Medicines & Healthcare products
Regulatory Agency

Public Assessment Report

National Procedure

Clindamycin + Benzoyl Peroxide 10 mg/g + 30 mg/g Gel

clindamycin phosphate and anhydrous benzoyl peroxide (as hydrous benzoyl peroxide)

PL 35533/0212

Aspire Pharma Limited

LAY SUMMARY

Clindamycin + Benzoyl Peroxide 10 mg/g + 30 mg/g Gel
clindamycin phosphate and anhydrous benzoyl peroxide (as hydrous benzoyl peroxide)

This is a summary of the Public Assessment Report (PAR) for Clindamycin + Benzoyl Peroxide 10 mg/g + 30 mg/g Gel. It explains how this product was assessed and its authorisation recommended, as well as its conditions of use. It is not intended to provide practical advice on how to use this product.

This product will be referred to as Clindamycin + Benzoyl Peroxide Gel in this lay summary for ease of reading.

This product have been authorised by Medicines and Healthcare products Regulatory Agency (MHRA) for the United Kingdom. This procedure takes into account the outcome of a decentralised (DC) procedure in European Union Member States (and/or Iceland, Liechtenstein, Norway) on 18 March 2024 (procedure number: SI/H/0218/002/DC). This is known as the MR/DC Reliance Procedure.

This application were approved under Regulation 52B of the Human Medicines Regulation 2012, as amended (previously Article 10(3) of Directive 2001/83/EC, as amended).

For practical information about using Clindamycin + Benzoyl Peroxide Gel, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

What is Clindamycin + Benzoyl Peroxide Gel and what is it used for?
This application is for a hybrid medicine. This means that the medicine is similar to a reference medicine already authorised, called Duac Once Daily 10 mg/g + 50 mg/g: albeit with certain differences. In this case, Clindamycin + Benzoyl Peroxide Gel is a lower strength to the reference product (one of the active substances, anhydrous benzoyl peroxide as hydrous benzoyl peroxide, is at a lower strength in Clindamycin + Benzoyl Peroxide Gel).

Clindamycin + Benzoyl Peroxide Gel is used for treating mild to moderate acne on the skin.

How does Clindamycin + Benzoyl Peroxide Gel work?
Clindamycin + Benzoyl Peroxide Gel belongs to a group of medicines known as ‘anti-acne preparations’. Clindamycin + Benzoyl Peroxide Gel contains two medicines: clindamycin and benzoyl peroxide.

- Clindamycin is an antibiotic which stops the bacteria involved in acne from reproducing.
- Benzoyl peroxide reduces blackheads and whiteheads. It also kills the bacteria involved in acne.

How is Clindamycin + Benzoyl Peroxide Gel used?
The pharmaceutical form of this medicine is a gel, and the route of administration is application to the skin.

- The patient should use Clindamycin + Benzoyl Peroxide Gel once a day in the evening.
- It may take 2 to 5 weeks before the patient sees the effect of this medicine.

- The patient should not use the gel for more than 12 weeks at one time. The doctor will tell their patient how long their treatment will last.

How to apply this medicine

1. Completely remove any make-up.
2. Wash the affected area of skin well. Then rinse with warm water and gently pat dry.
3. Put a **thin film** of gel on the **entire** area of affected skin, using the fingertips.
4. Apply to all of the areas of the skin which have acne, not just to the individual spots. If the gel does not rub into the skin easily, the patient is using too much.
   - For the face only, use an amount of gel from the tube which reaches from the tip of the finger to the first joint (the first crease on the finger). This is a 'finger tip'.
   - For the face and back, use two and a half 'finger tips' in total.
5. If the patient get a lot of dryness or skin peeling, they can use an oil-free, fragrance free, hypoallergenic moisturiser, use Clindamycin + Benzoyl Peroxide Gel less frequently or stop treatment for a short period, to allow the skin to adjust to the treatment. This medicine may not work properly if it is not applied every day.
6. **Wash the hands** after using the gel.
7. After it has dried, the patient can use a non-greasy make-up.

