Public Assessment Report

Decentralised Procedure

Clindamycin 75 mg Capsules, hard
Clindamycin 150 mg Capsules, hard
Clindamycin 300 mg Capsules, hard
(clindamycin hydrochloride)

Procedure No: UK/H/6914/001-003/DC

UK Licence No: PL 42765/0007-0009

Renata (UK) Limited
LAY SUMMARY

Clindamycin 75 mg Capsules, hard
Clindamycin 150 mg Capsules, hard
Clindamycin 300 mg Capsules, hard

(clindamycin hydrochloride)

This is a summary of the Public Assessment Report (PAR) for Clindamycin 75 mg Capsules, hard (PL 42765/0007; UK/H/6914/001/DC), Clindamycin 150 mg Capsules, hard (PL 42765/0008; UK/H/6914/002/DC) and Clindamycin 300 mg Capsules, hard (PL 42765/0009; UK/H/6914/003/DC). It explains how the applications for Clindamycin 75 mg, 150 mg and 300 mg Capsules, hard 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 Clindamycin 75 mg, 150 mg and 300 mg Capsules, hard.

For practical information about using Clindamycin 75 mg, 150 mg and 300 mg Capsules, hard, patients should read the package leaflet or contact their doctor or pharmacist.

For ease of reading, these products will be referred to as ‘Clindamycin Capsules’ or ‘Clindamycin 75 mg, 150 mg and 300 mg Capsules’ for the remainder of this lay summary.

What are Clindamycin Capsules and what are they used for?
Clindamycin 75 mg, 150 mg and 300 mg Capsules are ‘generic medicines’. This means that Clindamycin 75 mg, 150 mg and 300 mg Capsules are similar to ‘reference medicines’ already authorised in the European Union (EU) called Dalacin C 75 mg Capsules/Clindamycin 75 mg Capsules (PL 00057/0958; Pfizer Limited, UK), Dalacin C 150 mg Capsules/Clindamycin 150 mg Capsules (PL 00057/0957; Pfizer Limited, UK) and Dalacin C 300 mg Hard Capsules (Pfizer spol. s.r.o., Czech Republic), respectively. For ease of reading, the reference products will be referred to as ‘Dalacin C 75 mg and 150 mg Capsules (Pfizer Limited, UK) and Dalacin C 300 mg Hard Capsules (Pfizer spol. s.r.o., Czech Republic)’.

Clindamycin Capsules are used in the treatment of serious bacterial infections.

How do Clindamycin capsules work?
These medicines contain the active ingredient clindamycin hydrochloride, which is an antibiotic. It works by stopping the bacteria which are the cause of the infection from multiplying.

How are Clindamycin Capsules used?
The pharmaceutical form for these medicines is capsules, hard and the route of administration is oral (by mouth).

These medicines can only be obtained with a prescription.

The patient should always take Clindamycin Capsules exactly as the patient’s doctor or pharmacist has instructed. The patient should check with his/her doctor or pharmacist if unsure.

Clindamycin Capsules should be swallowed whole with a full glass of water.

Adults and Elderly Patients
The recommended dose is between 150 and 450 mg every 6 hours, depending on the severity of your infection.
Use in children
This medicine is used for children who are able to swallow capsules. The recommended dose in children is between 3 and 6mg per kg of bodyweight every six hours, depending on the severity of the infection. The child’s doctor will work out the number of capsules that the child should have.

Long term use of Clindamycin Capsules
If the patient has to take Clindamycin Capsules for a long time, the patient’s doctor may arrange regular liver, kidney and blood tests. The patient should not miss these check-ups with his/her doctor.

Long term use can also make the patient more likely to get other infections that do not respond to Clindamycin treatment.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration and the duration of treatment.

What benefits of Clindamycin Capsules have been shown in studies?
Because Clindamycin 75 mg, 150 mg and 300 mg Capsules’ are generic medicines, studies in patients have been limited to tests to determine that they are bioequivalent to the reference medicines, Dalacin C 75 mg and 150 mg Capsules (Pfizer Limited, UK) and Dalacin C 300 mg Hard Capsules (Pfizer spol. s.r.o., Czech Republic), respectively.

Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Clindamycin capsules?
As Clindamycin 75 mg, 150 mg and 300 mg Capsules are generic medicines, their possible side effects are taken as being the same as those of the reference medicines, Dalacin C 75 mg and 150 mg Capsules (Pfizer Limited, UK) and Dalacin C 300 mg Hard Capsules (Pfizer spol. s.r.o., Czech Republic), respectively.

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

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

Why were Clindamycin Capsules approved?
It was concluded that, in accordance with EU requirements, Clindamycin Capsules have been shown to have comparable quality and to be bioequivalent to Dalacin C 75 mg and 150 mg Capsules (Pfizer Limited, UK) and Dalacin C 300 mg Hard Capsules (Pfizer spol. s.r.o., Czech Republic), respectively. Therefore, the MHRA decided that, as for Dalacin C 75 mg and 150 mg Capsules (Pfizer Limited, UK) and Dalacin C 300 mg Hard Capsules (Pfizer spol. s.r.o., Czech Republic), respectively, the benefits outweigh the identified risks and recommended that Clindamycin Capsules can be approved for use.

What measures are being taken to ensure the safe and effective use of Clindamycin Capsules?
A Risk Management Plan (RMP) has been developed to ensure that Clindamycin Capsules are used as safely as possible. Based on this plan, safety information has been included in the Summaries of Product Characteristics (SmPCs) and the package leaflet for Clindamycin Capsules 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 and reviewed continuously.

Other information about Clindamycin Capsules
Ireland and the UK agreed to grant Marketing Authorisations for Clindamycin Capsules on 14 December 2018. Marketing Authorisation for Clindamycin Capsules were granted in the UK to Renata (UK) Limited on 11 January 2019.
The full PAR for Clindamycin Capsules follows this summary.

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

This summary was last updated in March 2019.
SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy, Ireland and the UK considered that the applications for Clindamycin 75 mg, 150 mg and 300 mg hard capsules (PL 42765/0007-0008; UK/H/6914/001-003/DC) could be approved. These products are prescription-only medicines (legal classification POM) and are indicated for the treatment of serious infections caused by anaerobic bacteria, including intra-abdominal infections, skin and soft tissue infections. As needed, clindamycin should be administered in conjunction with another antibacterial agent that is active against gram negative aerobic bacteria. Clindamycin Capsules are also indicated for the treatment of tonsillitis and dental infection.

Consideration should be given to official guidance regarding the appropriate use of antibacterial agents.

Clindamycin does not penetrate the blood/brain barrier in therapeutically effective quantities.

These were applications made according to Article 10(1) of Directive 2001/83/EC, as amended. The European reference products are Dalacin C 75 mg Capsules/Clindamycin 75 mg Capsules (PL 00057/0958; Pfizer Limited, UK), Dalacin C 150 mg Capsules/Clindamycin 150 mg Capsules (PL 00057/0957; Pfizer Limited, UK) and Dalacin C 300 mg Hard Capsules (Pfizer spol. s.r.o., Czech Republic), respectively. Dalacin C 75 mg Capsules/Clindamycin 75 mg Capsules (Pfizer Limited, UK) and Dalacin C 150 mg Capsules/Clindamycin 150 mg Capsules (Pfizer Limited, UK) were authorised in the UK on 20 February 1989. Dalacin C 300 mg Hard Capsules (Marketing Authorisation Number 15/166/72-B/C; Pfizer spol. s.r.o., Czech Republic) was authorised in the Czech Republic on 16 May 1972.

These products contain the active substance clindamycin (as clindamycin hydrochloride), which is a lincosamide antibiotic with a primarily bacteriostatic action against Gram-positive aerobes and a wide range of anaerobic bacteria. Lincosamides such as clindamycin bind to the 50S subunit of the bacterial ribosome, similarly to macrolides such as erythromycin, and inhibit the early stages of protein synthesis. The action of clindamycin is predominantly bacteriostatic although high concentrations may be slowly bactericidal against sensitive strains.

