Loratadine 10 mg Tablets

PL 25298/0019

UKPAR

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LAY SUMMARY

Loratadine 10 mg Tablets

This is a summary of the Public Assessment Report (PAR) for Loratadine 10 mg Tablets (PL 25298/0019). It explains how the application for Loratadine 10 mg Tablets was assessed and its authorisation recommended, as well as the conditions of use. It is not intended to provide practical advice on how to use Loratadine 10 mg Tablets.

For practical information about using Loratadine 10 mg Tablets, patients should read the package leaflet or contact their doctor or pharmacist.

The product may be referred to as ‘Loratadine Tablets’ in this report.

What are Loratadine Tablets and what are they used for?
This medicine is the same as Loratadine 10 mg Tablets (PL 20117/0069; Morningside Healthcare Limited), which are already authorised in the UK. The licence holder (Morningside Healthcare Limited) for Loratadine 10 mg Tablets (PL 20117/0069) has agreed that its own scientific data can be used as a basis for the grant of an identical licence for Loratadine 10 mg Tablets (PL 25298/0019) (informed consent).

Loratadine Tablets are used in adults and children to relieve allergy symptoms such as sneezing, runny nose, and itchy and/or burning eyes, whether these are due to hayfever or whether they occur at other times of the year. Loratadine Tablets may also be used to relieve the symptoms associated with chronic idiopathic urticaria such as rash, itching and hives.

How do Loratadine Tablets work?
The active ingredient, loratadine, is one of a group of medicines called non-sedating antihistamines used to relieve the symptoms of some allergies. It works by counteracting the effects of histamine, which is produced naturally by the body’s defence system, but may be over-produced in allergic reactions.

How are Loratadine Tablets used?
Loratadine Tablets are taken by mouth; the tablets should be swallowed with water.

Dosage
Adults, the elderly, children aged 12 years and over:
One tablet to be swallowed once daily.

Children aged 2 to 12 years:
If the child weighs more than 30 kg, one tablet taken once daily is recommended.

If the child weighs less than 30 kg, the 10mg strength tablet is not recommended.

The patient or caregiver should ask the doctor or pharmacist for advice if unsure about how many tablets to take or when to take them.

Loratadine 10 mg tablets are not recommended in children under 2 years.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.
Loratadine Tablets can be obtained without a prescription, at pharmacies, supermarkets and other retail outlets without the supervision of a pharmacist.

**What benefits of Loratadine Tablets have been shown in studies?**
The application for Loratadine Tablets (PL 25298/0019) is considered to be identical to the previously authorised licence for Loratadine 10 mg Tablets (PL 20117/0069; Morningside Healthcare Limited), with the same benefits and risks. So, no new studies have been provided for Loratadine Tablets (PL 25298/0019). However, reference is made to the studies for Loratadine 10 mg Tablets PL 20117/0069; Morningside Healthcare Limited).

**What are the possible side effects from Loratadine Tablets?**
Like all medicines, Loratadine Tablets can cause side effects, although not everybody gets them.

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

For the full list of restrictions, see the package leaflet.

**Why are Loratadine Tablets approved?**
No new or unexpected safety concerns arose from this application. The MHRA, therefore, considered that the benefits of Loratadine Tablets outweigh their risks; and the grant of a Marketing Authorisation was recommended.

**What measures are being taken to ensure the safe and effective use of Loratadine Tablets?**
A Risk Management Plan has been developed to ensure that Loratadine 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 Loratadine 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/reviewed continuously.

**Other information about Loratadine Tablets**
A Marketing Authorisation was granted in the UK to Brown & Burk UK Limited on 10 December 2015.

The full PAR for Loratadine Tablets follows this summary.

For more information about treatment with Loratadine Tablets, read the package leaflet, or contact your doctor or pharmacist.

This summary was last updated in January 2016.
Loratadine 10 mg Tablets

PL 25298/0019

SCIENTIFIC DISCUSSION

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INTRODUCTION

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Brown & Burk UK Limited a Marketing Authorisation for the medicinal product Loratadine 10 mg Tablets (PL 25298/0019) on 10 December 2015. The product is a General Sales Licence (GSL) medicine indicated for the symptomatic treatment of allergic rhinitis and chronic idiopathic urticaria.

The application was submitted as a simple abridged (informed consent) application according to Article 10c of Directive 2001/83/EC, as amended. Loratadine 10 mg Tablets (PL 25298/0019) cross-refers to the reference product Loratadine 10 mg Tablets (PL 20117/0069), which was authorised on 09 April 2008 to Morningside Healthcare Limited following a series of the Change of Authorisation (COA) procedures of Loratadine 10 mg Tablets (PL 18866/0014; Rockspring Healthcare Limited). Loratadine 10 mg Tablets (PL 18866/0014; Rockspring Healthcare Limited) was authorised on 08 October 2002 as a duplicate application to Loratadine 10 mg Tablets, PL 18866/0002 (Rockspring Healthcare Limited), which was authorised under Article 4.8a(iii) of Directive 65/65/EC on 17 June 2002.

Loratadine 10 mg Tablets contain the active ingredient, loratadine, which is a long-acting tricyclic antihistamine with selective peripheral H1 receptor antagonistic activity. Loratadine has no clinically significant sedative or anticholinergic properties in the majority of the population and when used at the recommended dosage.