For further information on how Clindamycin + Benzoyl Peroxide Gel is used, refer to the PIL and Summary of Product Characteristics (SmPC) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

This medicine can only be obtained with a prescription.

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

What benefits of Clindamycin + Benzoyl Peroxide Gel have been shown in studies?
No additional studies were needed as Clindamycin + Benzoyl Peroxide Gel contains the same active substances as the reference medicine, and satisfactory data to justify the differences have been provided.

What are the possible side effects of Clindamycin + Benzoyl Peroxide Gel?
For the full list of all side effects reported with this medicine, see Section 4 of the PIL or the SmPC available on the MHRA website.

If a patient gets any side effects, they should talk to their doctor, pharmacist or nurse. This includes any possible side effects not listed in the product information or the PIL that comes with the medicine. Patients can also report suspected side effects themselves, or a report can be made on their behalf by someone else who cares for them, directly via the Yellow Card scheme at https://yellowcard.mhra.gov.uk or search for 'MHRA Yellow Card' online. By reporting side effects, patients can help provide more information on the safety of this medicine.

As Clindamycin + Benzoyl Peroxide Gel is a hybrid medicine and is therapeutically equivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

Why was Clindamycin + Benzoyl Peroxide Gel approved?
It was concluded that Clindamycin + Benzoyl Peroxide Gel has been shown to be therapeutically equivalent to the reference medicine MHRA decided that the benefits are greater than the risks and recommended that this medicine can be approved for use.

What measures are being taken to ensure the safe and effective use of Clindamycin + Benzoyl Peroxide Gel?
As for all newly authorised medicines, a Risk Management Plan (RMP) has been developed for Clindamycin + Benzoyl Peroxide Gel. The RMP details the important risks of Clindamycin + Benzoyl Peroxide Gel, how these risks can be minimised, any uncertainties about Clindamycin + Benzoyl Peroxide Gel (missing information), and how more information will be obtained about the important risks and uncertainties.

There are no safety concerns, specified in the RMP, associated with use of Clindamycin + Benzoyl Peroxide Gel.

The information included in the SmPC and the PIL is compiled based on the available quality, non-clinical and clinical data, and includes appropriate precautions to be followed by healthcare professionals and patients. Side effects of Clindamycin + Benzoyl Peroxide Gel are continuously monitored and reviewed including all reports of suspected side-effects from patients, their carers, and healthcare professionals.

An RMP and a summary of the pharmacovigilance system have been provided with this application and are satisfactory.

Other information about Clindamycin + Benzoyl Peroxide Gel
A marketing authorisation was granted in the United Kingdom on 30 December 2024.

The full PAR for Clindamycin + Benzoyl Peroxide Gel follows this summary.

This summary was last updated in February 2025.

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I. INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the Medicines and Healthcare products Regulatory Agency (MHRA) considered that the application for Clindamycin + Benzoyl Peroxide 10 mg/g + 30 mg/g Gel (PL 35533/0212) could be approved. This product will be referred to as Clindamycin + Benzoyl Peroxide Gel in this scientific discussion for ease of reading.

The product is approved for the following indication:

- the topical treatment of mild to moderate acne vulgaris, particularly inflammatory lesions, in adults and adolescents aged 12 years and above (see sections 4.4 and 5.1 of the Summary of Product Characteristics (SmPC)).

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

Clindamycin + Benzoyl Peroxide Gel contains the active substances clindamycin phosphate and anhydrous benzoyl peroxide (as hydrous benzoyl peroxide). Clindamycin is a lincosamide antibiotic with bacteriostatic action against Gram-positive aerobes and a wide range of anaerobic bacteria. Lincosamides such as clindamycin bind to the 23S subunit of the bacterial ribosome 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.

