

POLLENASE 4MG TABLETS (CHLORPHENAMINE MALEATE)

PL 22959/0004

UKPAR

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POLLENASE 4MG TABLETS (CHLORPHENAMINE MALEATE)

PL 22959/0004

LAY SUMMARY

The MHRA granted Line Range Limited a Marketing Authorisation (licence) for the medicinal product Pollenase 4mg Tablets (PL 22959/0004) on 31st May 2006. This medicine is an antihistamine drug, which is used to control allergic reactions. This medicinal product is available at pharmacies only.

Pollenase tablets contain the active ingredient chlorphenamine maleate which is used to treat symptoms of hayfever and is also effective in, and widely used for, the relief of the itchy skin reaction to insect bites and food allergies. The tablets can also be used to help relieve pruritus (itchy conditions of the vulval and anal areas) and the runny nose often experienced with rhinitis.

No new or unexpected safety concerns arose from this simple application and it was, therefore, judged that the benefits of taking Pollenase 4mg Tablets outweigh the risks, hence a Marketing Authorisation has been granted.

POLLENASE 4MG TABLETS (CHLORPHENAMINE MALEATE)

PL 22959/0004

SCIENTIFIC DISCUSSION

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INTRODUCTION

The UK granted a marketing authorisation for the medicinal product Pollenase 4mg Tablets (PL 22959/0004) to Line Range Limited on 31st May 2006. This medicinal product is available as a Pharmacy only product (P). The product was originally licensed to Natural Options Health Products Limited on 24th February 2006, however, it underwent a Change of Ownership to transfer the licence to Line Range Limited, which was completed on 31st May 2006.

The application was submitted according to article 10.1(a)(i) of Directive 2001/83/EC, cross-referring to Chlorpheniramine tablets BP 4mg (PL 05544/5907R), which was granted a marketing authorisation on 30th November 1989.

No new data was 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 public assessment report was generated for it.

The product contains the active ingredient chlorphenamine maleate which is a potent histamine H₁-receptor antagonist. Pollenase tablets are indicated for the symptomatic control of allergic conditions responsive to antihistamines e.g. hayfever, vasomotor rhinitis, urticaria, angioneurotic oedema, food allergies, drug and serum reactions, pruritus ani or vulvae and insect bites.

PHARMACEUTICAL ASSESSMENT

INTRODUCTION

This is an abridged application made under Article 10.1(a)(i) of EC Directive 2001/83 and is considered to be an identical product to that of PL 05544/5907R (Chlorpheniramine tablets BP 4mg). The licence was held by Sussex Pharmaceuticals Ltd, granted 30th November 1989.

EXPERT REPORTS

Satisfactory statements provided.

PRODUCT LITERATURE

1. SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

The SPC supplied is satisfactory and consistent with the cross-reference product.

2. LABELLING

The label supplied is satisfactory and consistent with the cross-reference product.

3. PATIENT INFORMATION LEAFLET (PIL)

The PIL supplied is satisfactory and consistent with the cross-reference product.

4. MARKETING AUTHORISATION APPLICATION (MAA)

The MAA form is satisfactory and consistent with the cross-reference product.

RECOMMENDATION

Grant of a Marketing Authorisation is acceptable.

PRECLINICAL ASSESSMENT

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

CLINICAL ASSESSMENT

As this is a duplicate application for PL 05544/5907R, no new clinical data have been supplied and none are required.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

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

PRECLINICAL

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

EFFICACY

Chlorphenamine maleate is a well known drug and has been used as an antihistamine for many years. This application is identical to the previously approved marketing authorisation for Chlorpheniramine tablets BP 4mg (PL 05544/5907R).

No new or unexpected safety concerns arise from this application.

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 chlorphenamine maleate is considered to have demonstrated the therapeutic value of the compound. The risk benefit is therefore considered to be positive.

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STEPS TAKEN FOR ASSESSMENT

1	The MHRA received the marketing authorisation application for PL 18284/0006 on 04/02/2004.
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 13/09/2004.
3	Following assessment of the application the MHRA requested further information on 05/11/2004, 07/12/2005 and 20/01/2006.
4	The applicant responded to the MHRA's requests, providing further information on 06/06/2005, 20/01/2006 and 31/01/2006.
5	The application subsequently went through a Change of Ownership and was granted on 31/05/2006.

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STEPS TAKEN AFTER ASSESSMENT

Date submitted	Application type	Scope	Outcome

POLLENASE 4MG TABLETS (CHLORPHENAMINE MALEATE)

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SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Pollenase 4mg Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 4mg chlorphenamine (as maleate).
Also contains lactose monohydrate as excipient.

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Tablet

Pale yellow uncoated biconvex tablets with a break line on one face.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

The symptomatic control of allergic conditions responsive to antihistamines eg. hayfever, vasomotor rhinitis, urticaria, angioneurotic oedema, food allergies, drug and serum reactions, pruritus ani or vulvae and insect bites.

