CETIRIZINE HYDROCHLORIDE 5MG/5ML SOLUTION
PL 18970/0002

UKPAR

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CETIRIZINE HYDROCHLORIDE 5MG/5ML SOLUTION
PL 18970/0002

LAY SUMMARY

The MHRA granted Cipla Chanelle Ltd. a Marketing Authorisation (licence) for the medicinal product Cetirizine Hydrochloride 5mg/5ml Solution (PL 18970/0002). Cetirizine Hydrochloride 5mg/5ml Solution will also be marketed by PLIVA Pharma Ltd. This product is to be sold as a pharmacy only medicine for the treatment of hayfever (seasonal allergic rhinitis), perennial allergic rhinitis (a similar condition to hayfever, caused by allergies that continue throughout the year) and urticaria (swelling, redness and itchy skin).

Cetirizine Hydrochloride 5mg/5ml Solution contains the active ingredient cetirizine hydrochloride, which is an antihistamine.

No new or unexpected safety concerns arose from this application and it was therefore judged that the benefits of taking Cetirizine Hydrochloride 5mg/5ml Solution outweigh the risks, hence a Marketing Authorisation has been granted.
CETIRIZINE HYDROCHLORIDE 5MG/5ML SOLUTION
PL 18970/0002

SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the UK granted a Marketing Authorisation for the medicinal product Cetirizine Hydrochloride 5mg/5ml Solution (PL 18970/0002) to Cipla Chanelle Ltd. on 23 July 2007. The product is available through pharmacies.

The application was submitted as an abridged application according to Article 10.1 of Directive 2001/83/EC, claiming essential similarity to the original product Zirtek Allergy Solution 1mg/ml (UCB Watford Ltd.). The reference product has only been authorised in the UK since March 2000, but has been marketed in Belgium since June 1991, so the 10-year period of data exclusivity has expired.

The product contains the active ingredient cetirizine hydrochloride, an antihistamine.

Cetirizine Hydrochloride 5mg/5ml Solution is indicated for the symptomatic treatment of seasonal allergic rhinitis, perennial rhinitis and chronic idiopathic urticaria.

No bioequivalence study has been performed. The product can be considered exempt from this requirement due to the nature of the formulation and the solubility of the drug in a range of pH media at the required concentration.
PHARMACEUTICAL ASSESSMENT

COMPOSITION

The product is formulated as an oral solution containing the active ingredient cetirizine hydrochloride at a strength of 5mg/5ml. The excipients present are methyl parahydroxybenzoate, propyl parahydroxybenzoate, sorbitol solution, glycerol, sodium citrate, citric acid, propylene glycol, monoammonium glycyrrhizinate, pineapple flavour, sweet orange flavour and purified water.

The solution is presented in amber type III glass bottles with child resistant and tamper evident polypropylene closures, in packs of 75ml, 100ml and 200ml.

DRUG SUBSTANCE

Cetirizine hydrochloride

Synthesis of the drug substance from the designated starting material has been adequately described and appropriate in-process controls and intermediate specifications are applied. Satisfactory identification tests are in place for all starting materials and reagents and these are supported by relevant certificates of analysis.

Cetirizine hydrochloride is tested as per the European Pharmacopeial specification.

Analytical methods have been appropriately validated and are satisfactory for ensuring compliance with the relevant specifications.

Batch analysis data are provided and comply with the proposed specification.

Appropriate stability data have been generated which support a retest period of 24 months, with no specific storage instructions.

DRUG PRODUCT

Cetirizine Hydrochloride 5mg/5ml Solution was developed on the basis of Zirtek Allergy Solution 1mg/ml with minor changes made to the formulation to improve viscosity and taste.

Other ingredients

All of the excipients (except for the flavouring agents) comply with their respective European Pharmacopeial monograph and are used in other licensed products for oral use at similar concentrations (or above) to those in this formulation. In-house specifications have been provided with details of the analytical methods used for monoammonium glycyrrhizinate and the flavouring agents (pineapple flavour and sweet orange flavour).

Satisfactory certificates of analysis have been provided for all excipients.

None of the excipients used contain material of animal or human origin.
Impurity Profile
The impurity profiles for a single batch of the reference Zirtek Allergy Solution 1mg/ml and test product were found to be similar. The data support a claim of essential similarity for the two products.

Manufacture
A full description and a detailed flow-chart of the manufacturing method, including in-process control steps has been provided.