Although clindamycin phosphate is inactive *in-vitro*, rapid *in-vivo* hydrolysis converts this compound to the antibacterial active clindamycin. Clindamycin activity has been demonstrated clinically in comedones from acne patients at sufficient levels to be active against most strains of Propionibacterium acnes. Clindamycin *in-vitro* inhibits all Propionibacterium acnes cultures tested (MIC 0.4 mcg/ml). Free fatty acids on the skin surface have been decreased from approximately 14% to 2% following application of clindamycin.

Benzoyl peroxide is mildly keratolytic acting against comedones at all stages of their development. It is an oxidising agent with bactericidal activity against Propionibacterium acnes, the organism implicated in acne vulgaris. Furthermore, it is sebostatic, counteracting the excessive sebum production associated with acne.

This product have been authorised by MHRA for the United Kingdom. This procedure takes into account the outcome of a decentralised (DC) procedure in European Union Member States (and/or Iceland, Liechtenstein, Norway) on 18 March 2024 (procedure number: SI/H/0218/002/DC).

For the scientific discussion of the quality, non-clinical and clinical assessment conducted during the DC procedure, please refer to the Reference Member State (RMS) Public Assessment Report, available on the RMS regulatory agency website or on the Heads of Medicines Agencies website.

This application were approved under Regulation 52B of the Human Medicines Regulation 2012, as amended (previously Article 10.3 of Directive 2001/83/EC, as amended), claiming to be a hybrid medicinal product) of a suitable originator product, Duac Once Daily 10 mg/g + 50 mg/g that has been licensed for a suitable time, in line with the legal requirements.

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The MHRA has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place for this product at all sites responsible for the manufacture, assembly and batch release of this product.

A Risk Management Plan (RMP) and a summary of the pharmacovigilance system have been provided with this application and are satisfactory.

A marketing authorisation was granted on 30 December 2024.

II. PRODUCT INFORMATION

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

The SmPC is in line with current guidelines and is satisfactory.

PATIENT INFORMATION LEAFLET (PIL)

The PIL is in line with current guidelines and is satisfactory.

LABEL

The labelling is in line with current guidelines and is satisfactory.

III. QUALITY ASPECTS

The MHRA considered that the quality data submitted for this application is satisfactory.

The grant of a marketing authorisation was recommended.

IV. NON-CLINICAL ASPECTS

The MHRA considered that the non-clinical data submitted for this application is satisfactory.

The grant of a marketing authorisation was recommended.

V. CLINICAL ASPECTS

The MHRA considered that the clinical data submitted for this application is satisfactory.

The grant of a marketing authorisation was recommended.

VI. RISK MANAGEMENT PLAN (RMP)

The applicant has submitted an RMP, in accordance with the requirements of Regulation 182 of The Human Medicines Regulation 2012, as amended. The applicant proposes only routine pharmacovigilance and routine risk minimisation measures for all safety concerns. This is acceptable.

VII. USER CONSULTATION

A full colour mock-up of the Patient Information Leaflet (PIL) was provided with the application in accordance with legal requirements, including user consultation.

VIII. OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION

The quality of the product is acceptable, and no non-clinical or clinical safety concerns have been identified. Clinical experience with clindamycin phosphate and anhydrous benzoyl peroxide (as hydrous benzoyl peroxide) is considered to have demonstrated the therapeutic value of the compound. The benefit/risk is, therefore, considered to be positive.

The SmPC, PIL and labelling are satisfactory.

In accordance with legal requirements, the current approved UK versions of the SmPC and PIL for this product are available on the MHRA website.

IX. TABLE OF CONTENT OF THE PAR UPDATE

Steps taken after the initial procedure with an influence on the Public Assessment Report (non-safety variations of clinical significance).

Please note that only non-safety variations of clinical significance are recorded below and in the annexes to this PAR. The assessment of safety variations, where significant changes are made, are recorded on the MHRA website or European Medicines Agency (EMA) website. Minor changes to the marketing authorisation are recorded in the current SmPCs and/or PIL available on the MHRA website.

Application type	**Scope**	**Product information affected**	**Date of grant**	**Outcome**	**Assessment report attached Y/N**