CETIRIZINE HYDROCHLORIDE 10MG FILM-COATED TABLETS (PL 08137/0269)

UKPAR

TABLE OF CONTENTS

CETIRIZINE HYDROCHLORIDE 10MG FILM-COATED TABLETS (PL 08137/0269)

LAY SUMMARY

On 13 October 2009, the MHRA granted Neolab Limited a Marketing Authorisation (licence) for the medicinal product Cetirizine Hydrochloride 10mg Film-Coated Tablets (PL 08137/0269). This is a pharmacy medicine (P) for the relief of symptoms of seasonal allergic rhinitis (e.g. hay fever), perennial allergic rhinitis (e.g. year round allergies often due to dust mites or animal allergies) and urticaria (itchy, red, swollen skin). These symptoms include itchy skin rashes; sneezing; itchy, runny or blocked nose; red, itchy and watering eyes.

The active ingredient is cetirizine hydrochloride, which belongs to a group of medicines called antihistamines.

No new or unexpected safety concerns arose from these applications and it was, therefore, judged that the benefits of taking Cetirizine Hydrochloride 10mg Film-Coated Tablets outweigh the risks, hence a Marketing Authorisation has been granted.

CETIRIZINE HYDROCHLORIDE 10MG FILM-COATED TABLETS (PL 08137/0269)

SCIENTIFIC DISCUSSION

TABLE OF CONTENTS

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 10mg Film-Coated Tablets (PL 08137/0269) on 13th October 2009. The product is a Pharmacy medicine (P).

The application was submitted as simple abridged application according to article 10.1(c) of Directive 2001/83/EC, cross-referring to Cetirizine Hydrochloride 10mg Film-Coated Tablets (PL 08137/0053) granted to Neolab Limited on 17th June 2002.

No new data were submitted nor was it necessary for this simple application, as the data is identical to that of the previously granted cross-reference product. As the cross-reference product was granted prior to the introduction of current legislation, no PAR was generated.

Cetirizine Hydrochloride 10mg Film-Coated Tablets are indicated for the symptomatic treatment of allergic rhinitis (seasonal and perennial) associated allergic conjunctivitis (adults over 12 only), and chronic idiopathic urticaria.

The product contains the active substance cetirizine hydrochloride, which is one of a group of medicines called antihistamines.

PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 08137/0269
PROPRIETARY NAME: Cetirizine Hydrochloride 10mg Film-Coated Tablets
ACTIVE(S): Cetirizine hydrochloride
COMPANY NAME: Neolab Limited
E.C. ARTICLE: Article 10c (formerly 10.1(a)(i)) of Directive 2001/83/EC
LEGAL STATUS: P

1. INTRODUCTION

This is a simple, piggy back application for Cetirizine Hydrochloride 10mg Film-Coated Tablets submitted under Article 10c (formerly 10.1(a)(i)) of Directive 2001/83/EC. The proposed MA holder is Neolab Limited, 57 High Street, Odiham, Hants, RG29 1LF.

This application cross refers to Marketing Authorisation application for Cetirizine Hydrochloride 10mg Film-Coated Tablets (PL 08137/0053), which is currently registered in the UK. This application is considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 Name(s)

The proposed name of the products is Cetirizine Hydrochloride 10mg Film-Coated Tablets. The product has been named in line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes

The product contains cetirizine hydrochloride, equivalent to 10mg. They are to be stored in polyvinylchloride/aluminium foil blister packs contained in cardboard cartons in pack sizes of 7 and 14 tablets.

The proposed shelf-life of 3 years, with no specific storage instructions is consistent with the cross-reference product.

2.3 Legal status

On approval, the product will be subject to sale in a pharmacy only (P).

2.4 Marketing authorisation holder/Contact Persons/Company

The proposed Marketing Authorisation holder is Neolab Limited, 57 High Street, Odiham, Hants, RG29 1LF.

The QP responsible for pharmacovigilance is stated and their CV is included.

2.5 Manufacturers

The proposed manufacturing sites are consistent with those registered for the cross-reference product and evidence of GMP compliance has been provided.

2.6 Qualitative and quantitative composition

The proposed composition is consistent with the details registered for the cross-reference product.

2.7 Manufacturing process
The proposed manufacturing process is consistent with the details registered for the cross-reference product and the maximum batch size is stated.

2.8 Finished product/shelf-life specification
The proposed finished product specification is in line with the details registered for the cross-reference product.