In-process controls are satisfactory based on process validation data and controls on the finished product. Satisfactory process validation has been carried out.

Finished product specification
The proposed finished product specification is acceptable and the analytical methods used have been suitably validated. Suitable reference standards were used. Batch analysis data have demonstrated compliance with the proposed release specification.

Container Closure System
Satisfactory specifications and certificates of analysis have been provided for the packaging components.

Stability
Finished product stability data support the proposed shelf-life of 3 years and in-use shelf-life of 2 months with no storage recommendations.

SPC, PIL, Labels
The SPC, PIL and labels are pharmaceutically acceptable.

CONCLUSION
It is recommended that a Marketing Authorisation is granted for this application.

The requirements for essential similarity of the proposed and reference products have been met with respect to qualitative and quantitative content of the active substance, pharmaceutical form and bioequivalence.
PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with this application and none are required for an application of this type.
**CLINICAL ASSESSMENT**

**CLINICAL PHARMACOLOGY**

**General**

Cetirizine is a potent antihistamine with a low potential for drowsiness at pharmacologically active doses and has additional anti-allergic properties. It is a selective H₁-antagonist with negligible effects on other receptors and so is virtually free from anti-cholinergic and anti-serotonin effects. Cetirizine inhibits the histamine-mediated early phase of the allergic reaction and also reduces the migration of inflammatory cells and the release of certain mediators associated with the late allergic response.

Peak blood levels in the order of 0.3 µg/ml are attained between 30 and 60 minutes following the administration of a 10 mg oral dose of cetirizine.

The terminal half-life is approximately ten hours in adults and six hours in children aged between 6 to 12. This is consistent with the urinary excretion half-life of the drug. The cumulative urinary excretion represents about two-thirds of the dose given for both adults and children.

The apparent plasma clearance in children is higher than that measured in adults. A high proportion of cetirizine is bound to human plasma proteins.

**Pharmacokinetics – Bioequivalence Study**

Since both the test product and the essentially similar product are liquids, no formal bioequivalence studies are required.

**CLINICAL EFFICACY**

No formal efficacy data have been provided for this application and none are required.

**CLINICAL SAFETY**

No formal safety data derived from studies of patients have been provided for this application and none are required. The adverse events that have been documented for the originator product are listed in the Summary of Product Characteristics.

**CLINICAL EXPERT REPORT**

The clinical expert report has been written by an appropriately qualified medical doctor and is satisfactory.
SPC, PIL and LABELS

The SPC, PIL and labels are acceptable.

CONCLUSIONS

The efficacy and safety of Cetirizine Hydrochloride 5mg/5ml Solution are satisfactory for the grant of a Marketing Authorisation.
OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY
The important quality characteristics of Cetirizine Hydrochloride 5mg/5ml Solution are well defined and controlled. The specifications and batch analytical results indicate consistency from batch to batch. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

PRECLINICAL
No new preclinical data were submitted and none are required for an application of this type.

EFFICACY
No new or unexpected safety concerns arose from this application.

The SPC, PIL and labelling are satisfactory.

RISK BENEFIT ASSESSMENT
Clinical experience with cetirizine hydrochloride is considered to have demonstrated the therapeutic value of the compounds. The risk benefit is, therefore, considered to be positive.
CETIRIZINE HYDROCHLORIDE 5MG/5ML SOLUTION
PL 18970/0002

STEPS TAKEN FOR ASSESSMENT

1 The MHRA received the Marketing Authorisation application on 24 April 2002.

2 Following standard checks and communication with the applicant the MHRA considered the application valid on 22 July 2002.


5 The application was determined on 23 July 2007.
CETIRIZINE HYDROCHLORIDE 5MG/5ML SOLUTION
PL 18970/0002

STEPS TAKEN AFTER AUTHORISATION - SUMMARY

<table>
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<tr>
<th>Date submitted</th>
<th>Application Type</th>
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SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Cetirizine Hydrochloride 5 mg/5 ml Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml contains Cetirizine hydrochloride 1 mg.

Excipients

Cetirizine hydrochloride 5mg / 5 mL solution contains 2500 mg sorbitol (70%) per 5 ml

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution.