No new data were submitted nor were necessary to be submitted for this application, as the data are identical to those of the previously granted cross-reference product.
1. INTRODUCTION
This is a written consent application for Loratadine 10 mg Tablets (PL 25298/0019)) submitted under Article 10c of Directive 2001/83/EC, as amended.

The application cross-refers to Loratadine 10mg Tablets (PL 20117/0069; Morningside Healthcare Limited), which was authorised on 09 April 2008 after a series of Change of Authorisation (COA) procedures of Loratadine 10 mg Tablets (PL 18866/0014; Rockspring Healthcare Limited). Loratadine 10 mg Tablets (PL 18866/0014; Rockspring Healthcare Limited) was authorised on 08 October 2002 as a duplicate application of Loratadine 10 mg Tablets, PL 18866/0002 (Rockspring Healthcare Limited), which was authorised under Article 4.8a(iii) of Directive 65/65/EC on 17 June 2002. The application is considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM
2.1. Name
The proposed name of the product is Loratadine 10 mg Tablets. The product has been named in line with current requirements.

2.2. Strength, pharmaceutical form, route of administration, container and pack sizes
Each tablet contains 10 mg of loratadine. The product is supplied in 20 μm aluminium foil/250 μm polyvinylchloride blisters packaged into cardboard cartons, in a pack size of 7 tablets.

The proposed shelf life for the product is 3 years, with no special storage conditions.

The packaging, proposed shelf-life and storage conditions are consistent with the details registered for the cross-reference product.

2.3. Legal status
The product is available as a General Sales Licence (GSL) medicine.

2.4. Marketing Authorisation Holder/Contact Persons/Company
Brown & Burk UK Limited, 5 Marryat Close, Hounslow West, Middlesex, TW4 5DQ, United Kingdom.

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

2.5 Manufacturers
The proposed manufacturing sites are consistent with those registered for the cross-reference product and evidence of Good Manufacturing Practice (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 consistent 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 contain materials of animal or human origin. The supplier of lactose monohydrate has confirmed that the milk used in the production of lactose monohydrate is sourced from healthy animals under the same conditions as that intended for human consumption. In addition, the supplier has confirmed that no ruminant material other than calf rennet is used during the production of lactose monohydrate. This is consistent with the cross-reference product.

2.11. Bioequivalence
No bioequivalence data are required to support this simple abridged application because the proposed product is manufactured to the same formula and utilises the same processes as the reference product Loratadine 10 mg Tablets (PL 20117/0069; Morningside Healthcare Limited).

3. EXPERT REPORT
The applicant cross-refers to the data for Loratadine 10mg Tablets (PL 20117/0069; Morningside Healthcare Limited) to which this application is claimed to be identical. This is acceptable.

4. PRODUCT NAME & APPEARANCE
See Section 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 (SmPC)
The proposed SmPC is consistent with the details registered for the cross-reference product.

6. PATIENT INFORMATION LEAFLET (PIL) AND LABELLING
PIL
The PIL has been prepared in line with the details registered for the cross-reference product.

User-testing of the PIL for Loratadine 10 mg Tablets (PL 25298/0019) has been accepted based on the successful user-testing of the PIL for the reference product Loratadine 10 mg Tablets (PL 20117/0069; Morningside Healthcare Limited) as the ‘parent PIL’.

Carton and label
The proposed artwork is consistent with the artwork registered for the cross-reference product and
complies with statutory requirements. In line with current legislation, the applicant has also included the names of the product in Braille on the outer packaging.

7. CONCLUSION
The data submitted with the application is acceptable. The grant of a Marketing Authorisation is recommended.
NON-CLINICAL ASSESSMENT

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

Suitable justification has been provided for non-submission of an Environmental Risk Assessment. As the application is an identical version of an already authorised product, it is not expected that environmental exposure will increase following approval of the Marketing Authorisation for the proposed product.

The grant of a Marketing Authorisation is recommended.
CLINICAL ASSESSMENT

As this is an informed consent 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.

An acceptable Risk Management Plan (RMP) has been submitted. A summary of safety concerns is listed in the following table.

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<tr>
<th>Summary of safety concerns</th>
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<td>Important identified risks</td>
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<td>Important potential risks</td>
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<td>Missing information</td>
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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, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

QUALITY
The data for this application is consistent with those previously assessed for the cross-reference product 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
This application is identical to the previously granted licence for Loratadine 10 mg Tablets (PL 20117/0069; Morningside Healthcare Limited).

SAFETY
No new safety data were supplied or required for this application. Loratadine has a well-established safety profile. No new or unexpected safety concerns arose from this application.

PRODUCT LITERATURE
The SmPC and PIL are satisfactory, and consistent with those for the cross-reference product. The labelling text complies with statutory requirements and is satisfactory.

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 cross-reference product. Extensive clinical experience with loratadine is considered to have demonstrated the therapeutic value of the compound. The benefit/risk assessment is, therefore, considered to be positive.
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.
UKPAR Loratadine 10 mg Tablets

PL 25298/0019

LABELLING

Embossing area for batch details
B:XXXXXXXX
EXPMM/YYYY
will be Embossed online