4.2. Posology and method of administration

For oral use

Chlorphenamine tablets should be taken orally with a drink of water.

Normal dosage for adults and the elderly: one tablet three or four times a day.

Children from 6-12 years: half a tablet three or four times a day.

Children under 6 years: not recommended.

4.3. Contraindications

Hypersensitivity to chlorphenamine or to any of the excipients.

4.4. Special warnings and precautions for use

Patients should be warned of possible adverse effects when driving and machine operating and the dangers of taking alcohol with antihistamines.

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

4.5. Interactions with other medicinal products and other forms of interaction

There has been a report of adverse effects caused by concomitant use with phenytoin, but drug interactions are rare. The most serious problem is the possible potentiation of the effects of alcohol.

4.6. Pregnancy and lactation

Not recommended in pregnancy and lactation.

4.7. Effects on ability to drive and use machines

Chlorphenamine as with most antihistamines may cause drowsiness and dizziness and as such, there may well be an adverse effect on driving ability and handling of machinery.

4.8. Undesirable effects

Other adverse effects may include hypotension, muscular weakness, incoordination, euphoria, visual disturbances, tremor, agitation, insomnia, palpitations, bronchoconstriction, facial swelling, intestinal disturbance and higher doses may cause unwanted effects associated with anticholinergic action e.g. dry mouth, dry eyes, urinary retention and constipation. There is a possibility of nitrosamine formation when taken with dietary nitrite.

4.9. Overdose

Treatment for moderate overdose would be supportive. Treatment of large oral doses should include gastric lavage followed by activated charcoal. In the event of CNS excitement or convulsions, sedation and anticonvulsant treatment should be with intravenous diazepam. Severe respiratory depression may necessitate the use of mechanical ventilation and in severe poisoning, instability of the cardiovascular system and other vital systems is also possible.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

ATC code R06A B04 Antihistamines for systemic use

Chlorphenamine is a potent histamine H₁-receptor antagonist. It is an alkylamine derivative and probably achieves its effect by occupying receptor sites in effector cells. It is readily absorbed from the G.I tract and is normally effective in 30 to 60 minutes. There is significant plasma protein binding.

5.2. Pharmacokinetic properties

The drug is readily and rapidly absorbed from the G.I. tract and is usually effective within an hour. The half-life may be as long as 24 hours. The drug is largely inactivated in the liver and excreted as metabolites in the urine.

5.3. Preclinical safety data

There is no pre-clinical safety data that could be of relevance to the prescriber, which are not already included in other sections of the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Lactose monohydrate, Potato Starch, Magnesium Stearate, Anstead Dispersed Yellow 19248 (15% Quinoline Yellow E104).

6.2. Incompatibilities

None stated

6.3. Shelf life

3years

6.4. Special precautions for storage

Do not store above 25°C. Store in the original package.

6.5. Nature and contents of container

Pollenase Tablets are available in blister packs of 28, 30 and 60 tablets.

Specification details of blister packs :

- PVC (white,rigid,opaque) : 250 microns
- Aluminium foil (hard tempered) : 20 microns
- Primer (nitrocellulose) : 1.5 -2.5 gsm
- Heat seal lacquer : 6.5 - 8.5 gsm

They are also available in Securitainers and Tampertainers in packs of 100, 500 & 1000 tablet. All containers are made up of High Density Polypropylene body and Low Density Polyethylene cap.

6.6. Instruction for use and handling

None.

7. MARKETING AUTHORISATION HOLDER

Line Range Ltd,
16 Rancliffe Avenue
Keyworth,
Nottingham NG12 5HY
UK

- 8. MARKETING AUTHORISATION NUMBER**
PL 22959/0004
- 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**
31/05/2006
- 10 DATE OF REVISION OF THE TEXT**

**POLLENASE 4MG TABLETS (CHLORPHENAMINE MALEATE)
PL 22959/0004
PRODUCT INFORMATION LEAFLET TEXT**

**PATIENT INFORMATION LEAFLET
POLLENASE 4mg TABLETS
(Chlorphenamine Maleate)**

Read all of this leaflet carefully because it contains important information for you. This medicine is available without a prescription, for you to treat a mild illness without a doctor's help. Nevertheless you still need to use Pollenase 4mg Tablets carefully to get the best results from it.

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

In this leaflet

- 1. What Pollenase 4mg Tablets are and what they are used for**
- 2. Before you take Pollenase 4mg Tablets**
- 3. How to take Pollenase 4mg Tablets**
- 4. Possible side effects**
- 5. How to store Pollenase 4mg Tablets**
- 6. Further information**

1. What Pollenase 4mg Tablets are and what they are used for

The active ingredient in your tablets is chlorphenamine maleate. Chlorphenamine is an antihistamine drug, which is used to control allergic reactions.