A clear, colourless, pineapple and sweet orange flavoured solution with a sweet taste.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Cetirizine Hydrochloride 5 mg/5 ml Solution is indicated for the symptomatic treatment of seasonal allergic rhinitis, perennial rhinitis and chronic idiopathic urticaria in adults and children aged 6 years and over and additionally for the symptomatic treatment of seasonal allergic rhinitis in children between two to five years of age.

4.2 Posology and method of administration

Adults and children 6 years and above: 10 mg daily.

Adults and children aged 12 years and above: 10 ml once daily.
Children aged between 6 to 11 years: Either 5 ml twice daily or 10 ml once daily.

Children aged between 2-5 years: 5 mg daily.
Either 5 ml once daily or 2.5 ml twice daily.

At present there are insufficient clinical data to recommend the use of cetirizine in children under 2 years of age.

There are no data to suggest that the dose should be reduced in elderly patients.

In patients with renal insufficiency the dose should be reduced to half the normal recommended daily dose.

4.3 Contraindications

Cetirizine is contra-indicated in patients with a history of hypersensitivity to cetirizine or any of the excipients.

4.4 Special warnings and precautions for use

Do not exceed the recommended dose.
In patients with renal insufficiency the dosage should be reduced to half the usual recommended dose.
For patients whose symptoms persist, it is advisable to consult a doctor or pharmacist.
Patients with rare hereditary problems of fructose intolerance should not take this medicine. Methylparahydroxybenzoate and propylparahdroxybenzoate may cause allergic reactions (possibly delayed).

4.5 Interaction with other medicinal products and other forms of interaction

To date, there are no known interactions with any other drugs. Studies with diazepam and cimetidine have revealed no evidence of interactions. As with other antihistamines it is advisable to avoid excessive alcohol consumption.

Allergy testing: Use of Cetirizine must be discontinued three days before allergy tests.

4.6 Pregnancy and lactation

No adverse effects have been reported from animal studies. There has been little or no clinical experience of Cetirizine during pregnancy. As with other drugs, the use of cetirizine in pregnancy should be avoided. Cetirizine Hydrochloride 5 mg/5 ml
Solution is contraindicated in lactating women since the active ingredient cetirizine hydrochloride is excreted in breast milk.

4.7 Effects on ability to drive and use machines

At the recommended dose cetirizine does not cause drowsiness in the majority of people however rare cases have been reported. If affected do not drive or operate machinery.

4.8 Undesirable effects

In objective tests of psychomotor function, the incidence of sedation with cetirizine was similar to that of placebo. There have been occasional reports of mild and transient side effects such as drowsiness, fatigue, headache, dizziness, agitation, dry mouth and gastrointestinal discomfort. If desired the dose might be taken as 5 mg in the morning and 5 mg in the evening.

Undesirable effects reported from post-marketing experience are listed in the following table per System Organ Class and per frequency. The frequency has been defined as: very common (> 10 %); common (≤ 10 % and > 1 %); uncommon (≤ 1 % and > 0.1 %); rare (≤ 0.1 % and > 0.01 %); very rare (≤ 0.01 %, including isolated reports).

Cardiac disorders: Rare: tachycardia.
Eye disorders: Very rare: accommodation disorder, blurred vision.
General disorders and administration site conditions: Uncommon: asthenia, malaise; Rare: oedema.
Immune system disorders: Rare: hypersensitivity; Very rare: anaphylactic shock.
Hepatobiliary disorders: Rare: abnormal hepatic function (increased transaminases, alkaline, phosphatase, γ-GT and bilirubin).
Investigations: Rare: weight increase.
Nervous system disorders: Uncommon: paraesthesia; Rare: convulsions, movement disorders; Very rare: dysgeusia, syncope.
Psychiatric disorders: uncommon : agitation ; rare : aggression, confusion, depression, hallucination, insomnia.
Renal and urinary disorders: Very rare: dysuria, enuresis, micturition difficulties.
Skin and subcutaneous tissue disorders: Uncommon: pruritus, rash, Rare: urticaria, Very rare: angioneurotic oedema, erythema multiforme.

4.9 Overdose

a) Symptoms
Symptoms observed after an important overdose of cetirizine are mainly associated with CNS effects or with effects that could suggest an anticholinergic effect.

Adverse events reported after an intake of at least 5 times the recommended daily dose are: confusion, diarrhoea, dizziness, fatigue, headache, malaise, mydriasis, pruritus, restlessness, sedation, somnolence, stupor, tachycardia, tremor and urinary retention.

b) Management
Should overdose occur, symptomatic or supportive measures are recommended. The patient should be kept under clinical observation for at least 4 hours after ingestion, and his blood pressure, heart rate and vital signs monitored until stable. In symptomatic cases, ECG should be performed.

