MONTELUKAST 4 MG CHEWABLE TABLETS
MONTELUKAST 5 MG CHEWABLE TABLETS

(Montelukast sodium)

PL 24668/0238-41

UKPAR

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The MHRA granted Caduceus Pharma Ltd Marketing Authorisations (licences) for the medicinal products Montelukast 4 mg and 5 mg chewable tablets on 19 November 2012.

Montelukast 4 mg chewable tablets is a Prescription Only Medicine (POM) for children aged 2 to 5 years old.

Montelukast 5 mg chewable tablets is a Prescription Only Medicine (POM) for children and adolescents aged 6 to 14 years old.

Montelukast 4mg and 5mg chewable tablets are used for:
- the treatment of asthma in patients who are not adequately controlled on their medication and need additional therapy.
- asthma in patients who have not recently taken oral corticosteroids for their asthma and have shown that they are unable to use inhaled corticosteroids.
- prevention of the narrowing of airways triggered by exercise.

Montelukast is a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in the lungs. By blocking leukotrienes, montelukast improves asthma symptoms and helps control asthma.

No new or unexpected safety concerns arose from these applications and it was, therefore, judged that the benefits of taking Montelukast 4 mg and 5 mg chewable tablets outweigh the risks; hence Marketing Authorisations have been granted.
INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the MHRA granted Caduceus Pharma Ltd, Marketing Authorisations for the medicinal products Montelukast 4 mg and 5 mg chewable tablets (PL 24668/0238-41) on 19 November 2012.

Montelukast 4 mg chewable tablets is a Prescription-Only Medicine (POM) for children aged 2 to 5 years old, whereas Montelukast 5 mg chewable tablets is a POM for children and adolescents aged 6 to 14 years old.

Montelukast 4 mg and 5 mg chewable tablets are indicated:

- in the treatment of asthma as add-on therapy in patients 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.
- as an alternative treatment option to low-dose inhaled corticosteroids in patients with mild persistent asthma who do not have a recent history of serious asthma attacks that required oral corticosteroid use, and who have demonstrated that they are not capable of using inhaled corticosteroids (see section 4.2 of SmPC).
- for the prophylaxis of asthma for patients in which the predominant component is exercise-induced bronchoconstriction.

These are abridged applications submitted under Article 10(1) of Directive 2001/83/EC as amended, cross-referring to Singulair 5 mg chewable tablets (Merck Sharp & Dohme, Finland), which has been authorised in the EEA since 25 August 1997. The corresponding reference products in the UK are Singulair Paediatric 4 mg and 5 mg Chewable Tablets (Merck Sharp & Dohme Limited), which were first authorised in January 2001 and January 1998 respectively. The reference product used in the bioequivalence study was Singulair Junior® 5 mg Kautabletten (MSD Dieckmann Arzneimittel GMBH) taken from the German market. It has been confirmed that this product is identical to the equivalent product in the UK (Singulair Paediatric 5 mg Chewable Tablets).

Montelukast is an oral cysteinyl leukotriene D4 receptor antagonist indicated as add-on therapy in asthma patients who are inadequately controlled on inhaled corticosteroids and in whom “as needed” short acting β-agonists provided inadequate control of asthma. Montelukast may also be used as an alternative treatment option to low-dose inhaled corticosteroids in patients with mild persistent asthma who do not have a recent history of serious asthma attacks that required oral corticosteroid use and who have demonstrated that they are not capable of using inhaled corticosteroids. Montelukast is also indicated in prophylaxis of exercise-induced bronchoconstriction.

No new non-clinical studies were conducted, which is acceptable given that the applications were for products that are being considered as generic medicinal products of an originator product that have been licensed for over 10 years.

One bioequivalence study (single dose) was submitted to support these applications, comparing the test product Montelukast 5 mg chewable tablets (Caduceus Pharma Ltd) with the reference product Singulair Junior® 5 mg Kautabletten (MSD Dieckmann Arzneimittel GMBH).
With the exception of the bioequivalence study, no new clinical studies were conducted, which is acceptable given that the applications were for products that are being considered as generic medicinal products of an originator product that have been licensed for over 10 years. The bioequivalence study was carried out in accordance with Good Clinical Practice (GCP).

No new or unexpected safety concerns were raised during the assessment of these applications and it was, therefore, judged that the benefits of taking Montelukast 4 mg and 5 mg chewable tablets outweigh the risks; hence Marketing Authorisations have been granted.
PHARMACEUTICAL ASSESSMENT

ACTIVE SUBSTANCE

INN: Montelukast sodium


Structural formula:

![Structural formula image]

Molecular formula: \(C_{35}H_{35}ClN_4O_3S\)
Molecular mass: 608.18
Appearance: White to pale yellow powder, hygroscopic in nature.
Solubility: Soluble in methanol, ethanol and water. Practically insoluble in acetonitrile.

Montelukast is currently not the subject of a European Pharmacopoeia monograph.

Synthesis of the active substance from the designated starting materials has been adequately described and appropriate in-process controls and intermediate specifications are applied. Satisfactory specification tests are in place for all starting materials and reagents, and these are supported by relevant certificates of analysis.

An appropriate specification is provided for the active substance. Analytical methods have been appropriately validated and are satisfactory for ensuring compliance with the relevant specifications.

Appropriate proof-of-structure data have been supplied for the active substance. All potential known impurities have been identified and characterised. Satisfactory certificates of analysis have been provided for all working standards. Batch analysis data are provided and comply with the proposed specification.

Suitable specifications have been provided for all packaging used. The primary packaging has been shown to comply with current guidelines concerning contact with food.
Appropriate stability data have been generated supporting a suitable retest period when stored in the proposed packaging.

**MEDICINAL PRODUCT**

**Other ingredients**
Other ingredients consist of pharmaceutical excipients, microcrystalline cellulose, hydroxypropylcellulose, croscarmellose sodium, pigment blend [consisting of lactose monohydrate and iron oxide red (E172)], mannitol, silarom cherry flavour, aspartame and magnesium stearate.

All excipients used comply with their respective European Pharmacopoeia monograph with the exception of pigment blend and silarom cherry flavour which are controlled to suitable in-house specifications. In addition, the in-house specifications for pigment blend and silarom cherry flavour are in compliance with current EEC directives concerning the use of colouring agents. Satisfactory Certificates of Analysis have been provided for all excipients.

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 lactose is sourced from healthy animals under the same conditions as milk for human consumption.

No genetically modified organisms (GMO) have been used in the preparation of these products.

**Pharmaceutical development**
The objective of the development programme was to formulate robust, stable tablets containing 4 mg and 5 mg montelukast that could be considered as generic medicinal products of Singulair Paediatric 4mg and 5mg Chewable Tablets (Merck Sharp & Dohme). A satisfactory account of the pharmaceutical development has been provided.

Comparative *in vitro* dissolution and impurity profiles have been provided for the proposed and originator products.

**Manufacture**
A description and flow-chart of the manufacturing method has been provided.

Satisfactory batch formula have been provided for the manufacture of the product, along with an appropriate account of the manufacturing process. The manufacturing process has been validated at commercial scale and has shown satisfactory results.

**Finished product specification**
The finished product specification is satisfactory. Test methods have been described and have been adequately validated, as appropriate. Batch data have been provided and comply with the release specification. Certificates of Analysis have been provided for any working standards used.

**Container Closure System**
All strengths of the finished product are packaged in aluminium/aluminium blisters and are available in pack sizes of 7, 10, 14, 20, 28, 30, 49, 50, 56, 98, 100, 140 and 200 tablets.
It has been stated that not all pack sizes may be marketed, however, the marketing authorisation holder has committed to submitting the mock-ups for any pack size to the relevant regulatory authorities for approval before marketing.

Satisfactory specifications and certificates of analysis have been provided for all packaging components. All primary packaging complies with the current European regulations concerning materials in contact with food.

**Stability**
Stability studies were performed in accordance with current guidelines on batches of the finished product packed in the packaging proposed for marketing. The data from these studies support a shelf-life of 2 years with no special storage conditions.

**Bioequivalence/Bioavailability**
Satisfactory Certificates of Analysis have been provided for the test and reference batches used in the bioequivalence study.

**Summary of Product Characteristics (SmPC), Patient Information Leaflets (PIL) and Labelling**
The SmPCs, PILs and labelling are satisfactory.

A package leaflet has been submitted to the MHRA along with results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC, as amended. The leaflet conforms to the requirements. The test shows that the patients/users are able to act upon the information that the leaflet contains.

**MAA Form**
The MAA forms are satisfactory.

**Expert Report (Quality Overall Summary)**
A quality overall summary has been written by an appropriately qualified person and is a suitable summary of the pharmaceutical aspects of the dossier.

**Conclusion**
It is recommended that marketing authorisations are granted for these applications.
NON-CLINICAL ASSESSMENT

PHARMACODYNAMICS, PHARMACOKINETICS AND TOXICOLOGY
No new non-clinical data were submitted, which is acceptable given that the proposed products are generic medicinal products of originator products that have been licensed for over 10 years.

NON-CLINICAL EXPERT REPORT
The applicant’s non-clinical expert report has been written by an appropriately qualified person and is satisfactory, providing an appropriate review of the products’ pharmacology and toxicology.

ENVIRONMENTAL RISK ASSESSMENT
Since Montelukast 4 mg and 5 mg chewable tablets are intended for generic substitution, this will not lead to an increased exposure to the environment. An environmental risk assessment (ERA) is therefore not deemed necessary.

CONCLUSION
It is recommended that marketing authorisations are granted for these applications.
CLINICAL ASSESSMENT

CLINICAL PHARMACOLOGY

The clinical pharmacology of montelukast sodium is well-known. With the exception of the bioequivalence study, no pharmacokinetic or pharmacodynamic data were submitted for these applications, and none were required for applications of this type.

The following bioequivalence study was submitted:

An open label, randomised, two-treatment, two-sequence, single dose, crossover study to compare the pharmacokinetics of the test product Montelukast 5 mg chewable tablets (Caduceus Pharma Ltd) versus the reference product Singulair Junior® 5 mg Kautabletten (MSD Dieckmann Arzneimittel GMBH) in healthy adult volunteers under fasted conditions.

All volunteers received a single oral dose of either the test or reference product as a 1 x 5 mg tablet administered with 240 ml of water after an overnight fast. Blood samples were taken for the measurement of pharmacokinetic parameters at pre- and up to 24 hours post dose. The washout period between treatment periods was at least 9 days.

The pharmacokinetic results for montelukast are presented below (non-transformed values; arithmetic and geometric mean ± SD, ratios and 90% confidence intervals):

<table>
<thead>
<tr>
<th>Pharmacokinetic Parameter</th>
<th>Geometric Mean</th>
<th>Arithmetic Mean</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>AUC_{0-t} (ng.h/ml)</td>
<td>1656.033</td>
<td>1710.797</td>
<td>461.985</td>
</tr>
<tr>
<td>AUC_{0-∞} (ng.h/ml)</td>
<td>1711.030</td>
<td>1771.356</td>
<td>495.997</td>
</tr>
<tr>
<td>C_{max} (ng/ml)</td>
<td>294.335</td>
<td>306.451</td>
<td>84.797</td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>Pharmacokinetic Parameter</th>
<th>Geometric Mean</th>
<th>Arithmetic Mean</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>AUC_{0-t} (ng.h/ml)</td>
<td>1698.744</td>
<td>1742.494</td>
<td>409.380</td>
</tr>
<tr>
<td>AUC_{0-∞} (ng.h/ml)</td>
<td>1747.571</td>
<td>1795.333</td>
<td>434.468</td>
</tr>
<tr>
<td>C_{max} (ng/ml)</td>
<td>328.974</td>
<td>334.369</td>
<td>60.366</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pharmacokinetic Parameter</th>
<th>Ratio</th>
<th>90% Confidence Intervals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Lower 90% CI</td>
</tr>
<tr>
<td>AUC_{0-t}</td>
<td>1.02</td>
<td>0.99</td>
</tr>
<tr>
<td>AUC_{0-∞}</td>
<td>1.02</td>
<td>0.99</td>
</tr>
<tr>
<td>C_{max}</td>
<td>1.12</td>
<td>1.04</td>
</tr>
</tbody>
</table>

AUC_{0-t} area under the plasma concentration-time curve from time zero to t hours
AUC_{0-∞} area under the plasma concentration-time curve from time zero to infinity
C_{max} maximum plasma concentration
90% CI* 90% Geometric Confidence Interval using log-transformed data
The 90% confidence intervals for AUC and $C_{\text{max}}$ for test versus reference product for montelukast are within predefined acceptance criteria specified in "Guideline on the Investigation of Bioequivalence" (CPMP/EWP/QWP/1401/98 Rev 1/, Corr). Thus, the data support the claim that the test product is bioequivalent to the reference product.

As the 4 mg and 5 mg strengths of the product meet the criteria specified in “Guideline on the Investigation of Bioequivalence” (CPMP/EWP/QWP/1401/98 Rev 1/, Corr), the results and conclusions of the bioequivalence study on the 5 mg strength can be extrapolated to the 4 mg strength.

**Pharmacodynamics**
No new pharmacodynamic data were submitted and none were required for these applications.

**Efficacy**
No new efficacy data were submitted and none were required for these applications.

**Safety**
With the exception of the data generated during the bioequivalence study, no new safety data were submitted and none were required for these applications. No new or unexpected safety issues were raised by the bioequivalence data.

**Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL), Labels**
The SmPCs, PIL and labels are acceptable. The SmPCs are consistent with that for the originator products. The PIL is consistent with the SmPCs and in line with current guidelines. The labelling is in-line with current guidelines.

**Clinical Expert Report**
The clinical overview has been written by an appropriately qualified physician and is a suitable summary of the clinical aspects of the dossier.

**Pharmacovigilance System and Risk Management Plan**
The pharmacovigilance system, as described by the applicant, fulfils the requirements and provides adequate evidence that the applicant has the services of a qualified person responsible for pharmacovigilance, and has the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.

A suitable justification has been provided for not submitting a Risk Management Plan for these products.

**Conclusion**
There are no objections to the approval of these products from a clinical viewpoint.
IV OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT
QUALITY
The important quality characteristics of Montelukast 4 mg and 5 mg chewable tablets are well-defined and controlled. The specifications and batch analytical results indicate consistency from batch to batch. There are no outstanding quality issues that would have a negative impact on the benefit-risk balance.

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

EFFICACY
With the exception of the bioequivalence study, no new data were submitted and none are required for applications of this type.

Bioequivalence has been demonstrated between the applicant’s Montelukast 5 mg chewable tablets and its respective reference product Singulair Junior® 5 mg Kautabletten (MSD Dieckmann Arzneimittel GMBH). As the 4 mg and 5 mg strengths of the product meet the biowaiver criteria specified in the current guideline on investigation of bioequivalence (CPMP/EWP/QWP/1401/98rev 1/Corr**), the results and conclusions of the bioequivalence study on the 5 mg strength can be extrapolated to the 4 mg strength tablet.

SAFETY
With the exception of the bioequivalence study, no new data were submitted and none are required for applications of this type. As the safety profile of montelukast sodium is well-known, no additional data were required. No new or unexpected safety concerns arose from the safety data from the bioequivalence study.

PRODUCT LITERATURE
The SmPCs, PILs and labelling are satisfactory and consistent with that for the reference product, where appropriate.

BENEFIT-RISK ASSESSMENT
The quality of the products is acceptable, and no new non-clinical or clinical safety concerns have been identified. Bioequivalence has been demonstrated between the applicant’s test product and its respective reference product. Extensive clinical experience with montelukast sodium is considered to have demonstrated the therapeutic value of the compound. The benefit-risk is, therefore, considered to be positive.
STEPS TAKEN FOR ASSESSMENT

1. The MHRA received the marketing authorisation applications on 06 March 2009.

2. Following standard checks and communication with the applicant the MHRA considered the applications valid on 18 March 2009.

3. Following assessment of the applications the MHRA requested further information relating to the quality dossier on 01 July 2011 and the clinical dossier on 21 August 2009, 03 June 2010 and 08 February 2011.

4. The applicant responded to the MHRA’s requests, providing further information on the quality dossier on 27 February 2012 and clinical dossier on 03 March 2010, 29 July 2010 and 08 March 2011

5. The applications were determined on 19 November 2012.
MONTELUKAST 4 MG CHEWABLE TABLETS
MONTELUKAST 5 MG CHEWABLE TABLETS

PL 24668/0238-41

STEPS TAKEN AFTER ASSESSMENT

<table>
<thead>
<tr>
<th>Date submitted</th>
<th>Application type</th>
<th>Scope</th>
<th>Outcome</th>
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</tbody>
</table>
SUMMARY OF PRODUCT CHARACTERISTICS

In accordance with Directive 2010/84/EU the Summaries of Product Characteristics (SmPC) and Patient Information Leaflets (PIL) for products granted Marketing Authorisations at a national level are available on the MHRA website.
Module 3
PATIENT INFORMATION LEAFLET

In accordance with Directive 2010/84/EU the Summaries of Product Characteristics (SmPC) and Patient Information Leaflets (PIL) for products granted Marketing Authorisations at a national level are available on the MHRA website.
LABELLING

The following text is the approved labelling text. In accordance with medicines legislation, the product shall not be marketed in the UK until approval of the labelling mock-ups has been obtained.

<table>
<thead>
<tr>
<th>PARTICULARS TO APPEAR ON THE OUTER PACKAGING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outer Carton</td>
</tr>
</tbody>
</table>

1. **NAME OF THE MEDICINAL PRODUCT**

Montelukast 4 mg chewable tablets
Montelukast sodium

2. **STATEMENT OF ACTIVE SUBSTANCE(S)**

Each chewable tablet contains montelukast sodium equivalent to 4 mg montelukast.

3. **LIST OF EXCIPIENTS**

Also contains lactose and aspartame.
See the leaflet for further information.

4. **PHARMACEUTICAL FORM AND CONTENTS**

Chewable tablets.

7 tablets
10 tablets
14 tablets
20 tablets
28 tablets
30 tablets
49 tablets
50 tablets
56 tablets
98 tablets
100 tablets
140 tablets
200 tablets

5. **METHOD AND ROUTE(S) OF ADMINISTRATION**

Oral use.
Read the package leaflet before use.

6. **SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN**

Keep out of the sight and reach of children.

7. **OTHER SPECIAL WARNING(S), IF NECESSARY**

8. **EXPIRY DATE**

Expire date:
9. SPECIAL STORAGE CONDITIONS

This medicinal product does not require any special storage conditions.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Caduceus Pharma Limited.
6th Floor, 94 Wigmore Street, London W1U 3RF
United Kingdom

12. MARKETING AUTHORISATION NUMBER(S)

PL 24688/0238

13. BATCH NUMBER

Batch number:

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

montelukast 4mg chewable tablets
<table>
<thead>
<tr>
<th>MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blister</td>
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</table>

| 1. NAME OF THE MEDICINAL PRODUCT                  |
| Montelukast 4 mg chewable tablet                  |
| Montelukast sodium                               |

| 2. NAME OF THE MARKETING AUTHORISATION HOLDER    |
| Caduceus Pharma Ltd                              |

| 3. EXPIRY DATE                                   |
| Exp:                                             |

| 4. BATCH NUMBER                                  |
| Lot:                                             |

| 5. OTHER                                         |

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer Carton

1. NAME OF THE MEDICINAL PRODUCT

Montelukast 5 mg chewable tablets
Montelukast sodium

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each chewable tablet contains montelukast sodium equivalent to 5 mg montelukast.

3. LIST OF EXCIPIENTS

Also contains lactose and aspartame.
See the leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Chewable tablets.

7 tablets
10 tablets
14 tablets
20 tablets
28 tablets
30 tablets
49 tablets
50 tablets
56 tablets
98 tablets
100 tablets
140 tablets
200 tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

Expiry date:
9. **SPECIAL STORAGE CONDITIONS**

This medicinal product does not require any special storage conditions.

10. **SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

11. **NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Caduceus Pharma Limited.
6th Floor, 94 Wigmore Street, London W1U 3RF
United Kingdom

12. **MARKETING AUTHORISATION NUMBER(S)**

PL 24688/0239

13. **BATCH NUMBER**

Batch number:

14. **GENERAL CLASSIFICATION FOR SUPPLY**

POM

15. **INSTRUCTIONS ON USE**

16. **INFORMATION IN BRAILLE**

montelukast 5 mg chewable tablets
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| Caduceus Pharma Ltd                               |

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| Exp:                                              |

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| Lot:                                              |

| 5. OTHER                                          |
PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer Carton

1. NAME OF THE MEDICINAL PRODUCT

Montelukast 4 mg chewable tablets
Montelukast sodium

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each chewable tablet contains montelukast sodium equivalent to 4 mg montelukast.

3. LIST OF EXCIPIENTS

Also contains lactose and aspartame.
See the leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Chewable tablets.
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5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY


8. EXPIRY DATE

Expiry date:
9. **SPECIAL STORAGE CONDITIONS**

This medicinal product does not require any special storage conditions.

10. **SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

11. **NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Cadeceus Pharma Limited,
6th Floor, 94 Wigmore Street, London W1U 3RF
United Kingdom

12. **MARKETING AUTHORISATION NUMBER(S)**

PL 24688/0240

13. **BATCH NUMBER**

Batch number.

14. **GENERAL CLASSIFICATION FOR SUPPLY**

POM

15. **INSTRUCTIONS ON USE**

16. **INFORMATION IN BRAILLE**

montelukast 4mg chewable tablets
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Montelukast 4 mg chewable tablet
Montelukast sodium

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Caduceus Pharma Ltd

3. **EXPIRY DATE**

Exp:

4. **BATCH NUMBER**

Lot:

5. **OTHER**
PARTICULARS TO APPEAR ON THE OUTER PACKAGING
Outer Carton

1. NAME OF THE MEDICINAL PRODUCT
Montelukast 5 mg chewable tablets
Montelukast sodium

2. STATEMENT OF ACTIVE SUBSTANCE(S)
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3. LIST OF EXCIPIENTS
Also contains lactose and aspartame.
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Oral use.
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN
Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE
Expiry date:
9. SPECIAL STORAGE CONDITIONS

This medicinal product does not require any special storage conditions

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Caduceus Pharma Limited.
6th Floor, 94 Wigmore Street, London W1U 3RF
United Kingdom

12. MARKETING AUTHORISATION NUMBER(S)

PL 24688/0241

13. BATCH NUMBER

Batch number:

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

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**Blister**

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<th>2. NAME OF THE MARKETING AUTHORISATION HOLDER</th>
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<td>Caduceus Pharma Ltd</td>
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<th>4. BATCH NUMBER</th>
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<th>5. OTHER</th>
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