One bioequivalence study, comparing the applicant’s test product Clindamycin 300 mg hard Capsule with the reference product Dalacin C 300mg Hard Capsule (Pfizer spol. s r.o., Prague, Czech Republic) under fasting conditions, was submitted to support these applications. The bioequivalence study is stated to have been carried out in accordance with Good Clinical Practice (GCP).

With the exception of the bioequivalence study, no new clinical or non-clinical studies were conducted, which is acceptable given that the applications were based on being generic medicinal products of originator products that have been licensed for over 10 years.

The RMS has been assured that acceptable standards of Good Manufacturing Practice are in place for this product type at all sites responsible for the manufacture, assembly and batch release of these products.

For manufacturing sites within the Community, the RMS has accepted copies of current manufacturer authorisations issued by inspection services of the competent authorities as certification that acceptable standards of GMP are in place at those sites.

For manufacturing sites outside the Community, the RMS has accepted copies of current GMP Certificates of satisfactory inspection summary reports, ‘close-out letters’ or ‘exchange of information’ issued by the inspection services of the competent authorities (or those countries with which the EEA has a Mutual Recognition Agreement for their own territories) as certification that acceptable standards of GMP are in place at those non-Community sites.
The UK and Ireland considered that the applications could be approved at the end of procedure on 14 December 2018. After a subsequent national phase, Marketing Authorisations were granted in the UK to Renata (UK) Limited on 11 January 2019.

II QUALITY ASPECTS
II.1 Introduction
The submitted documentation concerning the proposed product is of sufficient quality and meets the current EU regulatory requirements.

The quality overall summary has been written by an appropriately qualified person and is a suitable summary of the pharmaceutical aspects of the dossier.

Clindamycin 75 mg Capsules, hard are hard gelatin capsules (dimension 14 mm) with a red-violet cap printed ‘RENATA’ in white and off-white to light cream body printed ‘Q 75’ in black containing white crystalline powder. Each capsule contains 75 mg clindamycin (as hydrochloride).

Clindamycin 150 mg Capsules, hard are hard gelatin capsules (dimension 18 mm), raspberry coloured cap printed ‘RENA TA’ in white and off-white to light cream body printed ‘Q 150’ in black containing white crystalline powder. Each capsule contains 150 mg clindamycin (as hydrochloride).

Clindamycin 300 mg Capsules, hard are hard gelatin capsules (dimension 21 mm), cornell red cap printed ‘RENA TA’ in white and off-white to light cream body printed ‘Q 300’ in black containing white crystalline powder. Each capsule contains 300 mg clindamycin (as hydrochloride).

The products also contain pharmaceutical excipients in the capsule powder and capsule shell, namely lactose monohydrate, maize starch, talc, gelatin, sodium laurilsulfate, iron oxide black (E172, and 150 mg strength only), iron oxide red (E172, 150 mg strength only), erythrosine (E127, 75 mg and 150 mg strengths only), brilliant blue (E133, 75 mg and 300 mg strength only), ponceau 4R (E124, 300 mg strength only), titanium dioxide (E171). The printing ink contains shellac (E904), black iron oxide (E172), potassium hydroxide (E525) and titanium dioxide (E171).

The finished products are packaged in aluminium-polyvinylidene chloride blisters. The products are available in the following pack sizes:
75 mg strength: 24 hard capsules
150 mg strength: 20, 30, 40 and 100 hard capsules
300 mg strength: 16, 24 and 32 hard capsules

Not all pack-sizes may be marketed.

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.

II.2 Drug substance
INN: Clindamycin hydrochloride
Chemical name: Methyl 7-chloro-6,7,8-trideoxy-6-[[2S,4R]-1-methyl-4-propylpyrrolidin-2yl]carbonyl]amino]-1-thio-L-threo-α-D-galacto-octopyranoside hydrochloride
Structure:

![Structure diagram]

Molecular formula: \( \text{C}_{18}\text{H}_{33}\text{ClN}_{2}\text{O}_{5}\text{S} \cdot \text{HCl} \)

Molecular weight: 461.5

Appearance: A white or almost white, crystalline powder

Solubility: Very soluble in water, slightly soluble in ethanol (96 per cent)

All aspects of the manufacture and control of the active substance clindamycin hydrochloride are are covered by a European Directorate for the Quality of Medicines and Healthcare (EDQM) Certificate of Suitability.