2.9 Drug substance specification
The proposed drug substance specification is consistent with the details registered for the cross-reference product.

2.10 TSE Compliance
With the exception of lactose monohydrate, none of the excipients are sourced from animal or human origins. The suppliers of lactose monohydrate have stated that the lactose is sourced from healthy animals under the same conditions as milk for human consumption.

3. EXPERT REPORTS
The applicant has included detailed expert reports in Module 2 of the application. Signed declarations and copies of the experts' CVs are enclosed in Module 1.4 for the quality, non-clinical and clinical experts. All are considered to have sufficient experience for their responsibilities.

4. PRODUCT NAME & APPEARANCE
See 2.1 for details of the proposed product name. The appearance of the product is identical to the cross-reference product.

5. SUMMARY OF PRODUCT CHARACTERISTICS (SPC)
The proposed SPC is consistent with the details registered for the cross-reference product.

6. PATIENT INFORMATION LEAFLET/CARTON
PIL

The patient information leaflet has been prepared in-line with the details registered for the cross-reference product.

Carton and blister

The proposed artwork is comparable to the artwork registered for the cross-reference product and complies with statutory requirements. In line with current legislation the applicant has also included sufficient space for a standard UK pharmacy dispensing label.

7. CONCLUSIONS
The data submitted with the application are acceptable. The grant of a Marketing Authorisation is recommended.

PRECLINICAL ASSESSMENT

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

CLINICAL ASSESSMENT

No new clinical data have been supplied with this application and none are required for an application of this type.

OVERALL CONCLUSION AND RISK-BENEFIT ASSESSMENT

QUALITY

The data for this application are consistent with that previously assessed for the cross-reference product and as such have been judged to be satisfactory.

PRECLINICAL

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

EFFICACY

Cetirizine hydrochloride is a well-known drug and has been used as an antihistamine for many years. This application is identical to a previously granted application for Cetirizine Hydrochloride 10mg Film-Coated Tablets (PL 08137/0053), granted to Neolab Limited on 17th June 2002.

No new or unexpected safety concerns arise from these applications.

The SPC, PIL and labelling are satisfactory and consistent with that for the cross-reference product.

RISK BENEFIT ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant's product is identical to the cross-reference product. Extensive clinical experience with cetirizine hydrochloride is considered to have demonstrated the therapeutic value of the compound. The risk-benefit is, therefore, considered to be positive.

CETIRIZINE HYDROCHLORIDE 10MG FILM-COATED TABLETS (PL 08137/0269)

STEPS TAKEN FOR ASSESMENT

1	The MHRA received the marketing authorisation applications on 21st January 2009
2	Following standard checks and communication with the applicant the MHRA considered the applications valid on 19th February 2009
3	Following assessment of the applications the MHRA requested further information on 17th April 2009 and 29th June 2009.
4	The applicant responded to the MHRA's requests, providing further information on 6th May 2009 and 17th August 2009
5	The applications were determined on 13th October 2009

CETIRIZINE HYDROCHLORIDE 10MG FILM-COATED TABLETS (PL 08137/0269)

STEPS TAKEN AFTER AUTHORISATION - SUMMARY

Date submitted	Application type	Scope	Outcome

1 NAME OF THE MEDICINAL PRODUCT

Cetirizine hydrochloride 10 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One film-coated tablet contains cetirizine hydrochloride 10 mg.
Each tablet contains 100.20 mg of lactose monohydrate.
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.
White, round tablets with a break line on one side and embossed with A on the other.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Adults and adolescents over 12 years of age:
Symptomatic treatment of allergic rhinitis (seasonal and perennial) associated allergic conjunctivitis, and chronic idiopathic urticaria.

Children 6-12 years:
Symptomatic treatment of allergic rhinitis (seasonal and perennial), and chronic idiopathic urticaria.

4.2 Posology and method of administration

Adults and adolescents over 12 years of age: 1 tablet (10 mg) once daily.
If drowsiness occurs, the tablet can be administered in the evening.

Children 6-12 years:
1 tablet (10 mg) once daily or ½ tablet (5mg) taken twice daily (morning and evening)

For children weighing less than 30 kg:
½ tablet (5mg) taken once daily.

Clinical trials in children have not exceeded four weeks.

