Public Assessment Report

UK PAR

Hydrocortisone 1% w/w Ointment

(Hydrocortisone)

UK Licence No: PL 04917/0145

Pinewood Laboratories Limited
LAY SUMMARY

Hydrocortisone 1% w/w Ointment
(Hydrocortisone)

This is a summary of the Public Assessment Report (PAR) for Hydrocortisone 1% w/w Ointment (PL 04917/0145). It explains how the application for Hydrocortisone 1% w/w Ointment 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 Hydrocortisone 1% w/w Ointment.

For practical information about using Hydrocortisone 1% w/w Ointment, patients should read the package leaflet or contact their doctor or pharmacist.

For ease of reading, Hydrocortisone 1% w/w Ointment may be referred to as ‘Hydrocortisone Ointment’ in this Lay Summary.

What is Hydrocortisone Ointment and what is it used for?
This medicine is the same as Hydrocortisone 1% w/w Ointment (PL 04917/0020; Pinewood Laboratories Limited), which is already authorised in the UK. The licence holder (Pinewood Laboratories Limited) for Hydrocortisone 1% w/w Ointment (PL 04917/0020; Pinewood Laboratories Limited) has agreed that its own scientific data can be used as a basis for the grant of an identical licence for Hydrocortisone Ointment (PL 04917/0145) (informed consent).

Hydrocortisone Ointment is used to reduce inflammation in a variety of inflammatory skin conditions including eczema and dermatitis of all types such as:
- inherited skin inflammation, scaliness or itchiness (atopic eczema)
- light-sensitive skin (photodermatitis)
- dermatitis between folds of skin (intertrigo)
- dermatitis caused by irritants or allergens
- lumps in the skin with itching (prurigo nodularis)
- scaly or crusty skin, ‘cradle cap’ (seborrhoeic dermatitis)
- insect bite reactions.

How do Hydrocortisone Ointment work?
Hydrocortisone Ointment contain the active substance, hydrocortisone which belongs to a group of medicines called corticosteroids.

How is Hydrocortisone Ointment used?
Hydrocortisone Ointment is a smooth off-white ointment for application to the skin only.

The medicine should always be taken exactly as advised by the patient’s doctor. The patient’s doctor will tell the patient how much to apply and how often, but the patient must check with his/her doctor if he/she is not sure.

Hydrocortisone Ointment can only be obtained with a prescription.

Please read section 3 of the package leaflet for detailed information on dosing recommendations and the duration of treatment.
What benefits of Hydrocortisone Ointment have been shown in studies?
The application for Hydrocortisone Ointment (PL 04917/0145) is considered to be identical to the previously authorised licence for Hydrocortisone 1% w/w Ointment (PL 04917/0020; Pinewood Laboratories Limited), with the same benefits and risks. So, no new studies have been provided for Hydrocortisone Ointment (PL 04917/0145). However, reference is made to the studies Hydrocortisone 1% w/w Ointment (PL 04917/0020; Pinewood Laboratories Limited).

What are the possible side effects of Hydrocortisone Ointment?
Like all medicines, Hydrocortisone Ointment can cause side effects, although not everybody gets them.

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

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

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

What measures are being taken to ensure the safe and effective use of Hydrocortisone Ointment?
A Risk Management Plan has been developed to ensure that Hydrocortisone Ointment 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 Hydrocortisone Ointment, 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 Hydrocortisone Ointment
A Marketing Authorisation was granted in the UK to Pinewood Laboratories Limited on 04 May 2018.

The full PAR for Hydrocortisone Ointment follows this summary.

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

This summary was last updated in June 2018.
Hydrocortisone 1% w/w Ointment

(Hydrocortisone)

PL 04917/0145

SCIENTIFIC DISCUSSION

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I. INTRODUCTION
The Medicines and Healthcare products Regulatory Agency (MHRA) granted Pinewood Laboratories Limited a Marketing Authorisation for the medicinal product Hydrocortisone 1% w/w Ointment (PL 04917/0145) on 04 May 2018.

The product has topical anti-inflammatory activity of value in the treatment of a wide variety of dermatological conditions, including the following: eczema and dermatitis of all types including atopic eczema, photodermatitis, intertrigo, primary irritant and allergic dermatitis, prurigo nodularis, seborrhoeic dermatitis and insect bite reactions.

The application was submitted as a simple abridged (informed consent) application according to Article 10c of Directive 2001/83/EC, as amended. The application for Hydrocortisone 1% w/w Ointment (PL 04917/0145) cross-refers to Hydrocortisone 1% w/w Ointment (PL 04917/0020; Pinewood Laboratories Limited), which was granted in the UK on 11 November 1997. Hydrocortisone 1% w/w Ointment (PL 04917/0020; Pinewood Laboratories Limited) cross-refers to Hydrocortisone Ointment 1% (PL 13606/0023; Co-Pharma Limited), which was approved in the UK on 09 October 1996. Hydrocortisone Ointment 1% cross-refers to Hydrocortisone Skin Ointment (PL 00109/0135; Roussel Laboratories Limited), which was approved on 15 October 1986.

The active substance hydrocortisone is an anti-inflammatory steroid. Its anti-inflammatory action is due to reduction in the vascular component of the inflammatory response and reduction in the formation of inflammatory fluid and cellular exudates. The granulation reaction is also decreased due to the inhibition effect of Hydrocortisone on connective tissue. Stabilisation of most cell granules and lysosomal membranes decreases the mediators involved in inflammatory response and reduces release of enzymes in prostaglandin synthesis. The vasoconstrictor action of Hydrocortisone may also contribute to its anti-inflammatory activity.

No new data were submitted nor were they required for this application, as the product is identical to that of the previously granted cross-reference product.

