CETREX 5MG/5ML SOLUTION
CETRASE 5MG/5ML SOLUTION
PL 18970/0004

UKPAR

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CETREX 5MG/5ML SOLUTION
CETRASE 5MG/5ML SOLUTION
PL 18970/0004

LAY SUMMARY

The MHRA granted Cipla Chanelle Ltd. a Marketing Authorisation (licence) for the medicinal product Cetrex 5mg/5ml Solution (PL 18970/0004). The same product will be marketed as Cetrase 5mg/5ml Solution by PLIVA Pharma Ltd. This is a general sales list (GSL) product 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 chronic idiopathic urticaria (swelling, redness and itchy skin) in adults and children aged 6 years and over.

Cetrex 5mg/5ml Solution and Cetrase 5mg/5ml Solution contain 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 Cetrex 5mg/5ml Solution and Cetrase 5mg/5ml Solution outweigh the risks, hence a Marketing Authorisation has been granted.

CETREX 5MG/5ML SOLUTION
CETRASE 5MG/5ML SOLUTION
PL 18970/0004

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 Cetrex 5mg/5ml Solution (PL 18970/0004) to Cipla Chanelle Ltd. on 23 July 2007. This is a general sales list product.

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.

Cetrex 5mg/5ml Solution and Cetrase 5mg/5ml Solution are indicated for the symptomatic treatment of seasonal allergic rhinitis, perennial rhinitis and chronic idiopathic urticaria in adults and children aged 6 years and over.

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 glycerrhizinate, 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 70ml.

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

Cetrex 5mg/5ml Solution and Cetrase 5mg/5ml Solution were 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 H_1 - 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 Cetrex 5mg/5ml Solution and Cetrase 5mg/5ml Solution are satisfactory for the grant of a Marketing Authorisation.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The important quality characteristics of Cetrex 5mg/5ml Solution and Cetrase 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.

CETREX 5MG/5ML SOLUTION
CETRASE 5MG/5ML SOLUTION
PL 18970/0004

STEPS TAKEN FOR ASSESMENT

1 The MHRA received the Marketing Authorisation application on 04 November 2004.

2 Following standard checks and communication with the applicant the MHRA considered the application valid on 24 November 2004.

3 Following assessment of the application the MHRA requested further information relating to the quality dossier on 01 March 2005, 29 November 2005 and 13 September 2006.

4 The applicant responded to the MHRA's requests, providing further information on 19 August 2005, 14 March 2006, 01 December 2006 and 06 July 2007 for the quality section.

5 The application was determined on 23 July 2007.

CETREX 5MG/5ML SOLUTION
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PL 18970/0004

STEPS TAKEN AFTER AUTHORISATION - SUMMARY

Date submitted	Application type	Scope	Outcome

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Cetrex 5 mg/5 ml Solution

Cetrase 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 solution (70%) per 5ml

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

Cetrex / Cetrase 5 mg/5 ml Solution is indicated for the symptomatic treatment of seasonal allergic rhinitis, perennial rhinitis, seasonal allergic rhinitis and chronic idiopathic urticaria in adults and children aged 6 years and over.

4.2 Posology and method of administration

Children under 6 years: Not recommended.
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.

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 propylparahydroxybenzoate 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. Cetrex / Cetrase 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, headaches, dizziness, drowsiness, 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).

Blood and lymphatic disorders: Very rare: thrombocytopenia.

Cardiac disorders: Rare: tachycardia.

Eye disorders : Very rare: accommodation disorder, blurred vision.

Gastro-intestinal disorders: Uncommon: diarrhoea.

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 H_1 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 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 glycerrhizinate

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: 70 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 18970/0004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

23/07/2007

10 DATE OF REVISION OF THE TEXT

23/07/2007

PATIENT INFORMATION LEAFLET

CIPLA CHANELLE LTD.

PACKAGE LEAFLET: INFORMATION FOR THE USER

Cetrex 5 mg/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 Cetrex 5 mg/ 5 ml Solution 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 your pharmacist.

In this leaflet:

1. WHAT CETREX 5 MG/ 5 ML SOLUTION 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 antihistamines, used to relieve symptoms of hay fever and other allergic conditions.

This medicine treats people suffering from 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) in adults and children aged 6 years and over.

Antihistamines such as Cetrex 5 mg/ 5 ml Solution relieve the unpleasant symptoms such as sneezing, an itchy, runny and blocked-up nose, itchy, red and watery eyes and itchy skin rashes, associated with this condition.

2. BEFORE YOU TAKE CETREX 5 MG/ 5 ML SOLUTION

Do not take Cetrex 5 mg/ 5 ml Solution

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

Cetrex 5 mg/ 5 ml Solution is not recommended for children under 6 years of age.