The benefit of gastric lavage is uncertain. Oral activated charcoal (50g for an adult, 10-15 g for a child) should be considered if more than 2.5 mg/kg cetirizine has been ingested within 1 hour.

There is no known specific antidote to cetirizine.

Cetirizine is not effectively removed by dialysis.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: R06A E07

Cetirizine is a potent antihistamine with a low potential for drowsiness at normal therapeutic doses, which has additional anti-allergic properties. It is a selective H₁ antagonist with negligible effects on other receptors and so is virtually free from anticholinergic and anti-serotonin effects. Cetirizine inhibits the histamine-mediated early phase of the allergic reaction and also reduces the migration of certain inflammatory cells and the release of certain mediators associated with the late allergic response.

5.2 Pharmacokinetic properties

Peak blood levels of the order of 0.3 micrograms/ml are reached between 30 and 60 minutes after the oral administration of a 10 mg dose of cetirizine. The terminal half-life is approximately ten hours in adults and six hours in children aged 6 - 12 years.

This is consistent with the urinary excretion half-life of the drug. The cumulative urinary excretion represents about two thirds of the administered dose for both adults and children.

The apparent plasma clearance in children is higher than that measured in adults. A high proportion of cetirizine is bound to human plasma proteins.

5.3 Preclinical safety data
No relevant information additional to that contained elsewhere in the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate (E216)
Sorbitol
Glycerol
Sodium citrate
Propylene glycol
Monoammonium glycrrhizinate
Pineapple flavour
Sweet orange flavour
Citric Acid

6.2 Incompatibilities

None

6.3 Shelf life

3 years.
Once opened, the contents of the bottle should be used within 2 months.

6.4 Special precautions for storage

No special storage conditions required.

6.5 Nature and contents of container

Type III soda lime silica amber glass bottles with tamper-evident and child-resistant polypropylene closure.
Pack size: 200 ml, 100 ml and 75 ml
6.6 Special precautions for disposal

No special requirements

7 MARKETING AUTHORISATION HOLDER

Cipla Chanelle Ltd.,
Loughrea,
Co. Galway,
Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

PL 18970/0002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

23/07/2007

10 DATE OF REVISION OF THE TEXT

23/07/2007
Cetirizine Hydrochloride 5mg/5ml Solution

PATIENT INFORMATION LEAFLET
CIPLA CHANELLE LTD.

PACKAGE LEAFLET: INFORMATION FOR THE USER

Cetirizine hydrochloride
5 mg/5ml Solution

Cetirizine hydrochloride

Please read this leaflet carefully because it contains important information for you.

This medicine is available without prescription, however you still need to read the leaflet before you use it.

Keep this leaflet. You may need to read it again.

Ask your pharmacist if you need advice or further information.

You must consult a doctor if your symptoms worsen or do not improve.

Read the leaflet before taking the solution. If you have any side effects not listed in this leaflet, please tell your doctor or your pharmacist.

In this leaflet:
1. What Cetirizine hydrochloride is and what it is used for
2. Before you take Cetirizine hydrochloride
3. How to take Cetirizine hydrochloride
4. Possible side effects
5. How to store Cetirizine hydrochloride
6. Further information

1. WHAT CETIRIZINE HYDROCHLORIDE IS AND WHAT IT IS USED FOR

Your medicine contains the active ingredient cetirizine hydrochloride. Cetirizine hydrochloride belongs to a family of medicines known as histamine H1 receptor antagonists.

This medicine treats people suffering from hay fever (seasonal allergic rhinitis), perennial allergic rhinitis (in a similar condition to hay fever), caused by allergens that continue throughout the year, and urticaria (hives) in adults and children aged 6 years and over.

It also helps to reduce the inflammation associated with rhinitis.

Antihistamines such as cetirizine hydrochloride relieve the unpleasant symptoms such as sneezing, itchy, runny and blocked nose, itchy, red and watery eyes, and itchy skin rash, associated with this condition.

2. BEFORE YOU TAKE CETIRIZINE HYDROCHLORIDE

Do not take Cetirizine hydrochloride
- if you are allergic to cetirizine hydrochloride or any of the other ingredients listed in section 6.
- if you have taken a medicine containing a related medicine (e.g. diphenhydramine) in the last 7 days.
- if you have had any allergic reactions to any of these medicines.
- if you are already taking the medicine.