Cetirizine is contraindicated in patients with severe renal impairment. In patients with moderate renal impairment the dose should be adjusted to 5 mg (½ tablet a day). Caution should be exercised in patients with mild to moderate renal impairment or impaired liver function.(see 4.4 Special warning and precautions for use).

There is no evidence that the dose needs to be modified for healthy elderly patients.

The duration of the treatment may vary depending on the symptoms.

4.3 Contraindications

Cetirizine hydrochloride 10 mg film coated tablets are contraindicated in
- patients with hypersensitivity to cetirizine hydrochloride or to any of the excipients
- In children under six years of age
- Patients with severe renal impairment

4.4 Special warnings and precautions for use

In some patients, long term treatment with cetirizine tablets may lead to an increased risk of caries due to mouth dryness. The patients should therefore be informed about the importance of oral hygiene.

At impaired hepatic function and renal function, the elimination of cetirizine may be impaired. Caution should be exercised when administering cetirizine to these patients. (see section 4.2 posology and section 4.3 contraindications).

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Cetirizine may potentiate the effects of alcohol. Therefore caution is recommended at concomitant use of alcohol.

Caution is recommended with concomitant use of CNS depressants.

4.5 Interaction with other medicinal products and other forms of interaction

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

Cetirizine may potentiate the effects of alcohol. Therefore caution is recommended at concomitant use of alcohol. Caution is recommended with the concomitant use of CNS depressants.

4.6 Pregnancy and lactation

Data on limited number of exposed pregnancies indicate no adverse effects of cetirizine on pregnancy or on health of foetus/new born child. To date no other relevant epidemiological data are available.

Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal / foetal development, parturition or post natal development (see section 5.3). Caution should be exercised when prescribing to pregnant women.

Breast feeding
No data concerning the excretion of cetirizine into human milk are available. Cetirizine should be avoided during lactation.

4.7 Effects on ability to drive and use machines

Cetirizine may have minor or moderate influence on the patient's ability to drive and use machines.

This should be considered when extra alertness is required e.g. when driving. Cetirizine may potentiate the effects of alcohol and CNS depressants.

4.8 Undesirable effects

Frequency estimates: Common (>1/100, <1/10); Uncommon (>1/1,000, <1/100); Rare (>1/10,000, <1/1,000); Very rare (<1/10,000):

Blood and lymphatic system disorders:
Very rare: thrombocytopenia

Immune system disorders:
Rare: Allergic reactions (see Skin and subcutaneous disorders)
Very rare: Anaphylactic shock

Psychiatric disorders:
Uncommon : Agitation
Rare: Aggression, confusion, depression, hallucination, insomnia

Nervous system:
Common: Somnolence, drowsiness
Uncommon: Headache, dizziness, paraesthesia.
Rare: Convulsions, movement disorders
Very rare : Dysgeusia, syncope

Eye disorders:
Very rare: Accommodation disorder, blurred vision

Cardiac disorders:
Rare: Tachycardia

Gastrointestinal disorders:

Common: dry mouth
Uncommon: gastrointestinal disorders (nausea, diarrhoea, abdominal pain, dyspepsia)

Hepatobiliary disorders:
Rare: Abnormal hepatic function (increased transaminases, alkaline phosphatase, gamma-GT, bilirubin)

Skin and subcutaneous tissue disorders:
Uncommon : Skin rash, pruritus
Rare: Urticaria
Very rare: Angioedema, erythema multiforme

Renal and urinary disorders:
Very rare: Dysuria, enuresis, micturition difficulties

General disorders:
Uncommon: asthenia, malaise
Rare: Oedema, weight increase

4.9 Overdose

There is limited experience of overdosing. 20 mg to a 2-year-old, 30 mg to a 3-year-old and 40 mg to an 11-year-old did not give any symptoms. 60 mg to a 4-year-old gave mild intoxication, 400 mg to a 14-year-old gave mild symptoms, while 400 to 500 mg to an adult gave no symptoms at all.

a) Symptoms
Cetirizine has a low sedative and anticholinergic effect. Adverse events reported after intake of at least five 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 four hours after ingestion, and the 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 (50 g for an adult, 10-15 g for a child) should be considered if more than 2.5 mg/kg cetirizine has been ingested within one hour,

There is no specific antidote.

Cetririzine is not effectively removed by dialysis

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: R06AE07

Pharmacotherapeutic group: Antihistamine for systemic use, piperazine derivative

Cetirizine hydrochloride is a racemate and an anti-allergic with specific histamine H1-receptor blocking characteristics.

