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V I C T O R D E S I G N		tel/fax: 01275 342028 • email: mail@victor-design.com
Distributor:	Aspar Pharmaceuticals Limited	
Product:	Cetirizine Hydrochloride 10 mg Tablets PIL (Aspars Own)	
Reference:	PIL-ASP_CETHcl-10	
PL number:	08977/0046	
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PACKAGE LEAFLET: INFORMATION FOR THE USER

Cetirizine Hydrochloride 10 mg Tablets

(Cetirizine Hydrochloride)

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

This medicine is available without prescription. However, you still need to use Cetirizine Hydrochloride 10 mg tablets carefully to get the best results from them.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 3 days.
- 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.

What is in this leaflet:

1. What these tablets are and what they are used for
2. What you need to know before you take these tablets
3. How to take Cetirizine Hydrochloride 10 mg tablets
4. Possible side effects
5. How to store these tablets
6. Contents of the pack and other information

1. WHAT THESE TABLETS ARE AND WHAT THEY ARE USED FOR

Cetirizine hydrochloride is the active ingredient of Cetirizine Hydrochloride 10 mg tablets. Cetirizine Hydrochloride 10 mg tablets are an anti allergy medication.

In adults and children aged 6 years and above, Cetirizine Hydrochloride 10 mg tablets are used:

- For the relief of symptoms of seasonal (hayfever) and year round allergies (e.g. sneezing, running or itchy nose, watery eyes).
- For the relief of chronic nettle rash.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE THESE TABLETS

Do not take Cetirizine Hydrochloride 10 mg tablets:

- If you are allergic (hypersensitive) to Cetirizine Hydrochloride, to any of the other ingredients of Cetirizine Hydrochloride 10 mg tablets, to hydroxyzine or to piperazine derivatives (closely related active substances of other medicines).
- If you have severe kidney problems.
- If you have or there is a family history of problems with galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.

Cetirizine Hydrochloride 10 mg tablets are not for use in children under 6 years of age.

Take special care with Cetirizine Hydrochloride 10 mg tablets

- If you have liver and kidney problems, please ask your doctor for advice; if necessary, your doctor may recommend a lower dose.
- When drinking alcohol while taking this medicine.
- If you are an epileptic patient or a patient at risk of convulsions (fits), you should ask your doctor for advice.
- If you have predisposition factors of urinary retention (eg: spinalcord lesion, prostatic hyperplasia) as cetirizine increases the risk of urinary retention.

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.

The available information on this medicine suggests no interactions with other medicines should be expected.

Allergy skin tests are inhibited by antihistamines and a wash-out period (of 3 days) is required before performing them.

Pregnancy and breast-feeding

Pregnancy: As with other drugs, use of Cetirizine Hydrochloride 10 mg tablets 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 use of the medicine during pregnancy should be discontinued.

Breast-feeding: Do not use this medicine while breast feeding because cetirizine passes into breast milk.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

A few people have experienced dizziness, drowsiness or fatigue after taking cetirizine. If affected, do not attempt any skilled task such as driving or operating machinery. Do not exceed the recommended dose.

Take special care if you drink alcohol while taking Cetirizine Hydrochloride 10 mg tablets- the effect may be increased.

Never drink and then drive or operate tools and machines.

Important information about some of the ingredients of Cetirizine Hydrochloride 10 mg tablets

This medicine contains lactose. 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 CETIRIZINE HYDROCHLORIDE 10 MG TABLETS

Always take Cetirizine Hydrochloride 10 mg tablets exactly as your doctor has told you. You should check with your doctor or your pharmacist if you are not sure.

Adults, elderly patients and children 12 years and over: 1 tablet daily

Children aged between 6 to 12 years: ½ tablet (5mg) twice daily

Patients with moderate kidney problems: ½ tablet (5mg) once daily

Method of administration

Cetirizine Hydrochloride 10 mg tablets can be taken with food or without food. The tablets should be swallowed with water.