Take special care with Cetirizine hydrochloride
- If you have ever been told you have diabetes or sugar problems, tell your doctor or pharmacist before taking this medicine, as you might need to take half the daily dose.
- If symptoms persist, then consult your doctor.

Do not take more medicine than usual unless your doctor tells you to.

Talking other medicines
- If you are taking or have recently taken any other medicines, including medicines obtained without a prescription, tell your doctor or pharmacist before taking this medicine.
- If you have an allergy, the medicine must be discontinued 2 days before the test.

Pregnancy and breast-feeding
- Pregnancy: If you are pregnant, your doctor should decide whether you should take this medicine.
- Breast-feeding: You should not take this medicine if you are breast-feeding.

Driving and using machines
- Cetirizine hydrochloride does not normally cause dizziness at the recommended dose. However, if adults react differently or suddenly, you should avoid driving or operating machinery.

It is important to tell your doctor or pharmacist if you have an intolerance to some sugars. Contact your doctor before taking this medicated product.

Important information about some of the ingredients of cetirizine hydrochloride
- Your medicine contains a small amount of paracetamol (0.2%) and propylparaben (4%).

These ingredients may cause allergy reactions in some people.

The medicine also contains sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicated product.

Further information
- Your doctor or pharmacist will be able to give you more information about Cetirizine hydrochloride.
### 3. HOW TO TAKE CETIRIZINE HYDROCHLORIDE

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

- **Adults and children 6 years and above**: 10mg daily.
- **Adults and children aged 12 years and above**: 10ml once daily.
- **Children aged 6 to 11 years**: Either 5ml once daily or 10ml once daily.

Children aged between 5 and 11 years:

**Either**: 5ml once daily of 2.5mg/5ml once daily.

- The medicine should not be given to children under 2 years of age.

Method of administration

- Take Cetirizine hydrochloride solution only.

If you take too much Cetirizine hydrochloride than you should:

- Contact your doctor or local emergency ward IMMEDIATELY. Take this leaflet and any medicine you still have with you. Symptoms of overdose include confusion, slurred speech, drowsiness. Do not call if you have taken too much of your medicine.

If you forget to take Cetirizine hydrochloride:

- If you forget to take your medicine, take a single dose as soon as you remember. However, do not take another dose within 24 hours.

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 can cause side effects, although not everybody gets them. The following side effects have been reported:

- **Uncommon (less than 1 in 100 patients but less than 1 in 1000 patients)**: Dizziness, fatigue, unpleasant taste.
- **Less common (less than 1 in 1000 patients but less than 1 in 10,000 patients)**: Headache, agitation, trembling, feeling of numbness or skin rash.
- **Rare (less than 1 in 10,000 patients)**: Rapid heartbeat, irritation of the skin, allergic reaction, abnormal liver function, weight increase, increased sweating, depression, dizziness, sleeping problems, muscle pain.
- **Very rare (less than 1 in 100,000 patients)**: Bruising, difficulty breathing, swelling of the tongue, change in sense of taste.

If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please let your doctor or pharmacist.

### 5. HOW TO STORE CETIRIZINE HYDROCHLORIDE

- Keep out of the reach and sight of children.

The expiry date is indicated on the label. "EXP“ is printed in red. Do not take your medicine after this date.

- Once opened, the content of the bottle should be used within 2 months.

- The medicine 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 any medicines no longer required. These measures will help to protect the environment.

### 6. FURTHER INFORMATION

What Cetirizine hydrochloride solution contains:

Cetirizine hydrochloride solution contains 1 mg of cetirizine hydrochloride. Each milliliter of solution contains 1 mg of cetirizine hydrochloride. The solution also contains maltodextrin (2%), propylparaben (0.01%), sorbic acid, sodium chloride, polyglycol monomethyl ether, polyethylene glycol monomethyl ether, propylene glycol, sweet orange flavour and citric acid.

What Cetirizine hydrochloride solution looks like and of contents of the pack:

- Cetirizine Hydrochloride 5mg/5ml Solution is a clear, colourless, viscous, smooth, sweet orange flavoured solution with a sweet taste.