Cetirizine inhibits cutaneous reactions in allergic individuals by VIP (Vasoactive Intestinal Polypeptide) and the P substance, neuropeptides that are considered involved in the allergic reaction. Effect is reached within 2 hours with a maximum effect after 4 hours, and remains for at least 24 hours. In allergic individuals, cetirizine inhibits the recruitment of eosinophiles after simulation with allergens and unselective histamine liberators, by a mechanism that is not primarily explained by the H1-receptor blocking characteristics of the pharmaceutical.

5.2 Pharmacokinetic properties

Cetirizine is absorbed with small inter-individual variations. Cetirizine has not been given intravenously, therefore the bioavailability, clearance and distribution volume (Vd) are unknown. Maximum plasma concentration is achieved within 1 hour and the terminal half-life is about 10 hours in adults and 6 hours in children between ages of 6-12 years. The grade of protein binding in plasma is about 93%. Cetirizine is metabolised to a small extent with a known inactive main metabolite. Cetirizine is eliminated to 60% in unchanged form via the kidneys within 96 hours. At repeated administration there is no accumulation at hand, nor is absorption or elimination affected. With impaired kidney function, the elimination is slower and the half-life is prolonged. Elimination will also be decreased in cases of hepatic impairment. There is no evidence that the pharmacokinetics of cetirizine is altered in elderly patients unless renal or hepatic function is reduced.

5.3 Preclinical safety data

Preclinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, toxicity to reproduction, genotoxicity or carcinogenicity.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core
Lactose monohydrate
Microcrystalline cellulose
Colloidal anhydrous silica
Maize starch
Talc
Magnesium stearate

Coating
Titanium dioxide (E171)
Hypromellose
Lactose monohydrate
Macrogol
Sodium citrate

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years.

6.4 Special precautions for storage

No special precautions for storage.

6.5 Nature and contents of container

Blister comprising of PVC/Aluminium foil with 7, and 14 tablets.
Not all packs may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Neolab Limited
57 High Street
Odiham
Hants
RG29 1LF

8 MARKETING AUTHORISATION NUMBER(S)
PL 08137/0269

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
13/10/2009

10 DATE OF REVISION OF THE TEXT
13/10/2009

PATIENT INFORMATION LEAFLET
CETIRIZINE HYDROCHLORIDE 10 mg FILM-COATED TABLETS
(cetirizine hydrochloride)

The name of this medicine is Cetirizine Hydrochloride 10 mg Film-Coated Tablets, which will be referred to as Cetirizine Tablets throughout this leaflet.

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- Do not pass this medicine on to others; it may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in the leaflet, please tell your doctor or pharmacist.

In this leaflet

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

The active ingredient in your tablets is cetirizine hydrochloride, which belongs to a group of medicines called antihistamines. These are used to relieve the symptoms of seasonal allergic rhinitis (e.g. hay fever), perennial allergic rhinitis (e.g. year round allergies often due to house dust mites or animal allergies) and urticaria (itchy, red, swollen skin). These symptoms include itchy skin rashes; sneezing; itchy, runny or blocked nose; red, itchy and watering eyes.

2. BEFORE YOU TAKE CETIRIZINE TABLETS

Do not take Cetirizine Tablets if you:
- are **allergic (hypersensitive)** to **cetirizine hydrochloride**, or any of the **other ingredients** in Cetirizine Tablets (these are listed in section 6, Further Information)
- are **breast-feeding**
- suffer from **severe kidney problems**

Cetirizine Tablets are not for use in children under 6 years of age.

Take special care with Cetirizine Tablets
Before you take Cetirizine Tablets you should tell your doctor if you:
- are pregnant, think you might be pregnant or are planning to become pregnant
- have liver or kidney problems
- have to have any allergy test (you should stop taking Cetirizine Tablets 3 days before you have the tests done).

Taking other medicines
Please tell your doctor if you are taking or have recently taken any of the following medicines, as they may decrease or increase the effect of Cetirizine Tablets and vice versa.
- medication for anxiety or stress (CNS depressants)

It may still be alright for you to take Cetirizine Tablets and your doctor will be able to decide what is suitable for you. Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking your medicine with food and drink
Cetirizine Tablets can be taken with or without food. Avoid alcohol consumption whilst taking Cetirizine Tablets.