Take special care with Cetrex 5 mg/ 5 ml Solution

- If you have ever had any kidney problems, tell your doctor or pharmacist before taking this medicine, as you might only 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.

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 allergy test 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
Cetrex 5 mg/ 5 ml Solution does not normally cause drowsiness at the recommended dose. However, individuals react differently so if affected, you should not drive or operate machinery.

Important information about some of the ingredients of Cetrex 5 mg/ 5 ml Solution
Your medicine contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216). These ingredients may cause allergic reactions (possibly delayed).
This 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 medicinal product.

3. HOW TO TAKE CETREX 5 MG/ 5 ML SOLUTION

Always take Cetrex 5 mg/ 5 ml Solution exactly as your doctor has told you. You should check with your doctor or your pharmacist if you are not sure.

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.

Method of administration
Take Cetrex 5 mg/ 5 ml Solution orally.

If you take more Cetrex 5 mg/ 5 ml Solution 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, blurred vision, dry mouth and drowsiness. Do not drive if you have taken too much of your medicine.

If you forget to take Cetrex 5 mg/ 5 ml Solution
If you forget to take you 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 you doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Cetrex 5 mg/ 5 ml Solution can cause side effects, although not everybody gets them.
The following side effects have been reported:

Uncommon (seen in more than 1 in 1,000 patients but less than 1 in 100 patients): Diarrhoea, fatigue, uneasiness, agitation, itching, pricking or numbness of skin or rash.

Rare (seen in more than 1 in 10,000 patients but less than 1 in 1,000 patients): Rapid heartbeat, inflammation of the skin, allergic reactions, abnormal liver function, weight increase, fits, aggression, confusion, depression, hallucination, sleeping problems, hives.

Very rare (seen in less than 1 in 10,000 patients): bruise easily, difficulty focussing, blurred vision, dizziness, loss of consciousness, difficulty breathing, swelling of the tongue, change in sense of taste, blackouts, loss of control of bladder, difficulty urinating or experiencing pain while urinating, skin inflammation.

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.

5. HOW TO STORE CETREX 5 MG/ 5 ML SOLUTION

Keep out of the reach and sight of children.

The expiry date is stated on the label. "Exp" is short for expiry. Do not take your medicine after this date.
Once opened, the content of the bottle should be used within 2 months.

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. FURTHER INFORMATION

What Cetrex 5 mg/ 5 ml Solution contain
The active substance is Cetirizine hydrochloride. Each ml of solution contains 1 mg of cetirizine hydrochloride. The solution also contains methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), sorbitol, glycerol, sodium citrate, propylene glycol, monoammonium glycerrhizinate, pineapple flavour, sweet orange flavour and citric acid.

What Cetrex 5 mg/ 5 ml Solution looks like and contents of the pack
Cetrex 5 mg/ 5 ml Solution is a clear, colourless, pineapple and sweet orange flavoured solution with a sweet taste.
Cetrex 5 mg/ 5 ml Solution is available in 70 ml bottles.

Marketing Authorisation Holder and Manufacturer
The Marketing Authorisation holder is Cipla Chanelle Ltd., Loughrea, Co Galway, Ireland.
The manufacturer is Chanelle Medical, Loughrea, Co. Galway, Ireland.
The distributor is **Chanelle Medical U.K. Ltd.**

This leaflet was last approved in: 05/2007 LA2387

PATIENT INFORMATION LEAFLET

PLIVA PHARMA LTD.

PACKAGE LEAFLET: INFORMATION FOR THE USER

Cetrase 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 Cetrase 5mg/5ml Solution 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 your pharmacist.

In this leaflet:

❶ What Cetrase 5mg/5ml Solution 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 antihistamines, used to relieve symptoms of hay fever and other allergic conditions.

This medicine treats people suffering from 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) in adults and children aged 6 years and over.

Antihistamines such as Cetrase 5mg/5ml Solution relieve the unpleasant symptoms such as sneezing, an itchy, runny and blocked-up nose, itchy, red and watery eyes and itchy skin rashes, associated with this condition.

❷ Before you take Cetrase 5mg/5ml Solution

Do not take Cetrase 5mg/5ml Solution

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

Cetrase 5mg/5ml Solution is not recommended for children under 6 years of age.

Take special care with Cetrase 5mg/5ml Solution

- If you have ever had any kidney problems, tell your doctor or pharmacist before taking this medicine, as you might only 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.

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 allergy test 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

Cetrase 5mg/5ml Solution does not normally cause drowsiness at the recommended dose. However, individuals react differently so if affected, you should not drive or operate machinery.

Important information about some of the ingredients of Cetrase 5mg/5ml Solution

Your medicine contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216). These ingredients may cause allergic reactions (possibly delayed).

This 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 medicinal product.

❸ How to take Cetrase 5mg/5ml Solution

Always take Cetrase 5mg/5ml Solution exactly as your doctor has told you. You should check with your doctor or your 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 between 6 to 11 years:
Either 5ml twice daily or 10ml once daily.

