an epileptic patient or a patient at risk of convulsions, you should ask your doctor for advice.

If you are going to have an allergy skin test, please tell your doctor that you currently take Zynor. Usually you will need to stop taking any medicines for a period of 3 days before the allergy skin test.

No clinically significant interactions have been observed between alcohol (at the blood level of 0.5 per mille (g/l) corresponding to one glass of wine) and cetirizine used at the recommended doses. However, there are no data available on the safety when higher doses of cetirizine and alcohol are taken together. Therefore, as it is the case with all antihistamines, it is recommended to avoid taking Zynor with alcohol.

Other medicines and Zynor
Tell your doctor or pharmacist if you are taking, or have recently taken or might take any other medicines.

Due to the profile of cetirizine, no interactions with other drugs are expected

Taking Zynor with food
Food does not affect noticeably the absorption of cetirizine.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

As with other drugs, use of Zynor should be avoided in pregnant women. Accidental use of the drug by a pregnant woman should not produce any harmful effects on the foetus. Nevertheless, the administration of the medicine should be discontinued.

You should not take Zynor during breast feeding because cetirizine passes into breast milk.

Driving and using machines
Clinical studies have produced no evidence of impaired attention, alertness and driving capabilities after taking Zynor at the recommended dose.

If you are intending to drive, engage in potentially hazardous activities or operate machinery, you should not exceed the recommended dose. You should closely observe your response to the drug.

If you are a sensitive patient, you may find that the simultaneous use of alcohol or other nervous depressant agents may additionally affect your attention and ability to react.

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

3 HOW TO TAKE ZYNOR

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How and when should you take Zynor?
These guidelines apply unless your doctor has given you different instructions on how to use Zynor. Please follow these instructions; otherwise Zynor may not be fully effective.

Tablets need to be swallowed with a glass of liquid.

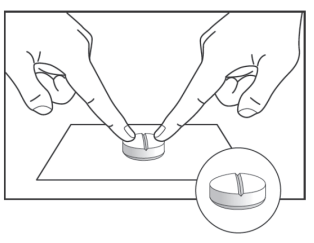
Adults and adolescents above 12 years old
10 mg once daily as 1 tablet.

Children between 6 and 12 years old
5 mg twice daily as a half tablet twice daily.

Patients with moderate renal impairment
Patients with moderate renal impairment are recommended to take 5 mg once daily.
If you suffer from severe kidney disease, please contact your doctor or pharmacist who may adjust the dose accordingly.
If your child suffers from kidney disease, please contact your doctor or pharmacist who may adjust the dose according to your child's needs.

The tablet can be divided into equal doses.

Directions for use
If your treatment with Zynor stipulates that you have to split tablets, you should ideally do so as follows.
Place the tablet on a hard, flat surface (such as a table top or plate) with the score line facing upwards. Then press with both of your index fingers (or thumbs) at the same time briefly and firmly on the outer edges to the left and right of the score line as shown in the graphical representation below.



If you feel that the effect of Zynor is too weak or too strong, please consult your doctor.

Duration of treatment
The duration of treatment depends on the type, duration and course of your complaints and is determined by your doctor.

Design Department Harlow

PRODUCT:	Colours:	Fonts: (Artwork)	Amends:	Approval:
Cetirizine (Zynor) 10mg FC Tabs All (RX), ULM, TEI	Cutter Guide PMS Process Black PMS Green	Body: Univers 55 Roman/ 65 Bold/ 55 Oblique 9pts Subhead: Univers 65 Bld 11pts Header: Univers 65 Bld 13pts	Draft: 2 Rev date: 30-04-13 Reviser: lw	Senior Artwork Co-ordinator Signed Date
Job No: 28169 Art No: x				☐ • Subject to Reg. Agency approval ☐ • Approved by Reg. Dept. for print
Designer: KA Date: 15-4-13	Tints used:		Artworker's Signature:	Signed Date
Component: Leaflet		Software used: Indesign CS6		
Dimensions: 148x420mm	Spellcheck: ☐			

Supplier Instructions Artwork, text and content must NOT be altered. The only exceptions to this are: bleeds, chokes, spreads or other adjustments required for print reproduction purposes only. If you have any difficulties please contact the Teva Artwork Team. We must receive a copy of the 3rd Party Vendors Proof before final approval can be made.