- Cetirizine Hydrochloride 5mg/5ml Solution is available in 7.5ml, 10ml, and 200ml bottles. Not all pack sizes may be available.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder is Quas-Chemie Ltd, Loughrea, Co. Galway, Ireland. The manufacturer is Chasenelle Medical, Loughrea, Co. Galway, Ireland. The distributor is Chasenelle Medical UK Ltd.

This leaflet was last approved: 06/2007.
Cetirizine Hydrochloride 5mg/5ml Solution

PATIENT INFORMATION LEAFLET
PLIVA PHARMA LTD.

PACKAGE LEAFLET INFORMATION FOR THE USER

Cetirizine Hydrochloride 5mg/5ml Solution

Cetirizine hydrochloride

Read all of this leaflet carefully because it contains important information for you. This medicine is available without prescription. However, you still need to take cetirizine hydrochloride carefully to get the best result from it.

- 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.
- 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.

In this leaflet:

1. What Cetirizine hydrochloride is and what it is used for
2. Before you take Cetirizine hydrochloride
3. How to take Cetirizine hydrochloride
4. Possible side effects
5. How to store Cetirizine hydrochloride

1. What Cetirizine hydrochloride is and what it is used for

Your medicine contains the active ingredient cetirizine hydrochloride, a non-sedating antihistamine. It is used to treat symptoms of hay fever and other allergic conditions.

This medicine treats people suffering from hay fever ( seasonal allergic rhinitis, perennial allergic rhinitis in similar condition to hay fever), caused by allergies that continue throughout the year and urticaria (hives, rashes) and acute urticaria in adults and children aged 6 years and over.

It also treats hives in children aged between 2 to 5 years.

Applications such as cetirizine hydrochloride release the unpleasant symptoms such as sneezing, itchy, runny and blocky nose, dry, red and watering eyes and itchy, dry and sore throat.

2. Before you take Cetirizine hydrochloride

Do not take:

- Cetirizine hydrochloride.
- If you are allergic to cetirizine hydrochloride or to any of the other ingredients listed in section 6.

Take special care with:

- Cetirizine hydrochloride.
- If you have ever had any kidney problems, tell your doctor or pharmacist before taking this medicine, as you may only need to take half the daily dose.
- If symptoms persist, then consult your doctor.
- Do not treat this medicine as usual unless your doctor tells you to.

Taking other medicines

If you are taking or have recently taken any other medicines, including medicines obtained without a prescription, tell your doctor or pharmacist before taking this medicine.

If taking an allergic this medicine must be discontinued 3 days before the test.

Pregnancy and breast-feeding

Pregnancy:

If you are pregnant, you should consult your doctor before taking this medicine.

Breast-feeding:

You should not take this medicine if you are breast-feeding.

Driving and using machines

Cetirizine hydrochloride does not normally cause drowsiness at the recommended dose. However, individuals may be differential as if affected, you should not drive or operate machinery.

Important information about some of the ingredients of Cetirizine hydrochloride

Your medicine contains the following substances:

- Xylitol (E420) and polyethylene glycol (E321) as preservatives.

These ingredients may cause allergic reactions (rarely severe).

This medicine contains no artificial colors or flavors.

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

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

Doses for children

Dosage:

Adults and children aged 6 years and above:

- One dose daily: 10ml

- Children aged 4 to 11 years:

- Children aged 4 to 10 years: 5ml daily

- Children aged 11 to 12 years: 10ml daily

- Children aged 12 to 17 years: 15ml daily

Further information

What Cetirizine hydrochloride solution contains

The active substance is Cetirizine hydrochloride. Each 5ml solution contains:

- Cetirizine hydrochloride 5mg (0.1%)

The solution also contains:

- Xylitol (E420) and polyethylene glycol (E321), water, sodium citrate (E331), sucrose, propylene glycol, monosodium glutamate, preservatives, natural lemon flavor and citric acid.

What to do if you think you have taken too much

If you think you have taken too much of this medicine, tell your doctor or pharmacist immediately.

If you take more Cetirizine hydrochloride than you should

Contact your doctor or local emergency ward.

What can happen if you forget to take your medicine

If you forget to take your medicine, take a single dose as soon as you remember. However, do not take another dose within 24 hours.

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 can cause side effects, although not everybody gets them.

The side effects include:

- Headache
- Nausea
- Dizziness
- Erythema multiforme
- Blurred vision
- Dry mouth and dryness

If you have any further questions on the use of this product, ask your doctor or pharmacist.