Its main use is for the relief of symptoms of hay fever and it is also used for the relief of the itchy skin reaction to insect bites and food allergies. The tablets can also be used to help relieve the runny nose often experienced with rhinitis and pruritus (itchy conditions of the vulval and anal areas).

2. Before you take Pollenase 4mg Tablets

Do not take these tablets if:

- You are allergic to chlorphenamine or any of the other ingredients (see section 6)
- You are pregnant or breast-feeding.

Tell your doctor or pharmacist before you take this medicine if:

- You are taking the anti-epileptic preparation Phenytoin (Epanutin).
- You have an intolerance to some sugars

Pregnancy and breast-feeding

Do not take Pollenase 4mg Tablets if you are pregnant or breast-feeding.

WARNING

May cause drowsiness. If affected do not drive or operate machinery.
Avoid alcoholic drink.

Important information about some of the ingredients of Pollenase 4mg Tablets. Pollenase 4mg tablets contain lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars you should not take this medicine.

Taking other medicines

Avoid drinking alcohol at the same time as taking Pollenase 4 mg Tablets as this may cause drowsiness.

Tell your doctor or pharmacist if you are taking any other medicines, including those you have bought yourself.

3. How to take Pollenase 4mg Tablets:

The normal dose for adults, the elderly and children over 12 years is one tablet 3 or 4 times a day and for children from 6 to 12 years half a tablet 3 or 4 times a day. They are not suitable for children below the age of 6.

Take the tablets as instructed with a good drink of water.

If symptoms do not go away, talk to your pharmacist or doctor.

Do not take more tablets than stated but if an overdose should occur, seek medical advice immediately.

If you should miss a dose, do not double up to compensate the missed dose, but wait until the next dose time and continue with your normal routine.

4. Possible side effects

Like all medicines, Pollenase 4mg Tablets can have side effects.

As can happen with any medicine, a few people may develop an allergic reaction.

If you experience the following:

- Difficulty in breathing
- Swelling of the lips, face and neck

Tell your doctor immediately or go to the casualty department of your nearest hospital.

Side effects are uncommon but they may show as visual disturbances, a lowered blood pressure and abnormal heart beat, incoordination, muscular weakness, euphoria, the occasional twitching or shaking of the hands and arms, agitation, difficulty in sleeping, difficulty in breathing, dry eyes and mouth, a puffy face, diarrhoea or constipation and inability to pass urine.

If you experience these or any unusual reaction, you must tell your doctor or pharmacist.

5. How to store Pollenase 4mg Tablets

Do not store above 25°C and keep the tablets in the original package in order to protect from moisture.

Keep out of the reach and sight of children.

Do not take them after the expiry date shown on the pack.

6. Further information

What does each tablet contain?

These are small, uncoated yellow tablets, which contain 4mg of Chlorphenamine Maleate as the active ingredient.

They also contain Lactose Monohydrate, Starch, Magnesium Stearate and a colour, Ansteads Dispersed Yellow (19248) and Quinoline Yellow (E104).

What is in the pack?

Pollenase 4mg Tablets are supplied in containers of 100, 500 and 1000 and blister packs of 28, 30 and 60.*

Who supplies these Pollenase 4mg Tablets?

Pollenase 4mg Tablets are manufactured by Sussex Pharmaceutical Ltd, East Grinstead, West Sussex, RH19 2HL for the Marketing Authorisation holder, Line Range Ltd., Keyworth, Nottingham NG12 5HY.

Leaflet revised January 2006

* not all pack sizes may be marked.

**POLLENASE 4MG TABLETS (CHLORPHENAMINE MALEATE)
PL 22959/0004
LABEL**

CARTON



BLISTER FOIL



LABEL

Pollenase 4mg Tablets
Chlorphenamine maleate


For relief from hayfever, insect bites and skin allergy. 100 Tablets

Each tablet contains 4mg Chlorphenamine maleate. Also contains lactose monohydrate. Please read the enclosed leaflet carefully before use. For oral use only.

Dosage: To be swallowed with a drink of water. Adults, the elderly and children over 12 years: 1 tablet to be taken 3 to 4 times a day. Children aged 6 to 12 years: half a tablet to be taken 3 to 4 times a day. Do not take if pregnant. Not recommended for children under 6 years of age.

Pollenase 4mg Tablets
Chlorphenamine maleate

For relief from hayfever, insect bites and skin allergy



100 Tablets

Warning; Do not exceed the stated dose. May cause drowsiness. If affected, do not drive or operate machinery. Avoid alcoholic drink.

KEEP OUT OF THE REACH & SIGHT OF CHILDREN.

Do not store above 25°C.

Keep in the original package to protect from moisture.

PL 22959 / 0004

MA Holder:
Line Range Ltd., Keyworth,
Nottingham NG12 5HY.