Montelukast 10mg film-coated tablets

PL 17907/0474

UKPAR

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MONTELUKAST 10MG FILM-COATED TABLETS

PL 17907/0474

LAY SUMMARY

This is a summary of the public assessment report (PAR) for Montelukast 10mg film-coated tablets (PL 17907/0474). It explains how Montelukast 10mg film-coated 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 Montelukast 10mg film-coated tablets.

For practical information about using Montelukast 10mg film-coated tablets, patients should read the package leaflet or contact their doctor or pharmacist.

What are Montelukast 10mg film-coated tablets and what are they used for?
This medicine is the same as the Montelukast 10 mg film-coated tablets authorised to Unimark Remedies s.r.o. Unimark Remedies s.r.o. has agreed that the marketing authorisation for their product can be used as a basis for the grant of an identical marketing authorisation (informed consent).

Montelukast 10mg film-coated tablets are used in patients of 15 years of age and older to treat asthma.

How do Montelukast 10mg film-coated tablets work?
Montelukast is a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in the lungs and also cause allergy symptoms. By blocking leukotrienes, montelukast improves asthma symptoms, helps control asthma and improves seasonal allergy symptoms (also known as hay fever and seasonal allergic rhinitis).

How are Montelukast 10mg film-coated tablets used?
One tablet should be taken every day in the evening. The tablets should be swallowed whole with a liquid. The tablets may be taken with or without food.

The tablets can only be obtained with a prescription.

What benefits of Montelukast 10mg film-coated tablets have been shown in studies?
Montelukast 10mg film-coated tablets from Bristol Laboratories Limited are considered to be identical to the previously authorised reference product from Unimark Remedies s.r.o., with the same benefits and risks. Therefore, no new studies have been provided for Montelukast 10mg film-coated tablets but reference is made to the medicine authorised to Unimark Remedies s.r.o.
What are the possible side effects from Montelukast 10mg film-coated tablets?
The most common side effect with Montelukast 10mg film-coated tablets, which affects more than 1 in 10 people, is upper respiratory infection.

For the full list of all side effects reported with Montelukast 10mg film-coated tablets, see section 4 of the package leaflet. For the full list of restrictions, see the package leaflet.

Why are Montelukast 10mg film-coated tablets approved?
The MHRA decided that the benefits of Montelukast 10mg film-coated tablets are greater than their risks and recommended that they be approved for use.

What measures are being taken to ensure the safe and effective use of Montelukast 10mg film-coated tablets?
A Risk Management Plan has been developed to ensure Montelukast 10mg film-coated 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 Montelukast 10mg film-coated 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 Montelukast 10mg film-coated tablets
A Marketing Authorisation was granted in the UK on 10 November 2014.

This summary was last updated in January 2015.

The full PAR for Montelukast 10mg film-coated tablets follows this summary.
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SCIENTIFIC DISCUSSION

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INTRODUCTION

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Bristol Laboratories Limited a Marketing Authorisation for the medicinal product Montelukast 10mg film-coated tablets (PL 17907/0474) on 10 November 2014. This is a prescription only medicine (POM).

Montelukast 10mg film-coated tablets are indicated in the treatment of asthma as add-on therapy in adults and adolescents from 15 years of age and older with mild to moderate persistent asthma who are inadequately controlled on inhaled corticosteroids and in whom “as needed” short acting β-agonists provide inadequate clinical control of asthma. In those asthmatic patients in whom Montelukast film-coated tablet is indicated in asthma, Montelukast Film-coated tablet can also provide symptomatic relief of seasonal allergic rhinitis.

Montelukast film-coated tablets are also indicated for the prophylaxis of asthma in which the predominant component is exercise-induced bronchoconstriction.

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 Montelukast 10 mg film-coated tablets (PL 40499/0003), which were authorised to Unimark Remedies s.r.o. on 8 April 2013.

Montelukast is a leukotriene receptor antagonist.

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**

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<th>LICENCE NO:</th>
<th>PL 17907/0474</th>
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<tr>
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<td>Montelukast 10mg film-coated tablets</td>
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<td>Article 10c of Directive 2001/83/EC, as amended</td>
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1. **INTRODUCTION**

This is an abridged application for Montelukast 10mg film-coated tablets, submitted under Article 10c of Directive 2001/83/EC, as amended.

The application cross-refers to Montelukast 10 mg film-coated tablets (PL 40499/0003). 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 packaged into polyamide-aluminium foil-PVC/aluminium blister packages. The blister are packaged in to carton

A pack size of 30 tablets per carton has been authorised.

2.3 **Legal status**

The tablets have been granted POM status.

2.4 **Marketing Authorisation Holder**

The Marketing Authorisation Holder is Bristol Laboratories Limited, Unit 3, Canalside, Northbridge Road, Berkhamsted, Herts HP4 1EG, United Kingdom.

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’s 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 label are identical to those of the reference product, apart from the necessary administrative updates to reflect the change in Marketing Authorisation Holder, 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 Montelukast 10 mg film-coated tablets authorised to Unimark Remedies s.r.o. (PL 40499/0003) 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 labels 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.
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STEPS TAKEN FOR ASSESSMENT

1. The MHRA received the Marketing Authorisation application on 12 February 2014.
2. Following standard checks and communication with the applicant the MHRA considered the application valid on 13 February 2014.
3. Following assessment of the application the MHRA requested further information relating to the dossier on 8 May 2014.
4. The applicant responded to the MHRA’s requests, providing further information on 2 July 2014.
5. The application was granted on 10 November 2014.
# STEPS TAKEN AFTER INITIAL AUTHORISATION

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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.