Last amend:

If you take more Zynor than you should
If you think you have taken an overdose of Zynor please inform your doctor. Your doctor will then decide what measures, if any, should be taken.

After an overdose, the side effects described below may occur with increased intensity. Adverse effects such as confusion, diarrhoea, dizziness, tiredness, headache, ailing, dilating of pupil, itching, restlessness, sedation, somnolence, stupor, abnormal rapid heart rate, tremors and urinary retention have been reported.

If you forget to take Zynor
Do not take a double dose to make up for a forgotten dose.

If you stop taking Zynor
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4 POSSIBLE SIDE EFFECTS

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

The following side effects have been reported in post marketing experience.

Common (may affect up to 1 in 10 people):
- fatigue,
- dry mouth, nausea, diarrhoea,
- dizziness, headache,
- somnolence (sleepiness),
- pharyngitis, rhinitis (in children)

Uncommon (may affect up to 1 in 100 people):
- abdominal pain,
- asthenia (extreme fatigue), malaise,
- paresthesia (abnormal feelings of the skin),
- agitation,
- pruritus (itchy skin), rash

Rare (may affect up to 1 in 1,000 people):
- tachycardia (heart beating too fast),
- allergic reactions,
- oedema (swelling),
- liver function abnormal,
- weight increased,
- convulsions,
- aggression, confusion, depression, hallucination, insomnia,
- urticaria (hives)

Very rare (may affect up to 1 in 10,000 people):
- thrombocytopenia (low levels of blood platelets),
- accommodation disorder (difficulty focusing), blurred vision, oculogyration (eyes having uncontrolled circular movements),
- syncope, dyskinesia (involuntary movements), dystonia (abnormal prolonged muscular contractions),tremor, dysgeusia (altered taste),
- tic (habit spasm),
- abnormal elimination of urine (bed wetting, pain and/or difficulty passing water),
- angioedema (serious allergic reaction which causes swelling of the face or throat), fixed drug eruption
- severe allergic reactions,

Not known (frequency cannot be estimated from the available data):
- amnesia, memory impairment
- increased appetite,
- suicidal ideation (recurring thoughts of or preoccupation with suicide)
- vertigo (sensation of rotation or movement)
- urinary retention (inability to completely empty the urinary bladder)

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

At the first signs of a hypersensitivity reaction, stop taking Zynor. Your doctor will then assess the severity and decide on any further measures that may be necessary.

5 HOW TO STORE ZYNOR

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the box and blister after EXP: .The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 CONTENTS OF THE PACK AND OTHER INFORMATION

What Zynor contains
The active substance is cetirizine dihydrochloride.

One film-coated tablet contains 10 mg cetirizine dihydrochloride.

The other ingredients are lactose monohydrate, microcrystalline cellulose, colloidal silica, magnesium stearate, titanium dioxide (E171), hypromellose (E464) and macrogol.

What Zynor looks like and contents of the pack
The film-coated tablet is white to almost white, round, biconvex with breakscore on one side and approximately 6.5 mm in diameter.

The tablet can be divided into equal doses.

PVC//PVDC/alu blisters.
Blister with 7, 14, 15, 20, 28, 30, 50 and 100 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Teva Pharma B.V.
Computerweg 10
3542 DR Utrecht
The Netherlands

Manufacturer:
Merckle GmbH,
Ludwig-Merckle-Strasse 3,
D-89143 Blaubeuren,
Germany

Teva Sante,
Rue Bellocier,
89100 Sens,
France

This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark:	Cetirizine Teva
France:	RATIO CONSEIL ALLERGIE CETIRIZINE 10 mg, comprimé pelliculé sécable
Ireland:	Zynor 10 mg Film-coated Tablets
Italy:	Cetirizina Teva
Spain:	Cetirizina Tevagen 10 mg comprimidos recubiertos con película EFG
Sweden:	Cetiriva 10mg filmdragerade tabletter
United Kingdom:	Cetirizine 10 mg Film-Coated Tablets

This leaflet was last revised in April 2013.

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