Pregnancy and breast-feeding
Tell your doctor if you are pregnant, think you might be pregnant, or are planning to become pregnant. Do not take Cetirizine Tablets whilst breast-feeding.

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

Driving and using machines

If you experience any tiredness, confusion and/or blurring of vision whilst taking Cetirizine Tablets do not drive or operate machines.

Important information about some of the ingredients of Cetirizine Tablets
This product 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 TABLETS

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

Dosage
The usual dosage is:

Adults, elderly and children over 12 years: Take one tablet (10mg) once daily.

Children aged 6 - 12 years: Take one tablet (10mg) once daily or half a tablet (5mg) twice daily (morning and evening).

Children weighing less than 30 kg: Half a tablet (5 mg) should be taken once daily.

Not recommended for children under 6 years of age.

If drowsiness occurs, your tablet can be taken in the evening.

If you have kidney problems talk to your doctor before taking this medicine. You may need a different dose to that stated above.

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CETIRIZINE HYDROCHLORIDE 10 mg FILM-COATED TABLETS

CETIRIZINE HYDROCHLORIDE 10 mg FILM-COATED TABLETS

Method of administration

For oral use.

If you take more Cetirizine Tablets than you should

If you have accidentally taken more than the recommended dose, contact your nearest hospital casualty department or tell your doctor or pharmacist **immediately**. Remember to take the pack and any remaining tablets with you.

The most common signs and symptoms of overdose may include feeling unwell, confused, restless, shaky, dizzy, tired or very sleepy. You may also notice a rapid heart beat, having dilated pupils or blurred vision, and experience headache, itching, diarrhoea, or difficulty urinating.

If you forget to take Cetirizine Tablets

If you have forgotten to take your tablet, take it as soon as you remember and then wait 24 hours before taking your next 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 Tablets can cause side effects, although not everybody gets them. If you get any of the following symptoms after taking these tablets **you should contact your doctor immediately:**

- **any sudden wheeziness, difficulty in breathing**
- **dizziness**
- **swelling of the eyelids, face, lips or throat**

The following side effects have also been reported:

Common side effects (seen in less than 1 in 10 patients but in more than 1 in 100 patients):
- drowsiness
- dry mouth

Uncommon side effects (seen in less than 1 in 100 patients but in more than 1 per 1000 patients):
- agitation
- headache, dizziness
- paraesthesia (feeling of pins and needles)
- nausea (feeling sick)
- diarrhoea, stomach ache, indigestion
- rash, itching, hives
- feelings of weakness

Rare side effects (seen in less than 1 in 1000 patients):
- feelings of aggression, confusion and depression
- hallucinations
- difficulty in sleeping
- convulsions, unusual movement of limbs
- rapid heart beat
- oedema (swelling of the feet or ankles)
- unusual weight gain
- changes in liver function tests, indicating the possibility of damage to the liver.

Page 3

Very rare side effects (seen in less than 1 in 10,000 patients):
- distorted sense of taste
- fainting, blurred vision
- severe blistering skin rash
- difficult and/or painful urination
- loss of urinary control
- an increased tendency to bruise or bleed easily

Long term treatment with Cetirizine Tablets can lead to a dry mouth, it is therefore important that adequate oral hygiene is maintained.

If any of these 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 CETIRIZINE TABLETS

Keep out of the reach and sight of children.

Do not take this medicine after the expiry date (Exp.) stated. 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. FURTHER INFORMATION

What Cetirizine Tablets contain:

The active ingredient is cetirizine hydrochloride. Each tablet contains 10 mg of cetirizine hydrochloride.

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

What Cetirizine Tablets look like and the contents of the pack:

Cetirizine Tablets are round, white, film coated tablets, with an "A" marked on one side, and with a break-line on the other.

Your medicine is available in packs containing 7 and 14 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Neolab Limited
57 High Street
Odiham
Hants. RG29 1LF.