5. How to store Cetirizine hydrochloride

Store out of reach of children.

Keep in a cool, dry place.

Do not use after the expiry date.

PL 18970/0002

This leaflet was last updated 05/2007

PL 18970/0002

L2801
Cetirizine Hydrochloride 5mg/5ml Solution

LABELLING
CIPLA CHANELLE LTD.

Antihistamine solution for oral use.
Each 5ml contains cetirizine hydrochloride 1mg. Also contains propylene glycol, glycerol and sorbitol solution (70%), methylparaben (0.01%), and propylparaben (0.01%).

Warnings:
Consult your doctor before taking this medicine if you are pregnant or breastfeeding.
Cetirizine hydrochloride does not normally cause drowsiness at the recommended dose. However, individuals react differently so, if affected, you should not drive or operate machinery.

If symptoms persist consult your doctor.

If swallowed, wash out mouth and gargle with water.

Do not exceed stated dose.

Cetirizine Hydrochloride
5 mg/5 ml Solution
Relieves symptoms from seasonal hayfever (adults and children aged 12 years and over), and year round hayfever, itching, and itchy, watery eyes (adults and children aged 12 years and over).

75 ml

BN
Exp

5 mg/5 ml Solution
Relieves symptoms from seasonal hayfever (adults and children aged 2 years and over) and year round hayfever, itching, and itchy, watery eyes (adults and children aged 12 years and over).

75 ml

BN
Exp

Cetirizine Hydrochloride

5 mg/5 ml Solution
Relieves symptoms from seasonal hayfever (adults and children aged 2 years and over) and year round hayfever, itching, and itchy, watery eyes (adults and children aged 12 years and over).

75 ml

BN
Exp

Distributed by: Chandelle Medical U.K. Ltd.

CIPLA CHANELLE LTD.

Cetirizine Hydrochloride

5 mg/5 ml Solution
Relieves symptoms from seasonal hayfever (adults and children aged 2 years and over) and year round hayfever, itching, and itchy, watery eyes (adults and children aged 12 years and over).

75 ml

BN
Exp

Distributed by: Chandelle Medical U.K. Ltd.
Cetirizine Hydrochloride 5mg/5ml Solution

5mg/5ml Solution

Antihistamine solution for oral use.
Each 5ml contains cetirizine hydrochloride 5mg. Also contains propylene glycol, glycerol and sodium citrate 7.5%, maltol, parahydroxybenzoate E219 and propyl parahydroxybenzoate E218. Please read enclosed leaflet before use.

Dosage: Symptoms of hayfever:
Children aged 2 years and over
Chewable tablets 5mg once daily
Children aged 12 years and over
Chewable tablets 10mg once daily
Symptoms of other allergic conditions, skin rash or itchy, watery eyes:
Adults and children aged 12 years and over
Chewable tablets 5mg or 10mg twice daily
Children aged 2 to 11 years
Chewable tablets 5mg or 10mg twice daily
Do not give to children under 2 years of age.

Cetirizine Hydrochloride
6 mg/6 ml Solution

Relieves symptoms from seasonal hayfever (adults and children aged 2 years and over) and year round hayfever, skin rash or itchy, watery eyes (adults and children aged 2 years and over).

Antihistamine solution for oral use.
Each 1ml contains cetirizine hydrochloride 1mg. Also contains propylene glycol, glycerol and sodium citrate 7.5%, maltol, parahydroxybenzoate E219 and propyl parahydroxybenzoate E218. Please read enclosed leaflet before use for further information.

Dosage: Symptoms of hayfever:
Adults and children aged 12 years and above
10 ml once daily
Children aged between 6 to 11 years:
Either 5 ml twice daily or 10 ml once daily
Children aged between 2 to 5 years:
Either 5 ml once daily or 2.5 ml twice daily
Symptoms of other allergic conditions, skin rash or itchy, watery eyes:
Adults and children aged 12 years and above
10 ml once daily
Children aged between 6 to 11 years:
Either 5 ml twice daily or 10 ml once daily
Do not give to children under 2 years of age.

Cetirizine Hydrochloride 5mg/5ml Solution

Relieves symptoms from seasonal hayfever (adults and children aged 2 years and over) and year round hayfever, skin rash or itchy, watery eyes (adults and children aged 2 years and over).