II.3 Medicinal Product

Pharmaceutical Development

The objective of the development programme was to formulate stable products that could be considered generic medicinal products of the currently licensed products, Dalacin C 75 mg Capsules/Clindamycin 75 mg Capsules (Pfizer Limited, UK), Dalacin C 150 mg Capsules/Clindamycin 150 mg Capsules (Pfizer Limited, UK) and Dalacin C 300 mg Hard Capsules (Pfizer spol. s.r.o., Czech Republic).

A satisfactory account of the pharmaceutical development has been provided.

Comparative in vitro dissolution and impurity profiles have been provided for the applicant’s products versus the reference products.

With the exception of erythrosine (E127), brilliant blue (E133) and ponceau 4R (E124), which are controlled to suitable in-house specifications,, all excipients comply with their respective European Pharmacopoeia monographs.

With the exception of lactose monohydrate and gelatin, none of the excipients are sourced from animal or human origin. The supplier of lactose monohydrate has confirmed that it is sourced from healthy animals under the same conditions as milk 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. The suppliers of gelatin has provided a Certificate of Suitability from the European Directorate for the Quality of Medicines and Healthcare (EDQM) to show that it is manufactured in line with current European guidelines concerning the minimising of risk of transmission of Bovine Spongiform Encephalopathy/Transmissible Spongiform Encephalopathies (BSE/TSE). These products do not contain or consist of genetically modified organisms (GMO).

Manufacturing Process

Satisfactory batch formulae have been provided for the manufacture of the products, along with an appropriate description of the manufacturing process. Suitable in-process controls are in place to ensure the quality of the finished product. Process validation has been carried out on two full scale blend batches. The results are satisfactory. In addition, the Marketing Authorisation Holder has committed to performing process validation studies on future commercial scale production batches.
Control of Finished Product
The finished product specifications proposed are acceptable. Test methods have been described that have been adequately validated. Batch data that comply with the release specifications have been provided. Certificates of Analysis have been provided for all working standards used.

Stability of the product
Finished product stability studies were performed in accordance with current guidelines on batches of finished product in the packaging proposed for marketing. Based on the results, a shelf-life of 2 years, with no special storage instructions, has been approved.

II.4 Discussion on chemical, pharmaceutical and biological aspects
It is recommended that Marketing Authorisations are granted for Clindamycin 75 mg, 150 mg and 300 mg Capsules, hard.

III NON-CLINICAL ASPECTS
III.1 Introduction
The pharmacodynamic, pharmacokinetic and toxicological properties of clindamycin hydrochloride are well known. No new non-clinical data have been submitted for these applications and none are required.

The applicant has provided an overview based on published literature. The non-clinical overview has been written by an appropriately qualified person and is satisfactory, providing an appropriate review of the product's pharmacology and toxicology.

III.2 Pharmacology
No new pharmacology data are required for these applications and none have been submitted.

III.3 Pharmacokinetics
No new pharmacokinetic data are required for these applications and none have been submitted.

III.4 Toxicology
No new toxicology data are required for these applications and none have been submitted.

III.5 Ecotoxicity/Environmental risk Assessment (ERA)
The Marketing Authorisation Holder has provided adequate justification for not submitting an Environment Risk Assessment (ERA). As the applications are generic versions of already authorised products, it is not expected that environmental exposure to clindamycin will increase following approval of the Marketing Authorisations for the proposed products. An Environmental Risk Assessment is therefore not deemed necessary.

III.6 Discussion of the non-clinical aspects
It is recommended that Marketing Authorisations are granted for Clindamycin 75 mg, 150 mg and 300 mg Capsules, hard.

IV. CLINICAL ASPECTS
IV.1 Introduction
With the exception of the bioequivalence study detailed below, no new clinical studies have been performed and none are required for this type of application. The applicant's clinical overview has been written by an appropriately qualified person and is considered acceptable.