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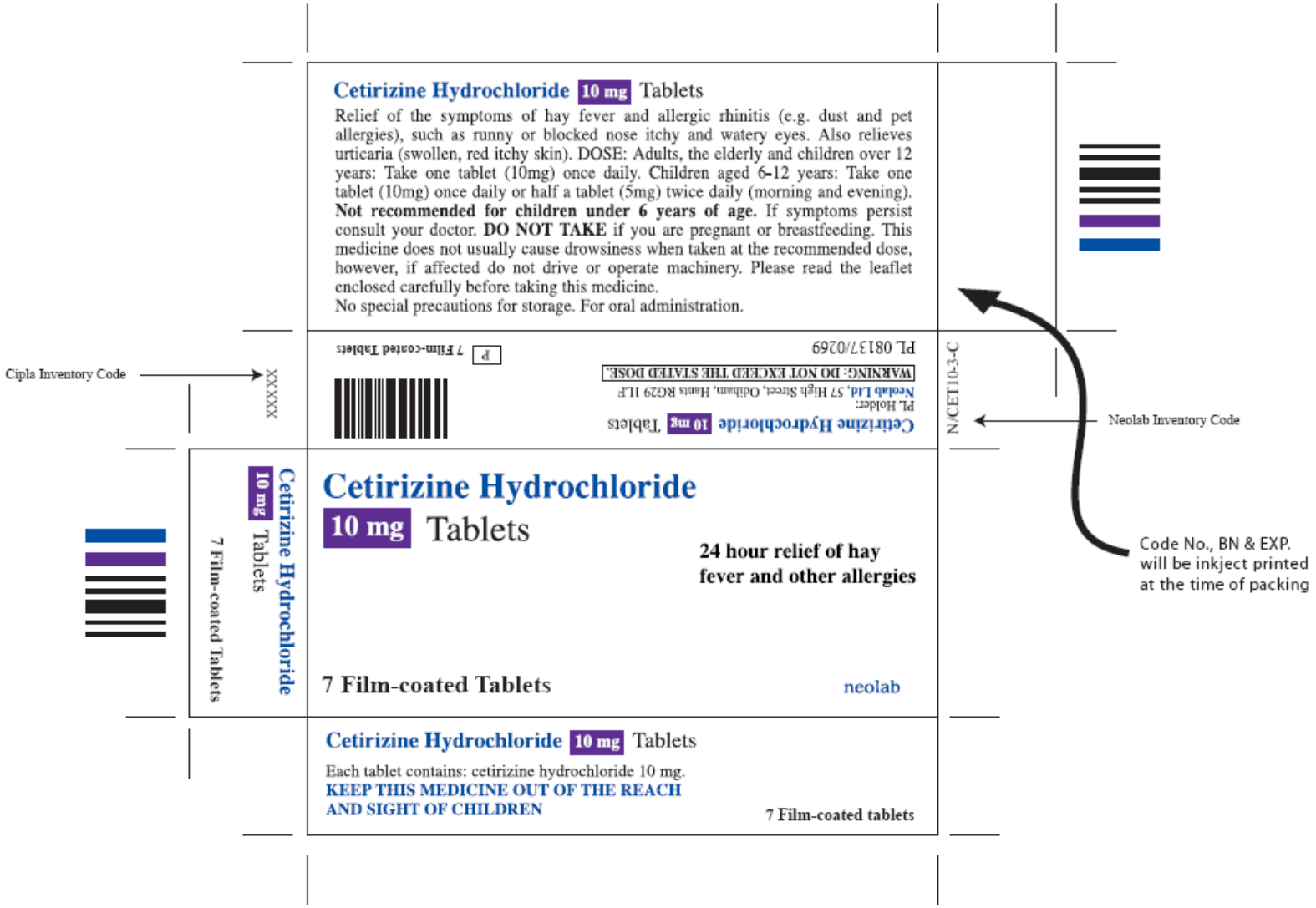
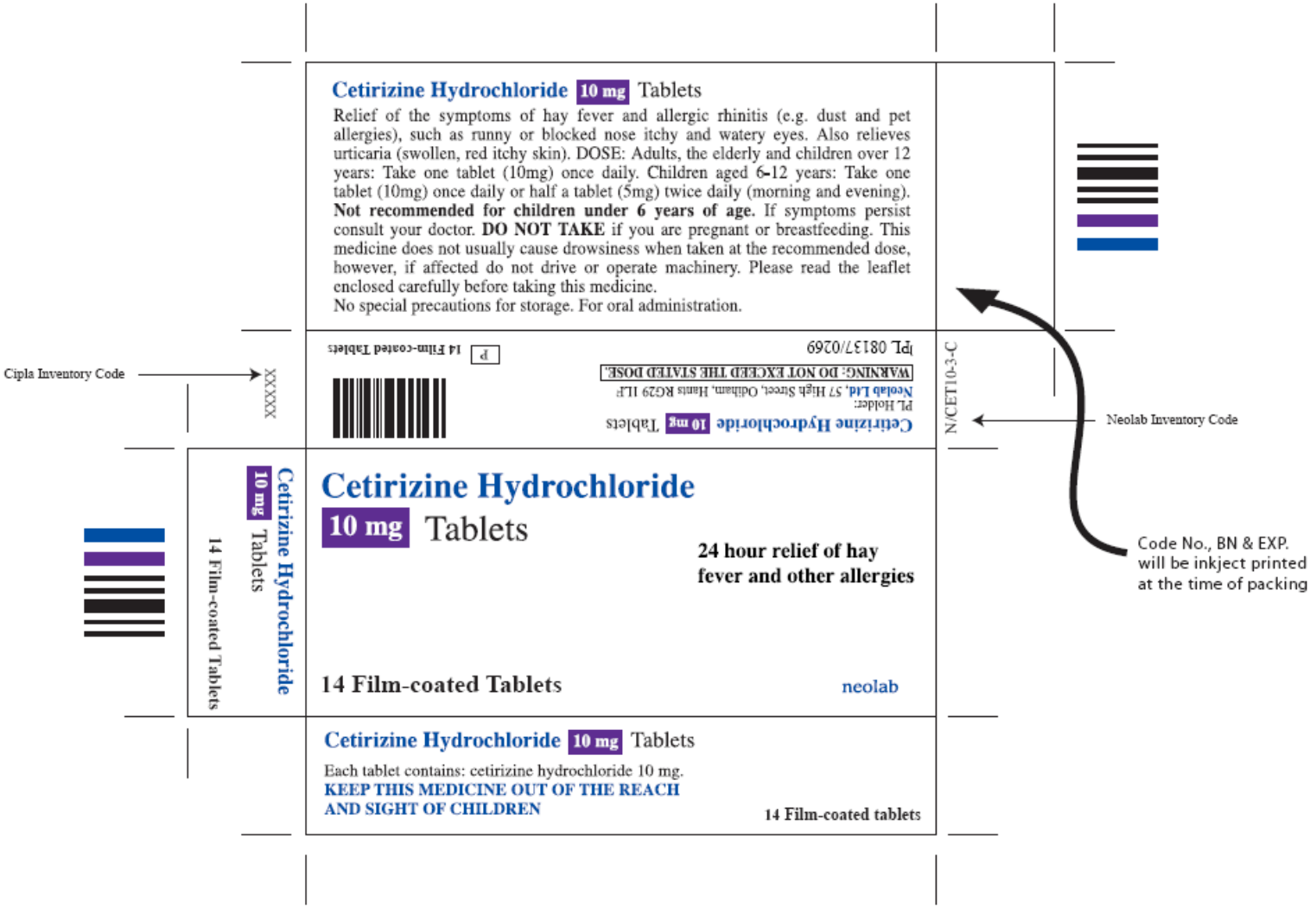