II. QUALITY ASPECTS
II.1 INTRODUCTION
This is an informed consent application for Hydrocortisone 1% w/w Ointment (PL 04917/0145) submitted under Article 10c of Directive 2001/83/EC, as amended.

The application for Hydrocortisone 1% w/w Ointment (PL 04917/0145) cross-refers to Hydrocortisone 1% w/w Ointment (PL 04917/0020; Pinewood Laboratories Limited), which was granted in the UK on 11 November 1997. Hydrocortisone 1% w/w Ointment (PL 04917/0020; Pinewood Laboratories Limited) cross-refers to Hydrocortisone Ointment 1% (PL 13606/0023; Co-Pharma Limited), which was approved in the UK on 09 October 1996. Hydrocortisone Ointment 1% cross-refers to Hydrocortisone Skin Ointment (PL 00109/0135; Roussel Laboratories Limited), which was approved on 15 October 1986. The application is considered valid.

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

II.3 Medicinal Product Name
The proposed name of the product is Hydrocortisone 1% w/w Ointment. The product has been named in line with current requirements.
Strength, pharmaceutical form, route of administration, container and pack sizes
Each 1 gram of the ointment contains 10 mg of hydrocortisone (i.e. 1 %w/w). The ointment is applied to the skin.

The product is packaged in a collapsible aluminium tube, with a membrane seal at the nozzle, internal epoxy lacquer, latex end seal band in the crimp seal and a white plastic cap for reclosure after piercing membrane.

The product is available in pack sizes of 5g, 10g, 15g, 20g, 30g and 50g. Not all pack sizes may be marketed.

The proposed shelf life for the product is 60 months, with the special storage conditions ‘Do not store above 25° C.’

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

Legal status
The product is available as a Prescription only Medicine (POM).

Marketing Authorisation Holder/Contact Persons/Company

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 composition is 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 size is stated.

Finished product/shelf-life specification
The proposed finished product specification is consistent with the details registered for the cross-reference product.

TSE Compliance
None of the excipients contain materials of animal or human origin.

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 Hydrocortisone 1% w/w Ointment (PL 04917/0020; Pinewood Laboratories Limited).
**Product Name and Appearance**
See Section II.3 ‘Medicinal Product, Name’ for details of the proposed product name. The appearance of the product is identical to the cross-reference product.

**Summary of Product Characteristics (SmPC)**
The proposed SmPC is consistent with the details registered for the cross-reference product.

**Patient Information Leaflet (PIL) and Labelling**
PIL
The PIL has been prepared in line with the details registered for the cross-reference product.

**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 name of the product in Braille on the outer packaging and has included sufficient space for a standard UK pharmacy dispensing label.

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

III. NON-CLINICAL ASPECTS

**Introduction**
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.

**Ecotoxicity/Environmental Risk Assessment (ERA)**
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 of hydrocortisone will increase following approval of the Marketing Authorisation for the proposed product.

**Discussion on the non-clinical aspects**
The grant of a Marketing Authorisation is recommended.

IV. CLINICAL ASPECTS

**Introduction**
As this 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.

**Pharmacovigilance and Risk Management Plan (RMP)**
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.
Routine pharmacovigilance and routine risk minimisation activities are proposed for all safety concerns.

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

V. USER CONSULTATION
A user consultation with target patient groups on the Patient Information Leaflet (PIL) has been performed on the basis of a bridging report making reference to the PIL for Hydrocortisone 1% w/w Ointment (PL 04917/0020; Pinewood Laboratories Limited). The bridging report has been found to be acceptable.

VI. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

QUALITY
The data for this application are 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
No new efficacy data were supplied or required for this application. Hydrocortisone has a well-established efficacy profile. The product is identical to the previously granted licence for Hydrocortisone 1% w/w Ointment (PL 04917/0020; Pinewood Laboratories Limited).

SAFETY
No new safety data were supplied or required for this application. Hydrocortisone has a well-established safety profile. This product is identical to the previously authorised Hydrocortisone 1% w/w Ointment (PL 04917/0020; Pinewood Laboratories Limited).

PRODUCT LITERATURE
The SmPC and PIL are satisfactory, and consistent with those for the respective 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 hydrocortisone is considered to have demonstrated the therapeutic value of the compound. The benefit/risk assessment is, therefore, considered to be positive.
In accordance with Directive 2010/84/EU, the current version of the SmPC and PIL is available on the MHRA website. The current labelling is presented below:

Hydrocortisone 1% w/w Ointment

Each 1 gram of ointment contains 10 mg of hydrocortisone (i.e. 1% w/w).
Also contains Liquid Paraffin, White Soft Paraffin and Wool fat (see leaflet for further information).

For cutaneous use.
**DIRECTIONS FOR USE:**
Use as directed by the physician.
Please read the enclosed leaflet carefully before use.
Do not use on the face, eyes, ano-genital region, broken or infected skin including cold sores, acne, impetigo and athlete’s foot.

Keep out of the sight and reach of children.
Do not store above 25°C.

**PL Holder and Manufacturer:**
Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland.
PL 04917/0145 23EC00594PW
Hydrocortisone
1% w/w Ointment

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Use as directed by the Physician. Please read the enclosed leaflet carefully before use. Do not use on the face, eyes, ano-genital region, broken or infected skin including cold sores, acne, impetigo and athlete’s foot.

Overprinting Area should be kept unvarnished & blank, without pre-printed text or colour (for Man., Exp. Date, Batch Number & 2D datamatrix code when available).

PL Holder and Manufacturer:
Pinepwood Laboratories Ltd.,
Ballymacarbry, Co. Waterford, Ireland.
PL 04917/0145

Hydrocortisone 1% w/w Ointment

(Hydrocortisone)

PL 04917/0145

**STEPS TAKEN AFTER AUTHORISATION - SUMMARY**

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