If you take more Cetirizine Hydrochloride 10 mg tablets than you should

Contact your doctor or Accident and Emergency department at your nearest hospital. Take this leaflet and any tablets you still have with you. Symptoms of overdose include confusion, diarrhoea, dizziness, tiredness, feeling generally unwell, dilated pupils, itching, restlessness, sleepiness, loss of consciousness, tremor, headache, abnormal rapid heart rate or problems passing urine.

If you forget to take Cetirizine Hydrochloride 10 mg tablets

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, Cetirizine Hydrochloride 10 mg tablets can cause side effects, although not everybody gets them.

The following side effect is very rare, but you must stop taking the tablets and speak to your doctor straight away if you notice these symptoms:

Rare side effects (may affect up to 1 in 1000 people)

- A severe allergic reaction including rash, itchiness and fever, swollen throat, face, eyelids or lips. This reaction may start soon after you first take the medicine, or it might start later.
- Convulsions or fits

Very rare side effects (may affect up to 1 in 10,000 people)

- Unusual bleeding or bruising
- Swelling of the skin particularly around the face

Not known (Not known: frequency cannot be estimated from the available data)

- In very rare cases people have thought about committing suicide and if you feel this way then stop taking the tablets and see your doctor.

The following side effects have also been reported.

Common side effects (may affect up to 1 in 10 people)

- Tiredness, feeling sleepy
- Pain in the abdomen
- Headache
- Dizziness
- Dry mouth
- Sore throat
- Nausea
- Cold-like symptoms of the nose (children only).
- Diarrhoea (children only)

Uncommon side effects (may affect up to 1 in 100 people)

- Itching and rash
- Tingling in the hands and feet
- Diarrhoea
- Feeling agitated.
- Feeling weak or generally unwell

Rare side effects (may affect up to 1 in 1000 people)

- Fast heart beat
- Oedema (generalised swelling due to water retention)
- Abnormal liver function test results (your doctor will know what to do)
- Increased weight
- Aggression, confusion, depression, hallucination (hearing or seeing things), sleeplessness
- Urticaria (hives).

Very rare side effects (may affect up to 1 in 10,000 people)

- Blurred vision, difficulty focussing
- Rotation of the eyes
- Bad taste in the mouth
- Tremor, tics
- Involuntary movements and/or jerking of the limbs
- Muscle spasms in the neck and shoulders
- Fainting
- A recurring rash
- Bed wetting, pain and/or difficulty passing water

Not known side effects

- Increased appetite
- Vertigo
- Urinary retention

Some cases of memory loss and/or impairment have also been reported.

Reporting of side effects

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

You can also report side effects directly via the Yellow Card Scheme, Website:

www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE THESE TABLETS

Keep out of the reach and sight of children.

Do not use Cetirizine Hydrochloride 10 mg tablets after the expiry date which is stated on the blister and the carton.

The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Cetirizine Hydrochloride 10 mg tablets contains

The active substance is Cetirizine hydrochloride. Each tablet contains 10 mg of Cetirizine hydrochloride.

The other ingredients are lactose monohydrate, microcrystalline cellulose, maize starch, colloidal anhydrous silica, magnesium stearate, talc, hypromellose, titanium dioxide (E171), macrogol 4000 and sodium citrate.

What Cetirizine Hydrochloride 10 mg tablets looks like and contents of the pack

Cetirizine Hydrochloride 10 mg tablets are white circular film-coated tablets, marked 'A' on one side with a break line on the other side and are available in blister packs containing 7, 14, 21, 28, 30 or 60 tablets in a pack. Not all pack sizes may be marketed.

Manufacturer:

Aspar Pharmaceuticals Ltd., Capitol Way, London NW9 0EQ

Manufacturer and MA Holder:

Aspar pharmaceuticals Ltd., Albany House, Acrewood Way, St Albans, AL4 0JY, United Kingdom.

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