IV.2 Pharmacokinetics
In support of these applications, the applicant submitted the following bioequivalence study:
Clindamycin 75 mg, 150 mg and 300 mg Capsules, hard

Study:
An open-label, randomised, two-treatment, two-period, two-sequence, single-dose, crossover bioequivalence study comparing the pharmacokinetics of the test product, Clindamycin 300 mg hard capsules, to those of the reference product, Dalacin C 300 mg Hard Capsules (Pfizer spol. s r.o., Czech Republic), in normal, healthy, adult, male and female, human subjects, under fasting conditions.

Subjects were given a single dose of either treatment with approximately 240 ml of water after an overnight fast of at least 10 hours. Blood samples were collected for the measurement of pharmacokinetic parameters pre-dose and up to 24 hours post dose. Each treatment was separated by a washout period of 7 days.

A summary of the main pharmacokinetic results is presented in the table below:

Table 1 - The geometric mean and 90% confidence interval based on least squares mean obtained from ANOVA for the ln-transformed pharmacokinetic parameters C<sub>max</sub> and AUC<sub>0-t</sub> are summarized in the following table (N=32):

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Geometric mean</th>
<th>Reference (R)</th>
<th>% Ratio</th>
<th>90% Confidence Interval for In-transformed data</th>
</tr>
</thead>
<tbody>
<tr>
<td>AUC&lt;sub&gt;0-t&lt;/sub&gt;</td>
<td>22850.0943</td>
<td>23026.7309</td>
<td>99.2329</td>
<td>93.3521 - 105.4842</td>
</tr>
<tr>
<td>C&lt;sub&gt;max&lt;/sub&gt;</td>
<td>4571.5945</td>
<td>4511.8938</td>
<td>101.3232</td>
<td>96.9301 - 105.9153</td>
</tr>
</tbody>
</table>

*Geometric mean was taken as the antilog (exponential) of the least square mean of the log-transformed data.

The 90% confidence intervals of the test/reference ratio for AUC<sub>0-t</sub> and C<sub>max</sub> values for clindamycin for the 300 mg capsule strength lie within the acceptable limits of 80.00% to 125.00%, in line with the ‘Guideline on the Investigation of Bioequivalence (CPMP/EWP/QWP/1401/98 Rev 1/Corr**).

Thus, the data support the claim that the applicant’s 300 mg strength test product is bioequivalent to the reference product Dalacin C 300 mg Hard Capsules (Pfizer spol. s r.o., Czech Republic) under fasting conditions. As the 75 mg, 150 mg and 300 mg strength test products meet the biowaiver criteria specified in the current bioequivalence guidance, the results and conclusions of the bioequivalence study with the 300 mg capsule strength can be extrapolated to the 75 mg and 150 mg strength capsules.

IV.3 Pharmacodynamics
No new pharmacodynamic data were submitted and none are required for applications of this type.

IV.4 Clinical efficacy
No new efficacy data have been submitted and none are required for applications of this type.

IV.5 Clinical Safety
Apart from the safety reports from the bioequivalence study, no new data on safety have been submitted and none are required for applications of this type. No new or unexpected safety events were reported in the study.

IV.6 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 Clindamycin 75 mg, 150 mg and 300 mg Capsules, hard.

There are no differences from the reference product in terms of proposed uses, maximum pack size / strength or pharmaceutical form / formulation that would have any implications for safety.
In line with the reference product, the applicant proposes only routine pharmacovigilance and routine risk minimisation measures for all safety concerns (labelling in the SmPCs and the PIL). This is agreed.

A summary of safety concerns, as approved in the RMP, is listed below:

**Table 2: Summary of safety concerns**

<table>
<thead>
<tr>
<th>Important identified risks</th>
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</thead>
<tbody>
<tr>
<td>1. Pseudomembranous colitis</td>
</tr>
<tr>
<td>2. Hepatobiliary disorders</td>
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<tr>
<td>3. Antibiotic resistance</td>
</tr>
<tr>
<td>4. Interaction with vitamin K antagonists (e.g. warfarin, acenocoumarol and phenprocoumon)</td>
</tr>
<tr>
<td>5. Use in patients with severe renal impairment</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Important potential risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>6. Neuromuscular junction conduction disorders</td>
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<tr>
<td>7. Inappropriate dosing in children</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Missing information</th>
</tr>
</thead>
<tbody>
<tr>
<td>8. Exposure during pregnancy</td>
</tr>
<tr>
<td>9. Exposure during breast-feeding</td>
</tr>
</tbody>
</table>

**IV.7 Discussion of the clinical aspects**

It is recommended that Marketing Authorisations are granted for Clindamycin 75 mg, 150 mg and 300 mg Capsules, hard, from a clinical point of view.