Method of administration

Take Cetrase 5mg/5ml Solution solution orally.

If you take more Cetrase 5mg/5ml Solution 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, blurred vision, dry mouth and drowsiness. Do not drive if you have taken too much of your medicine.

If you forget to take Cetrase 5mg/5ml Solution

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.

❹ Possible side effects

Like all medicines, Cetrase 5mg/5ml Solution can cause side effects, although not everybody gets them.

The following side effects have been reported:

Uncommon (seen in more than 1 in 1,000 patients but less than 1 in 100 patients):

diarrhoea, fatigue, uneasiness, agitation, itching, pricking or numbness of skin or rash.

Rare (seen in more than 1 in 10,000 patients but less than 1 in 1,000 patients):

Rapid heartbeat, inflammation of the skin, allergic reactions, abnormal liver function, weight increase, fits, aggression, confusion, depression, hallucination, sleeping problems, hives.

Very rare (seen in less than 1 in 10,000 patients):

bruise easily, difficulty focussing, blurred vision, dizziness, loss of consciousness, difficulty breathing, swelling of the tongue, change in sense of taste, blackouts, loss of control of bladder, difficulty urinating or experiencing pain while urinating, skin inflammation.

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.

❺ How to store Cetrase 5mg/5ml Solution

Keep out of the reach and sight of children.

The expiry date is stated on the label. 'Exp' is short for expiry. Do not take your medicine after this date.

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

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.

❻ Further information

What Cetrase 5mg/5ml Solution contains

The active substance is Cetirizine hydrochloride. Each ml of solution contains 1mg of cetirizine hydrochloride. The solution also contains methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), sorbitol, glycerol, sodium citrate, propylene glycol, monoammonium glycerrhizinate, pineapple flavour, sweet orange flavour and citric acid.

What Cetrase 5mg/5ml Solution looks like and contents of the pack

Cetrase 5mg/5ml Solution is a clear, colourless, pineapple and sweet orange flavoured solution with a sweet taste.

Cetrase 5mg/5ml Solution is available in 70ml bottles.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation holder is

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

The manufacturer is

Chanelle Medical,
Loughrea, Co. Galway, Ireland.

The distributor is PLIVA Pharma Ltd.

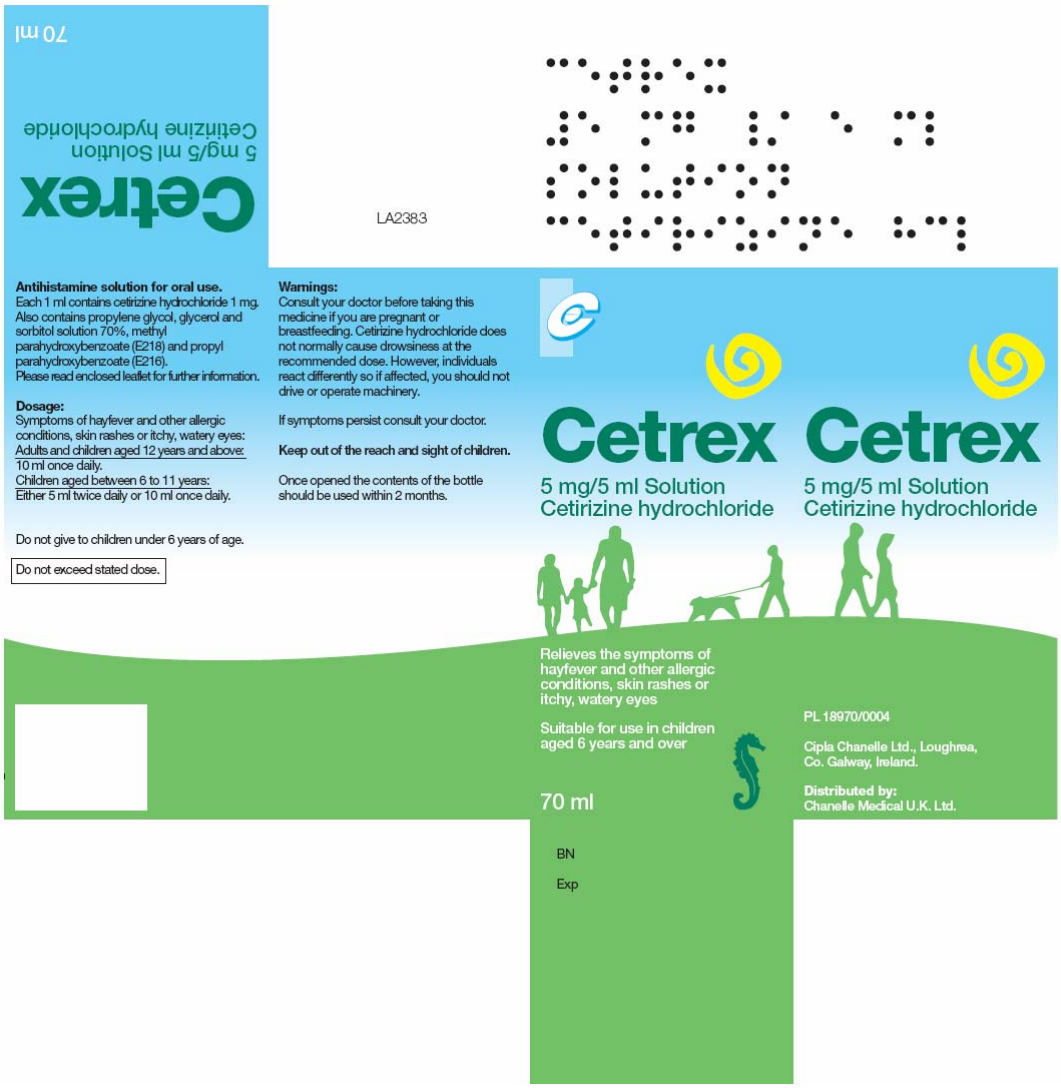
This leaflet was last approved in: 05/2007