Antihistamine solution for oral use.
Each 5ml contains cetirizine hydrochloride 5mg. Also contains propylene glycol, glycerol and sodium citrate 7.5%, maltol, parahydroxybenzoate E219 and propyl parahydroxybenzoate E218. Please read enclosed leaflet before use.

Dosage: Symptoms of hayfever:
Adults and children aged 12 years and above
Chewable tablets 5mg once daily
Children aged between 6 to 11 years:
Chewable tablets 5mg once daily
Children aged between 2 to 5 years:
Chewable tablets 5mg once daily
Children aged between 2 to 5 years:
Chewable tablets 2.5 mg twice daily
Symptoms of other allergic conditions, skin rash or itchy, watery eyes:
Adults and children aged 12 years and above
Chewable tablets 5mg or 10mg twice daily
Children aged 2 to 11 years
Chewable tablets 5mg or 10mg twice daily
Do not give to children under 2 years of age.
Cetirizine Hydrochloride 5mg/5ml Solution

200 ml

Antihistamine solution for oral use.
Each 1 ml contains cetirizine hydrochloride 5 mg, alcohol 4%, propylene glycol 5%, water for injection 85%, citric acid to pH 5, saccharin sodium, and benzoic acid as preservative.

Warnings:
Consult your doctor before taking this medicine if you are pregnant or breastfeeding.

Dosage:

- For adults and children aged 12 years and above: 10 ml once daily.
- For children aged 6 to 11 years: 5 ml once daily.
- For children aged 2 to 5 years: 2.5 ml once daily.
- Do not exceed stated dose.

Cetirizine Hydrochloride 5 mg/5 ml Solution

Relieves symptoms from seasonal hayfever (adults and children aged 2 years and over) and year round hayfever, skin rash or itching, watery eyes (adults and children aged 12 years and over).

Dosage:

- For adults and children aged 12 years and above: 10 ml once daily.
- For children aged 6 to 11 years: 5 ml once daily.
- For children aged 2 to 5 years: 2.5 ml once daily.
- Do not exceed stated dose.

Warnings:
Consult your doctor before taking this medicine if you are pregnant or breastfeeding.

Cetirizine Hydrochloride does not normally cause drowsiness at the recommended dose. However, individuals react differently so if affected, you should not drive or operate machinery.

If symptoms persist consult your doctor.

Keep out of the reach and sight of children.

Once opened, the contents of the bottle should be used within 2 months.

Do not exceed stated dose.
Cetirizine Hydrochloride Solution

PL 18970/0002

LABELLING
PLIVA PHARMA LTD.

Antihistamine solution for oral use. Each 1ml contains cetirizine hydrochloride 1mg. Also contains propylene glycol, glycerol and surfactant solution 70%, methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216).

Please read enclosed leaflet for further information.

Dosage: Symptoms of hay fever:
Adults and children aged 12 years and above: 10ml once daily.
Children aged between 6 to 11 years: Either 5ml twice daily or 10ml once daily.
Children aged between 2 to 5 years: Either 5ml once daily or 2.5ml twice daily.

Symptoms of other allergic conditions, skin rash or itchy, watery eyes:
Adults and children aged 12 years and above: 10ml once daily.
Children aged between 6 to 11 years: Either 5ml twice daily or 10ml once daily.
Do not give to children under 2 years of age.

Warnings: Consult your doctor before taking this medicine if you are pregnant or breastfeeding. Cetirizine hydrochloride does not normally cause drowsiness at the recommended dose. However, individuals react differently so, if affected, you should not drive or operate machinery.

If symptoms persist consult your doctor.

Once opened, the contents of the bottle should be used within 2 months.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

Cetirizine hydrochloride 5mg/5ml Solution

Relieves symptoms from seasonal hay fever (adults and children aged 2 years and over) and hay fever, skin rash and itchy, watery eyes (adults and children aged 12 years and over) 75ml

Batch:
Enp

Cetirizine hydrochloride 5mg/5ml Solution

Relieves symptoms from seasonal hay fever (adults and children aged 2 years and over) and year round hay fever, skin rash and itchy, watery eyes (adults and children aged 12 years and over) 75ml

DO NOT EXCEED THE STATED DOSE

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

Once opened, the contents of the bottle should be used within 2 months.

Distributed by: PLIVA Pharma Ltd., Vision House, Bedford Road, Peterfield, Hampshire, GU32 3QB, UK.

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