**V. USER CONSULTATION**

The package leaflet has been evaluated in accordance with the requirements of Articles 59(3) and 61(1) of Directive 2001/83/EC, as amended. The results indicate that the package leaflet is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that patients/users are able to act upon the information that it contains.

**VI. OVERALL CONCLUSION, BENEFIT-RISK ASSESSMENT AND RECOMMENDATION**

The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. The data provided support the claim that the applicant’s products and the reference products are interchangeable. Extensive clinical experience with clindamycin is considered to have demonstrated the therapeutic value of the compound.

The overall benefit/risk balance is, therefore, considered to be positive.

The grant of Marketing Authorisations is recommended.
Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and Labels

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

The following text is the currently approved label text. No label mock-ups have been provided for these products. In accordance with medicines legislation, these products shall not be marketed in the UK until approval of the label mock-ups has been obtained.
PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer Carton

1. NAME OF THE MEDICINAL PRODUCT

Clindamycin 75 mg Capsules, hard
Clindamycin 150 mg Capsules, hard
Clindamycin 300 mg Capsules, hard

Clindamycin

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each capsule contains clindamycin hydrochloride equivalent to 75 mg clindamycin.
Each capsule contains clindamycin hydrochloride equivalent to 150 mg clindamycin.
Each capsule contains clindamycin hydrochloride equivalent to 300 mg clindamycin.

3. LIST OF EXCIPIENTS

Contains Lactose monohydrate. Also contains Ponceau 4R (E124) (300 mg only). See package leaflet for further details.

4. PHARMACEUTICAL FORM AND CONTENTS

Hard capsules

75 mg
24 hard capsules

150 mg
20 hard capsules
30 hard capsules
40 hard capsules
100 hard capsules

300 mg
16 hard capsules
24 hard capsules
32 hard capsules

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.
Read the package leaflet before use.
Use as directed by your doctor.
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:

9. 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

Renata (UK) Limited
Greenway Business Centre
Harlow Business Park
Harlow
CM19 5QE
United Kingdom

12. MARKETING AUTHORISATION NUMBER(S)

PL 42765/0007
PL 42765/0008
PL 42765/0009

13. BATCH NUMBER

Lot:

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Clindamycin 75 mg Capsules, hard
Clindamycin 150 mg Capsules, hard
Clindamycin 300 mg Capsules, hard
17. **UNIQUE IDENTIFIER – 2D BARCODE**

<2D barcode carrying the unique identifier included>

18. **UNIQUE IDENTIFIER – HUMAN READABLE DATA**

<table>
<thead>
<tr>
<th>PC:</th>
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<tbody>
<tr>
<td>SN:</td>
</tr>
<tr>
<td>NN:</td>
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</table>
**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**Blister**

1. **NAME OF THE MEDICINAL PRODUCT**

   Clindamycin 75 mg Capsules, hard  
   Clindamycin 150 mg Capsules, hard  
   Clindamycin 300 mg Capsules, hard  

   Clindamycin

2. **NAME OF THE MARKETING AUTHORISATION HOLDER**

   Renata (UK) Limited

3. **EXPIRY DATE**

   EXP:

4. **BATCH NUMBER**

   Lot:

5. **OTHER**
# Annex 1

## Table of content of the PAR update for MRP and DCP

Steps taken after the initial procedure with an influence on the Public Assessment Report

<table>
<thead>
<tr>
<th>Scope</th>
<th>Procedure number</th>
<th>Product information affected</th>
<th>Date of start of the procedure</th>
<th>Date of end of procedure</th>
<th>Approval/non approval</th>
<th>Assessment report attached Y/N (version)</th>
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