Chlorphenamine 4mg Tablets

PL 36722/0056

UKPAR

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CHLORPHENAMINE 4MG TABLETS

PL 36722/0056

LAY SUMMARY

This is a summary of the public assessment report (PAR) for Chlorphenamine 4mg Tablets (PL 36722/0056). It explains how Chlorphenamine 4mg Tablets were assessed and their authorisation recommended, as well as their conditions of use. It is not intended to provide practical advice on how to use Chlorphenamine 4mg Tablets.

For practical information about using Chlorphenamine 4mg Tablets, patients should read the package leaflet or contact their doctor or pharmacist.

What are Chlorphenamine 4mg Tablets and what are they used for?
This medicine is the same as the medicine that is known under the names Chlorphenamine 4mg Tablets, Boots Allergy Relief 4 mg Tablets, Lloydspharmacy Allergy Relief 4 mg Tablets and Vantage Allergy Relief 4 mg Tablets (referred to as Allergy Relief 4 mg Tablets in the remainder of this report), which is already authorised to Bristol Laboratories Limited. Bristol Laboratories Limited has agreed that this Marketing Authorisation can be used as a basis for the grant of an identical Marketing Authorisation (informed consent).

This medicine is used to treat the itchiness, redness, swelling, tenderness and irritation that can be caused by hayfever and other allergies (e.g. pet, house dust mite and mould spore allergies); nettle rash and hives; skin allergies and dermatitis; prickly heat and heat rash; reactions to food, food additives or medicines; insect bites and stings; and the itchy rash of chickenpox.

How do Chlorphenamine 4mg Tablets work?
These tablets contain the active ingredient chlorphenamine maleate, an antihistamine which works by blocking histamine H1 receptors. This stops the chain reaction that causes the symptoms of the allergy.

How are Chlorphenamine 4mg Tablets used?
The tablets should be swallowed with a glass of water. The tablet can be divided into two equal doses.

Adults and children aged 12 years and over should take one tablet every 4 to 6 hours as needed. No more than six tablets should be taken in 24 hours. Children aged 6 to 12 years should take a 1/2 tablet every 4 to 6 hours as needed. No more than six half tablets should be taken in 24 hours.

Elderly patients should **t**alk to their doctor or pharmacist before they take this medicine as they may be more likely to get side effects including confusion and may need to take a lower daily dose.

The tablets should not be given to children under 6 years.

What benefits of Chlorphenamine 4mg Tablets have been shown in studies?
Chlorphenamine 4mg Tablets are considered to be identical to a previously authorised medicinal product, with the same benefits and risks. Therefore, no new studies have been provided but reference is made to the Marketing Authorisation owned by Bristol Laboratories Limited.

What are the possible side effects from Chlorphenamine 4mg Tablets?
Like all medicines Chlorphenamine 4mg Tablets can cause side effects, although not everybody gets them. The most common side effect is drowsiness. This drowsiness can be helpful if symptoms are particularly troublesome at night.

For the full list of all side effects reported with Chlorphenamine 4mg Tablets, see section 4 of the package leaflet. For the full list of restrictions, see the package leaflet.

Why are Chlorphenamine 4mg Tablets approved?
The MHRA decided that the benefits of Chlorphenamine 4mg Tablets are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Chlorphenamine 4mg Tablets?
A Risk Management Plan has been developed to ensure Chlorphenamine 4mg Tablets are used as safely as possible. Based on this plan, safety information has been included in the Summary of Product Characteristics and the package leaflet for Chlorphenamine 4mg Tablets, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored and reviewed continuously.

Other information about Chlorphenamine 4mg Tablets
A Marketing Authorisation was granted in the UK on 25 November 2015.

This summary was last updated in January 2016.

The full PAR for Chlorphenamine 4mg Tablets follows this summary.

CHLORPHENAMINE 4MG TABLETS

PL 36722/0056

SCIENTIFIC DISCUSSION

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INTRODUCTION

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Special Concept Development (UK) Limited a Marketing Authorisation for the medicinal product Chlorphenamine 4mg Tablets (PL 36722/0056) on 25 November 2015. This is a Pharmacy (P) medicine.

Chlorphenamine 4mg Tablets are indicated for symptomatic control of all allergic conditions responsive to antihistamines, including hay fever, vasomotor rhinitis, urticaria, angioneurotic oedema, food allergies, drug and serum reactions and insect bites. The tablets are also indicated for the symptomatic relief of itch associated with chickenpox.

This application was submitted as an abridged application, according to Article 10c of Directive 2001/83/EC, as amended, cross-referring to the Marketing Authorisation for Allergy Relief 4 mg Tablets (PL 17907/0349), which is already authorised to Bristol Laboratories Limited.

Chlorphenamine is a potent histamine H1, receptor antagonist. Antihistamines diminish or abolish the actions of histamine in the body by competitive reversible blockade of histamine H1-receptor sites on tissues. Chlorphenamine also has anticholinergic activity. Antihistamines act to prevent the release of histamine, prostaglandins and leukotrienes and have been shown to prevent the migration of inflammatory mediators. The actions of chlorphenamine include inhibition of histamine on smooth muscle, capillary permeability and hence reduction of oedema and wheal in hypersensitivity reactions such as allergy and anaphylaxis.

No new data were submitted nor were necessary for this simple application, as the data are identical to those provided for the previously authorised product.

PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 36722/0056
PROPRIETARY NAME: Chlorphenamine 4mg Tablets
ACTIVE: Chlorphenamine maleate
COMPANY NAME: Special Concept Development (UK) Limited
E.C. ARTICLE: Article 10c of Directive 2001/83/EC, as amended
LEGAL STATUS: P

1. INTRODUCTION

This is an abridged application for Chlorphenamine 4mg Tablets, submitted under Article 10c of Directive 2001/83/EC, as amended.

The application cross-refers to Allergy Relief 4 mg Tablets (PL 17907/0349) which were authorised to Bristol Laboratories Limited on 15 June 2010 following a change of ownership. Prior to this the reference product was authorised under PL 19348/0082 to LPC Medical (UK) Ltd following a change of ownership on 27 January 2005. Prior to this the reference product was authorised under PL 11382/0036 to Eastern Pharmaceuticals Ltd on 9 March 2000.

The current application is considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 Name

The name of the product is acceptable.

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

The tablets have the same strength, form and route of administration as the reference product.

The tablets are stored in either polypropylene bottles, each with a tamper evident high density polyethylene (HDPE) closure, containing 100, 500 or 1000 tablets, or in polyvinyl chloride (PVC) (250 microns)/aluminium foil (20 microns) blister packs of 28, 30 or 60 tablets.

The shelf life of the tablets is 36 months when the storage precaution ‘do not store above 25ºC’ is applied. In addition, the storage precaution ‘store in the original package’ applies to tablets stored in the blister packs and ‘keep container tightly closed’ applies to tablets stored in the bottles.

2.3 Legal status

This is a Pharmacy (P) medicine.

2.4 Marketing Authorisation Holder

The Marketing Authorisation Holder is Special Concept Development (UK) Limited, Units 1-7 Colonial Way, Watford, Hertfordshire WD24 4YR, UK.

The Qualified Person (QP) responsible for pharmacovigilance is stated and a satisfactory CV has been provided.

2.5 Manufacturers
The manufacturing sites are identical to those of the reference product and are acceptable.

2.6 Qualitative and quantitative composition
The product composition is identical to that of the reference product and is acceptable.

2.7 Manufacturing process
The manufacturing process is identical to that of the reference product and is acceptable.

2.8 Finished product/shelf-life specification
The finished product specification is identical to that of the reference product and is acceptable.

2.9 Drug substance specification
The drug substance specification is identical to that of the reference product and is acceptable.

2.10 TSE Compliance
A satisfactory declaration of compliance with current TSE/BSE regulations has been provided by the supplier of lactose.

2.11 Bioequivalence
No bioequivalence data are required to support this simple abridged application because the product is identical to a product that is already authorised.

3. EXPERT REPORTS
These are acceptable.

4. PRODUCT NAME AND APPEARANCE
The name of the product is acceptable. The appearance of the tablets is in line with the reference product and is acceptable.

5. SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)
The Summary of Product Characteristics is identical to that of the reference product, apart from the necessary administrative updates to reflect the change in Marketing Authorisation, and is acceptable.

6. PATIENT INFORMATION LEAFLET (PIL) AND LABELLING
The PIL and labels are identical to those of the reference product, apart from the necessary administrative updates to reflect the change in Marketing Authorisation, and are acceptable.

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

NON-CLINICAL ASSESSMENT

As this is an abridged application submitted under Article 10c of Directive 2001/83/EC, as amended, no new non-clinical data have been supplied and none are required.

The Marketing Authorisation Holder has provided adequate justification for not submitting an Environment Risk Assessment (ERA).

The grant of a Marketing Authorisation is recommended.

CLINICAL ASSESSMENT

As this is an abridged application submitted under Article 10c of Directive 2001/83/EC, as amended, no new clinical data have been supplied and none are required.

The Marketing Authorisation Holder has provided details of a suitable pharmacovigilance system that fulfils the requirements and provides adequate evidence that they have the services of a qualified person responsible for pharmacovigilance, and have the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.

The Risk Management Plan is considered adequate. Routine risk minimisation is provided through the Summary of Product Characteristics and the Patient Information Leaflet and this is sufficient.

The grant of a Marketing Authorisation is recommended.

OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

QUALITY

The data for this application are consistent with the data previously assessed for the Marketing Authorisation for Allergy Relief 4 mg Tablets (PL 17907/0349) and, as such, have been judged to be satisfactory.

NON-CLINICAL

No new non-clinical data were submitted and none are required for this type of application.

EFFICACY

The product is identical to that previously authorised; therefore, no efficacy data are needed.

SAFETY

No new or unexpected safety concerns arose from this application.

PRODUCT LITERATURE

The SmPC, PIL and label are identical to those previously approved, apart from the necessary administrative updates to reflect the change in Marketing Authorisation.

BENEFIT/RISK ASSESSMENT

The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. The applicant’s product is identical to the reference product. The benefit/risk balance is therefore considered to be positive.

STEPS TAKEN AFTER INITIAL AUTHORISATION

Date submitted	Application type	Scope	Outcome

SUMMARY OF PRODUCT CHARACTERISTICS

In accordance with Directive 2010/84/EU, the Summaries of Product Characteristics (SmPCs) for products granted Marketing Authorisations at a national level are available on the MHRA website.

PATIENT INFORMATION LEAFLET

In accordance with Directive 2010/84/EU, the Patient Information Leaflets (PILs) for products granted Marketing Authorisations at a national level are available on the MHRA website.

LABELLING

Blister:

Carton: