Public Assessment Report

UKPAR

Dexamethasone 0.5 mg Tablets

(dexamethasone)

UK Licence No: PL 20620/0093, 0096 and 0097

Lime Pharma Limited
LAY SUMMARY

Dexamethasone 0.5 mg Tablets
(dexamethasone, tablets, 0.5 mg)

This is a summary of the Public Assessment Report (PAR) for Dexamethasone 0.5 mg Tablets (PL 20620/0093, 0096 and 0097). It explains how Dexamethasone 0.5 mg 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 Dexamethasone 0.5 mg Tablets.

For practical information about using Dexamethasone 0.5 mg Tablets, patients should read the package leaflet or contact their doctor or pharmacist.

What are Dexamethasone 0.5 mg Tablets and what are they used for?
Dexamethasone 0.5 mg Tablets contain the active ingredient dexamethasone which belongs to a group of medicines called steroids. Their full name is corticosteroids. This medicine is used to treat various illnesses involving inflammation in the body. Dexamethasone reduces this inflammation, which could otherwise go on making the patient’s condition worse. The patient must take this medicine regularly to get maximum benefit from it.

This medicine is identical to Dexamethasone 0.5 mg Tablets (PL 17507/0052) which was granted a Marketing Authorisation on 13 June 2014.

How are Dexamethasone 0.5 mg Tablets used?
The patient must remember to always carry a Steroid Treatment Card. The patient must make sure their doctor or pharmacist gives them this and has filled out the details including the dose and how long they will have treatment.
If the patient has surgery, an accident or becomes unwell while taking this medicine, the patient must tell whoever is treating them that they are taking Dexamethasone 0.5 mg Tablets.

The patient should always take this medicine exactly as their doctor has told them. The patient must check with their doctor or pharmacist if they are not sure.

The dose is chosen by the patient’s doctor and usually depends on how serious the patient’s condition is.

Sometimes the patient may need blood or urine tests to work out how much they should take.

The tablets should be swallowed whole with some water. Do not chew them.

The patient must not stop taking Dexamethasone 0.5 mg Tablets suddenly. When the patient no longer needs them, the patient’s daily dose should be reduced gradually. However, the patient should speak to their doctor or pharmacist about the best way to safely reduce their daily dose.

Dexamethasone 0.5 mg Tablets can be obtained only with a prescription.

For further information on how Dexamethasone 0.5 mg Tablets are used, refer to the package leaflet and Summary of Product Characteristics available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.
How do Dexamethasone 0.5 mg Tablets work?
Dexamethasone belongs to a group of medicines called corticosteroids. These corticosteroids occur naturally in the body and help to maintain health and well-being.

Boosting the patient’s body with extra corticosteroid (such as dexamethasone) is an effective way to treat various illnesses involving inflammation in the body. Dexamethasone reduces this inflammation which could otherwise go on making the patient’s condition worse.

What benefits of Dexamethasone 0.5 mg Tablets have been shown in studies?
The applications for Dexamethasone 0.5 mg Tablets are considered to be identical to the previously authorised application for Dexamethasone 0.5 mg Tablets (PL 17507/0052), with the same benefits and risks. So, no new studies have been provided for Dexamethasone 0.5 mg Tablets. However, reference is made to the studies for Dexamethasone 0.5 mg Tablets (PL 17507/0052).

The company (Lime Pharma Limited) referred to data provided by Auden Mckenzie (Pharma Division) Ltd for the grant of the licence for Dexamethasone 0.5 mg Tablets (PL 17507/0052) as a basis for the grant of identical licences for Dexamethasone 0.5 mg Tablets (PL 20620/0093, 0096 and 0097).

What are the possible side effects from Dexamethasone 0.5 mg Tablets?
Like all medicines, this medicine can cause side effects, although not everybody gets them.

Dexamethasone 0.5 mg Tablets (PL 20620/0093, 0096 and 0097) are considered to be identical to the previously authorised application for Dexamethasone 0.5 mg Tablets (PL 17507/0052) with the same benefits and risks.

For a full list of all the side effects reported with Dexamethasone 0.5 mg Tablets see section 4 of the package leaflet, available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

Why are Dexamethasone 0.5 mg Tablets approved?
No new or unexpected safety concerns arose from these applications. The MHRA, therefore, considered that the benefits of Dexamethasone 0.5 mg Tablets outweigh their risks; and the grant of Marketing Authorisations (licences) was recommended.

What measures are being taken to ensure the safe and effective use of Dexamethasone 0.5 mg Tablets?
A Risk Management Plan has been developed to ensure that Dexamethasone 0.5 mg Tablets are used as safely as possible. Based on this plan, safety information has been included in the Summaries of Product Characteristics and the package leaflets for Dexamethasone 0.5 mg 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 Dexamethasone 0.5 mg Tablets
Marketing Authorisations were granted in the UK on 06 January 2015.

The full PAR for Dexamethasone 0.5 mg Tablets follows this summary.
For more information about treatment with Dexamethasone 0.5 mg Tablets read the package leaflet, or contact your doctor or pharmacist.

This summary was last updated in February 2015.
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<td>VI Overall conclusion, benefit/risk assessment and recommendation</td>
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I INTRODUCTION
The Medicines and Healthcare products Regulatory Agency (MHRA) granted Lime Pharma Limited Marketing Authorisations for the medicinal products Dexamethasone 0.5 mg Tablets (PL 20620/0093, 0096 and 0097) on 06 January 2015. The products are prescription-only medicines (POM) indicated in a wide variety of disorders amenable to glucocorticoid therapy, as well as an adjunct in the control of cerebral oedema.

These applications were submitted as abridged applications according to Article 10c of Directive 2001/83/EC, as amended.

The applications for Dexamethasone 0.5 mg Tablets cross-refer to Dexamethasone 0.5 mg Tablets (PL 17507/0052) which was authorised to Auden Mckenzie (Pharma Division) Ltd on 13 June 2014.

Dexamethasone is a synthetic glucocorticoid of which the anti-inflammatory potency on a weight for weight basis is 7 times greater than that of prednisolone. Pharmacological doses of corticosteroids/glucocorticoids are used when palliative anti-inflammatory or immunosuppressant effects are required to suppress the clinical manifestations of disease in a wide range of disorders considered to have inflammatory or immunological components.

Lack of mineralocorticoid (water and salt-retaining) properties makes dexamethasone particularly suitable for treating conditions where water retention would be a disadvantage, for example, cerebral oedema. Coupled with its long duration of action, dexamethasone is also indicated for conditions such as congenital adrenal hyperplasia which require suppression of corticotrophin secretion.

No new data were submitted nor were necessary to be submitted for these applications, as the data are identical to that of the previously granted cross-reference product.
II QUALITY ASPECTS

II.1 Introduction
These are abridged applications for Dexamethasone 0.5 mg Tablets (PL 20620/0093, 0096 and 0097) submitted under Article 10c of Directive 2001/83/EC, as amended.

The applications cross-refer to Dexamethasone 0.5 mg Tablets (PL 17507/0052) which was authorised to Auden Mckenzie (Pharma Division) Ltd on 13 June 2014. The applications are considered valid.

II.2 Drug Substance
Drug substance specification
The proposed drug substance specifications are consistent with the details registered for the cross-reference product.

II.3 Medicinal Product
Name
The proposed product name for these applications is Dexamethasone 0.5 mg Tablets. The product has been named in line with current requirements.

Strength, pharmaceutical form, route of administration, container and pack sizes
Each tablet contains 0.5 mg of dexamethasone. The route of administration is oral.

The finished product is packed into polyvinyl chloride (PVC)/aluminium blister strips and is available in pack sizes of 28, 50 and 100 tablets. Not all pack sizes may be marketed.

The proposed shelf life for the product is 24 months with the storage conditions ‘Store in the original package in order to protect from light.’

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

Legal status
On approval, the products will be available as prescription-only medicines (POM).

Marketing Authorisation Holder/Contact Persons/Company
Lime Pharma Limited, Mckenzie House, Bury Street, Ruislip, Middlesex, HA4 7TL, UK.

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

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.

Qualitative and quantitative composition
The proposed compositions are consistent with the details registered for the cross-reference product.

Manufacturing process
The proposed manufacturing process is consistent with the details registered for the cross-reference product and the maximum batch sizes are stated.
Finished product/shelf-life specification
The proposed finished product specifications are in line with the details registered for the cross-reference product.

TSE Compliance
None of the excipients contain materials of animal or human origin. This is consistent with the cross-reference product.

Bioequivalence
No bioequivalence data are required to support these simple abridged applications because the proposed products are manufactured to the same formula utilising the same processes as the cross-reference product, Dexamethasone 0.5 mg Tablets (PL 17507/0052).

Expert Report
The applicant cross-refers to the data for Dexamethasone 0.5 mg Tablets (PL 17507/0052) to which these applications are claimed to be identical. This is acceptable.

Product Name and Appearance
See Section II.3 ‘Medicinal Product; Name’ for details of the proposed product name. The appearance of each product is identical to that of the cross-reference product.

II.4 Discussion on chemical, pharmaceutical and biological aspects
The data submitted with the applications are acceptable. The grant of Marketing Authorisations is recommended.

II.5 Summaries of Product Characteristics (SmPC), Patient Information Leaflets (PIL) and Labels
The Summaries of Product Characteristics and Patient Information Leaflets (PILs) are consistent with the details registered for the cross-reference products.

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

The following text is the approved label text for Dexamethasone 0.5 mg Tablets. No label mock-ups have been provided. In accordance with medicines legislation, the product shall not be marketed in the UK until approval of the label mock-ups has been obtained:
Carton Labelling Text

1. NAME OF THE MEDICINAL PRODUCT
Dexamethasone 0.5 mg Tablets

2. STATEMENT OF ACTIVE SUBSTANCE(S)
Each tablet contains 0.5 mg dexamethasone.

3. LIST OF EXCIPIENTS
Also contains lactose monohydrate.

4. PHARMACEUTICAL FORM AND CONTENTS
28 Tablets
50 Tablets
100 tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION
For oral use
Please read the enclosed 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
Exp xx/yyyy

9. SPECIAL STORAGE CONDITIONS
Store in the original package in order to protect from light.

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
Lime Pharma Ltd.
Mckenzie House, Bury Street, Ruislip,
Middlesex. HA4 7TL, UK.
PAR Dexamethasone 0.5 mg Tablets

12. MARKETING AUTHORISATION NUMBER(S)
   PL No. 20620/0093

13. BATCH NUMBER<, DONATION AND PRODUCT CODES>
   B/N XXXX

14. GENERAL CLASSIFICATION FOR SUPPLY
   POM

15. INSTRUCTIONS ON USE
   -

16. INFORMATION IN BRAILLE
   Dexamethasone 0.5 mg Tablets

Blisters Label Text

1. NAME OF THE MEDICINAL PRODUCT
   Dexamethasone 0.5 mg Tablets

2. NAME OF THE MARKETING AUTHORISATION HOLDER
   PL Holder: Lime Pharma Ltd.

3. EXPIRY DATE
   EXP: MM/YYYY

4. BATCH NUMBER<, DONATION AND PRODUCT CODES>
   BN: XXXX
Carton Labelling Text

1. **NAME OF THE MEDICINAL PRODUCT**
   Dexamethasone 0.5 mg Tablets

2. **STATEMENT OF ACTIVE SUBSTANCE(S)**
   Each tablet contains 0.5 mg dexamethasone.

3. **LIST OF EXCIPIENTS**
   Also contains lactose monohydrate.

4. **PHARMACEUTICAL FORM AND CONTENTS**
   - 28 Tablets
   - 50 Tablets
   - 100 tablets

5. **METHOD AND ROUTE(S) OF ADMINISTRATION**
   For oral use
   Please read the enclosed 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**
   Exp xx/yyyy

9. **SPECIAL STORAGE CONDITIONS**
   Store in the original package in order to protect from light.

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**
    Lime Pharma Ltd.
    McKenzie House, Bury Street, Ruislip,
    Middlesex, HA4 7TL, UK.
12. MARKETING AUTHORISATION NUMBER(S)
PL No. 20620/0096

13. BATCH NUMBER<, DONATION AND PRODUCT CODES>
B/N XXXX

14. GENERAL CLASSIFICATION FOR SUPPLY
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15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE
Dexamethasone 0.5 mg Tablets

Blisters Label Text

1. NAME OF THE MEDICINAL PRODUCT
Dexamethasone 0.5 mg Tablets

2. NAME OF THE MARKETING AUTHORISATION HOLDER
PL Holder: Lime Pharma Ltd.

3. EXPIRY DATE
EXP: MM/YYYY

4. BATCH NUMBER<, DONATION AND PRODUCT CODES>
BN: XXXX
Carton Labelling Text

1. **NAME OF THE MEDICINAL PRODUCT**
   Dexamethasone 0.5 mg Tablets

2. **STATEMENT OF ACTIVE SUBSTANCE(S)**
   Each tablet contains 0.5 mg dexamethasone.

3. **LIST OF EXCIPIENTS**
   Also contains lactose monohydrate.

4. **PHARMACEUTICAL FORM AND CONTENTS**
   28 Tablets
   50 Tablets
   100 tablets

5. **METHOD AND ROUTE(S) OF ADMINISTRATION**
   For oral use
   Please read the enclosed 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**
   Exp xx/yyyy

9. **SPECIAL STORAGE CONDITIONS**
   Store in the original package in order to protect from light.

10. **SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**
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11. **NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**
    Lime Pharma Ltd.
    McKenzie House, Bury Street, Ruislip,
    Middlesex, HA4 7TL, UK.
<table>
<thead>
<tr>
<th></th>
<th>MARKETING AUTHORISATION NUMBER(S)</th>
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<tbody>
<tr>
<td></td>
<td>PL No. 20620/0097</td>
</tr>
<tr>
<td></td>
<td>BATCH NUMBER&lt;, DONATION AND PRODUCT CODES&gt;</td>
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<td></td>
<td>B/N XXXX</td>
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<td></td>
<td>GENERAL CLASSIFICATION FOR SUPPLY</td>
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<td>POM</td>
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<td>INSTRUCTIONS ON USE</td>
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<td></td>
<td>INFORMATION IN BRAILLE</td>
</tr>
</tbody>
</table>

Dexamethasone 0.5 mg Tablets

**Blister Label Text**

<table>
<thead>
<tr>
<th></th>
<th>NAME OF THE MEDICINAL PRODUCT</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Dexamethasone 0.5 mg Tablets</td>
</tr>
<tr>
<td></td>
<td>NAME OF THE MARKETING AUTHORISATION HOLDER</td>
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<td></td>
<td>PL Holder: Line Pharma Ltd.</td>
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<tr>
<td></td>
<td>EXPIRY DATE</td>
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<td></td>
<td>EXP: MM/YYYY</td>
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<td></td>
<td>BATCH NUMBER&lt;, DONATION AND PRODUCT CODES&gt;</td>
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<td></td>
<td>BN: XXXX</td>
</tr>
</tbody>
</table>
III NON-CLINICAL ASPECTS

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

Ecotoxicity/environmental risk assessment (ERA)
Suitable justification has been provided for non-submission of an Environmental Risk Assessment. As the applications are identical versions of an already authorised product, it is not expected that environmental exposure will increase following approval of the Marketing Authorisations for the proposed products.

Discussion on the non-clinical aspects
The grant of Marketing Authorisations is recommended.

IV CLINICAL ASPECTS

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

Risk Management Plan (RMP)
The marketing authorisation holder (MAH) has submitted a risk management plan (RMP), in accordance with the requirements of Directive 2001/83/EC as amended, describing the pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to Dexamethasone 0.5 mg Tablets.

A summary of safety concerns and planned risk minimisation activities, as approved in the RMP, are listed below:

Summary table of safety concerns:

<table>
<thead>
<tr>
<th>Important identified risks</th>
<th>Use in patients with infection</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Use in patient having any vaccinations</td>
</tr>
<tr>
<td></td>
<td>Use in patients with existing or previous history of severe affective disorders in themselves or in their first degree relatives and including depressive or manic-depressive illness and previous steroid psychosis</td>
</tr>
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<td></td>
<td>Use in patients with glaucoma</td>
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<tr>
<td></td>
<td>Use in patient history of tuberculosis (or X-ray changes)</td>
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<tr>
<td></td>
<td>Use in patient hypertension</td>
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<tr>
<td></td>
<td>Use in patient with recent myocardial infarction (rupture reported)</td>
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<tr>
<td></td>
<td>Use in patient with congestive heart failure</td>
</tr>
<tr>
<td></td>
<td>Use in patient with renal impairment</td>
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<tr>
<td></td>
<td>Use in patient with diabetes mellitus including family history</td>
</tr>
<tr>
<td></td>
<td>Use in patient with osteoporosis (post-menopausal women at special risk)</td>
</tr>
<tr>
<td></td>
<td>Use in patient with glaucoma (including family history)</td>
</tr>
</tbody>
</table>
### Summary table of Risk Minimisation Measures:

<table>
<thead>
<tr>
<th>Safety concern</th>
<th>Routine risk minimisation activities sufficient?</th>
<th>If yes, provide description of routine activity and justification</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Important identified risk</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Use in patients with infection</td>
<td>Yes</td>
<td>SmPC Section 4.3 (Contraindications), Section 4.4 (Special warnings and precautions for use) and Leaflet Section 2</td>
</tr>
<tr>
<td>Use in patient having any vaccinations</td>
<td>Yes</td>
<td>SmPC Section 4.3 (Contraindications), Section 4.5 (Interaction with other medicinal products and other forms of interaction) and Leaflet Section 2</td>
</tr>
<tr>
<td>Use in patients with existing or previous history of severe affective disorders in themselves or</td>
<td>Yes</td>
<td>SmPC Section 4.4 (Special warnings and special precautions for use) and Leaflet Section 2</td>
</tr>
<tr>
<td>Use in patients with glaucoma (including family history)</td>
<td>Yes</td>
<td>SmPC Section 4.4 (Special warnings and special precautions for use) and Leaflet Section 2</td>
</tr>
<tr>
<td>--------------------------------------------------------</td>
<td>-----</td>
<td>----------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Use in patient history of tuberculosis (or X-ray changes)</td>
<td>Yes</td>
<td>SmPC Section 4.4 (Special warnings and special precautions for use) and Leaflet Section 2</td>
</tr>
<tr>
<td>Use in patient hypertension</td>
<td>Yes</td>
<td>SmPC Section 4.4 (Special warnings and special precautions for use) and Leaflet Section 2</td>
</tr>
<tr>
<td>Use in patient with recent myocardial infarction (rupture reported)</td>
<td>Yes</td>
<td>SmPC Section 4.4 (Special warnings and special precautions for use) and Leaflet Section 2</td>
</tr>
<tr>
<td>Use in patient with congestive heart failure</td>
<td>Yes</td>
<td>SmPC Section 4.4 (Special warnings and special precautions for use) and Leaflet Section 2</td>
</tr>
<tr>
<td>Use in patient with renal impairment</td>
<td>Yes</td>
<td>SmPC Section 4.4 (Special warnings and special precautions for use) and Leaflet Section 2</td>
</tr>
<tr>
<td>Use in patient with diabetes mellitus including family history</td>
<td>Yes</td>
<td>SmPC Section 4.4 (Special warnings and special precautions for use) and Leaflet Section 2</td>
</tr>
<tr>
<td>Use in patient with osteoporosis (post-menopausal women at special risk)</td>
<td>Yes</td>
<td>SmPC Section 4.4 (Special warnings and special precautions for use) and Leaflet Section 2</td>
</tr>
<tr>
<td>Use in patient with corneal perforation</td>
<td>Yes</td>
<td>SmPC Section 4.4 (Special warnings and special precautions for use) and Leaflet Section 2</td>
</tr>
<tr>
<td>Use in patient with severe affective disorders (particularly if history of steroid-induced psychosis)</td>
<td>Yes</td>
<td>SmPC Section 4.4 (Special warnings and special precautions for use) and Leaflet Section 2</td>
</tr>
<tr>
<td>Use in patient with epilepsy</td>
<td>Yes</td>
<td>SmPC Section 4.4 (Special warnings and special precautions for use) and Leaflet Section 2</td>
</tr>
<tr>
<td>Use in patient with peptic ulcer, ulcerative colitis, diverticulitis, recent intestinal anastomoses</td>
<td>Yes</td>
<td>SmPC Section 4.4 (Special warnings and special precautions for use) and Leaflet Section 2</td>
</tr>
<tr>
<td>Use in patient with hypothyroidism</td>
<td>Yes</td>
<td>SmPC Section 4.4 (Special warnings and special precautions for use) and Leaflet Section 2</td>
</tr>
<tr>
<td>Use in patient with history</td>
<td>Yes</td>
<td>SmPC Section 4.4 (Special warnings and special precautions for use) and Leaflet Section 2</td>
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<tr>
<td>Condition</td>
<td>Use</td>
<td>Section</td>
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<tr>
<td>-----------</td>
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<tr>
<td>of steroid myopathy</td>
<td>Yes</td>
<td>SmPC Section 4.4 (Special warnings and special precautions for use) and Leaflet Section 2</td>
</tr>
<tr>
<td>Use in patient with hepatic impairment</td>
<td>Yes</td>
<td>SmPC Section 4.4 (Special warnings and special precautions for use) and Leaflet Section 2</td>
</tr>
<tr>
<td>Use in patient with myasthenia gravis</td>
<td>Yes</td>
<td>SmPC Section 4.4 (Special warnings and special precautions for use) and Leaflet Section 2</td>
</tr>
<tr>
<td>Use in patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption</td>
<td>Yes</td>
<td>SmPC Section 4.4 (Special warnings and special precautions for use) and Leaflet Section 2</td>
</tr>
<tr>
<td>Abrupt withdrawal after prolonged therapy with corticosteroids may lead to acute adrenal insufficiency, hypotension or death</td>
<td>Yes</td>
<td>SmPC Section 4.4 (Special warnings and special precautions for use) and Leaflet Section 2</td>
</tr>
<tr>
<td>Use in children &amp; Elderly</td>
<td>Yes</td>
<td>SmPC Section 4.4 (Special warnings and special precautions for use) and Leaflet Section 2</td>
</tr>
<tr>
<td>Use in Patients With Measles</td>
<td>Yes</td>
<td>SmPC Section 4.4 (Special warnings and special precautions for use) and Leaflet Section 2</td>
</tr>
<tr>
<td>Use in combination with Ritonavir, Indinavir, Lopinavir and Saquinavir</td>
<td>Yes</td>
<td>SmPC Section 4.5 (Interaction with other medicinal products and other forms of interaction) and Leaflet Section 2</td>
</tr>
<tr>
<td>Use in combination with drugs having hypokalaemic effects</td>
<td>Yes</td>
<td>SmPC Section 4.5 (Interaction with other medicinal products and other forms of interaction) and Leaflet Section 2</td>
</tr>
<tr>
<td>Use in combination with drugs having hypoglycaemic agents (including insulin),</td>
<td>Yes</td>
<td>SmPC Section 4.5 (Interaction with other medicinal products and other forms of interaction) and Leaflet Section 2</td>
</tr>
<tr>
<td>Use in combination with drugs having anticoagulant effect</td>
<td>Yes</td>
<td>SmPC Section 4.5 (Interaction with other medicinal products and other forms of interaction) and Leaflet Section 2</td>
</tr>
<tr>
<td>Use in combination with drugs having diuretics effect</td>
<td>Yes</td>
<td>SmPC Section 4.5 (Interaction with other medicinal products and other forms of interaction) and Leaflet Section 2</td>
</tr>
<tr>
<td>Use in combination with drugs having antihypertensives effect</td>
<td>Yes</td>
<td>SmPC Section 4.5 (Interaction with other medicinal products and other forms of interaction) and Leaflet Section 2</td>
</tr>
<tr>
<td>Use in pregnancy</td>
<td>Yes</td>
<td>SmPC Section 4.6 (Fertility, pregnancy and lactation) and Leaflet Section 2</td>
</tr>
</tbody>
</table>

**Important potential risks**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Use</th>
<th>Section</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use lactation</td>
<td>Yes</td>
<td>SmPC Section 4.6 (Fertility, pregnancy and lactation) and Leaflet Section 2</td>
</tr>
<tr>
<td>Hypersensitivity</td>
<td>Yes</td>
<td>SmPC Section 4.3 (Contraindications) and Leaflet Section 2</td>
</tr>
<tr>
<td>Dexamethasone crossing the placenta and causes congenital abnormalities</td>
<td>Yes</td>
<td>SmPC Section 4.6 (Fertility, pregnancy and lactation) and Leaflet Section 2</td>
</tr>
</tbody>
</table>
In line with the reference product, the proposed risk minimisation measures are sufficient to minimise the risks of the product in the proposed indications. The RMP is acceptable. No new risks have been identified for these products, which are not already recognised for the reference product.

Discussion on the clinical aspects
The grant of Marketing Authorisations is recommended.

V User consultation
User-testing of the PILs for Dexamethasone 0.5 mg Tablets has been accepted based on the bridging report provided by the applicant making reference to the successful user-testing of the PIL for to Dexamethasone 0.5 mg Tablets (PL 17507/0052) as the ‘parent PIL’.

VI Overall conclusion, benefit/risk assessment and recommendation
The quality of the products is acceptable, and no new non-clinical or clinical safety concerns have been identified. The applicant’s products are identical to the cross-reference product. Extensive clinical experience with dexamethasone is considered to have demonstrated the therapeutic value of the compound. The benefit/risk balance is, therefore, considered to be positive.