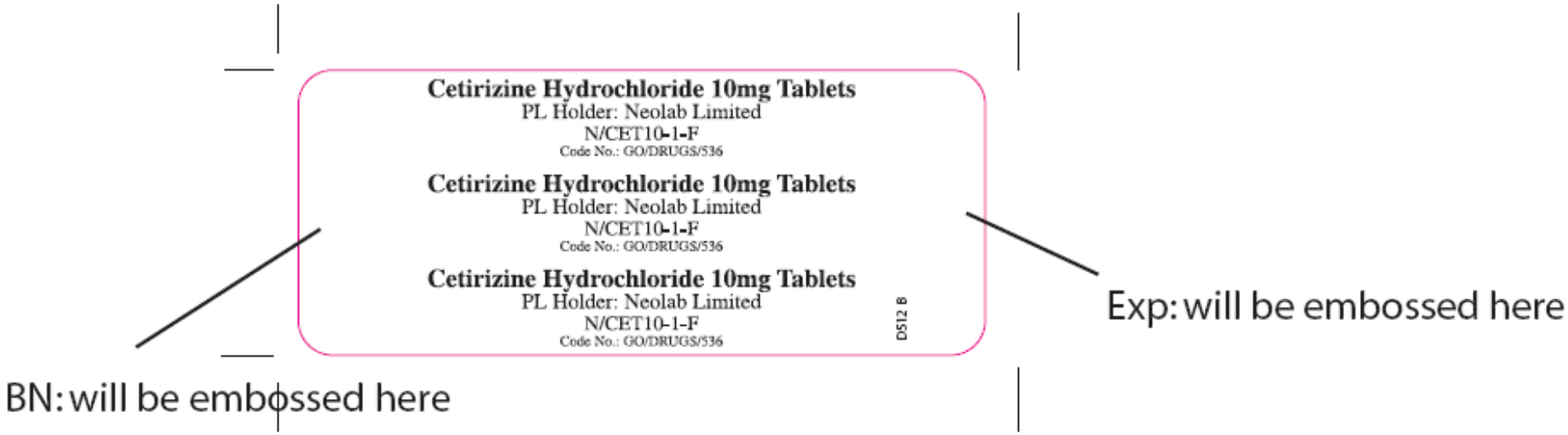
This information is available in alternative formats upon request.