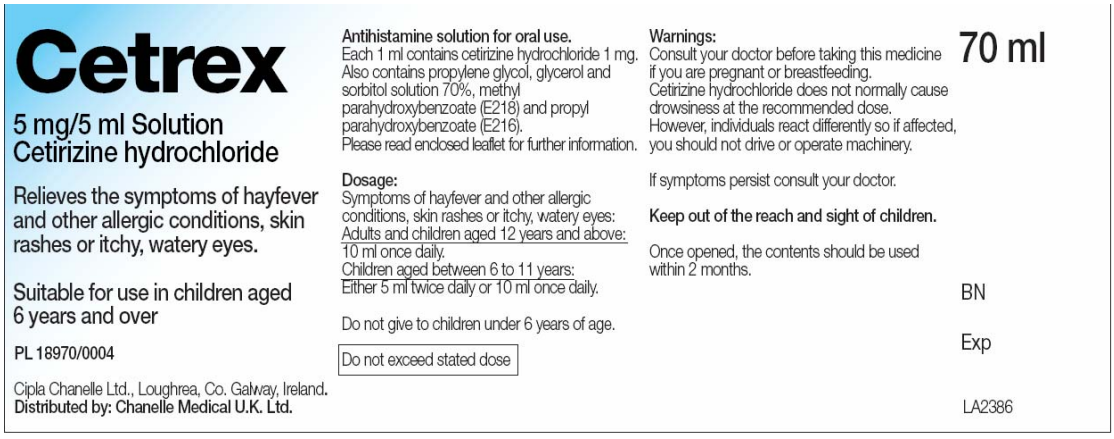
PL 18970/0004
56767-P1
LA2596

PLIVA

LABELLING

CIPLA CHANELLE LTD.





LABELLING

PLIVA PHARMA LTD.

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

Please read enclosed leaflet for further information.

Dosage:
Symptoms of hayfever and other allergic conditions, skin rashes 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 6 years of age.

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

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

MA Holder:
Cipla Chanelle Ltd,
Loughrea, Co. Galway, Ireland.
Distributed by:
PLIVA Pharma Ltd,
Vision House, Bedford Road,
Petersfield, Hampshire,
GU32 3QB, UK.

PL 18970/0004
56767-C1

DO NOT EXCEED THE STATED DOSE

PLIVA

Cetrase
5mg/5ml Solution
Cetirizine hydrochloride

Relieves symptoms from seasonal and year round hayfever, skin rashes and itchy, watery eyes.
Suitable for use in adults and children aged 6 years and over.

Batch:
Exp:

Cetrase
5mg/5ml Solution
Cetirizine hydrochloride

Relieves symptoms from seasonal and year round hayfever, skin rashes and itchy, watery eyes.
Suitable for use in adults and children aged 6 years and over.

70ml

LA2598

5 020220 567676

Cetrase 5mg/5ml Solution 70ml
Cetirizine hydrochloride

Relieves symptoms from seasonal and year round hayfever, skin rashes and itchy, watery eyes. Suitable for use in adults and children aged 6 years and over.
Antihistamine solution for oral use.
Each 1ml contains cetirizine hydrochloride 1mg.
Also contains propylene glycol, glycerol and sorbitol solution 70%, methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216). Please read enclosed leaflet for further information.
Dosage: Symptoms of hayfever and other allergic conditions, skin rashes 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 6 years of age.

DO NOT EXCEED THE STATED DOSE

Warnings:
Consult your doctor before taking this medicine if you are pregnant or breast-feeding.
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.

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