This leaflet was last approved in August 2009

Page 4


Cetirizine Hydrochloride 10 mg Tablets
Relief of the symptoms of hay fever and allergic rhinitis (e.g. dust and pet allergies), such as runny or blocked nose itchy and watery eyes. Also relieves urticaria (swollen, red itchy skin). DOSE: Adults, the elderly and children over 12 years: Take one tablet (10mg) once daily. Children aged 6-12 years: Take one tablet (10mg) once daily or half a tablet (5mg) twice daily (morning and evening). Not recommended for children under 6 years of age. If symptoms persist consult your doctor. DO NOT TAKE if you are pregnant or breastfeeding. This medicine does not usually cause drowsiness when taken at the recommended dose, however, if affected do not drive or operate machinery. Please read the leaflet enclosed carefully before taking this medicine.
No special precautions for storage. For oral administration.
Cipla Inventory Code
XXXXX
7 Film-coated Tablets
PL 08137/0269
WARNING: DO NOT EXCEED THE STATED DOSE.
Neolab Ltd, 57 High Street, Odiham, Hants RG29 1LF
PL Holder:
Cetirizine Hydrochloride 10 mg Tablets
N/CET10-3-C
Neolab Inventory Code
Cetirizine Hydrochloride
10 mg Tablets
24 hour relief of hay fever and other allergies
7 Film-coated Tablets
neolab
Cetirizine Hydrochloride 10 mg Tablets
Each tablet contains: cetirizine hydrochloride 10 mg.
KEEP THIS MEDICINE OUT OF THE REACH AND SIGHT OF CHILDREN
7 Film-coated tablets
Code No., BN & EXP. will be inkject printed at the time of packing


Cetirizine Hydrochloride 10 mg Tablets
Relief of the symptoms of hay fever and allergic rhinitis (e.g. dust and pet allergies), such as runny or blocked nose itchy and watery eyes. Also relieves urticaria (swollen, red itchy skin). DOSE: Adults, the elderly and children over 12 years: Take one tablet (10mg) once daily. Children aged 6-12 years: Take one tablet (10mg) once daily or half a tablet (5mg) twice daily (morning and evening). Not recommended for children under 6 years of age. If symptoms persist consult your doctor. DO NOT TAKE if you are pregnant or breastfeeding. This medicine does not usually cause drowsiness when taken at the recommended dose, however, if affected do not drive or operate machinery. Please read the leaflet enclosed carefully before taking this medicine.
No special precautions for storage. For oral administration.
Cipla Inventory Code
XXXXX
14 Film-coated Tablets
P
PL 08137/0269
WARNING: DO NOT EXCEED THE STATED DOSE.
PL Holder:
Neolab Ltd, 57 High Street, Odiham, Hants RG29 1LF
Cetirizine Hydrochloride 10 mg Tablets
N/CET10-3-C
Neolab Inventory Code
Cetirizine Hydrochloride
10 mg Tablets
24 hour relief of hay fever and other allergies
14 Film-coated Tablets
neolab
Cetirizine Hydrochloride 10 mg Tablets
14 Film-coated Tablets
Cetirizine Hydrochloride 10 mg Tablets
Each tablet contains: cetirizine hydrochloride 10 mg.
KEEP THIS MEDICINE OUT OF THE REACH AND SIGHT OF CHILDREN
14 Film-coated tablets
Code No., BN & EXP. will be inkject printed at the time of packing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PL Holder: Neolab Limited
N/CET10-1-F
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N/CET10-1-F
Code No.: GO/DRUGS/536
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PL Holder: Neolab Limited
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D512 B
BN: will be embossed here
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