Medicines & Healthcare products
Regulatory Agency

Public Assessment Report

National Procedure

Acnecide 10% w/w Gel

benzoyl peroxide (as hydrous benzoyl peroxide)

PL 10590/0074

Galderma (U.K.) Limited

LAY SUMMARY

Acnecide 10% w/w Gel
benzoyl peroxide (as hydrous benzoyl peroxide)

This is a summary of the Public Assessment Report (PAR) for Acnecide 10% w/w 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.

For practical information about using Acnecide 10% w/w Gel, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

What is Acnecide 10% w/w Gel and what is it used for?
This application is a full-dossier application. This means that the results of pharmaceutical, non-clinical and clinical tests have been submitted to show that this medicine is suitable for treating the specified indications.

The application is a line extension of the existing product Acnecide 5% w/w Gel (PL 10590/0006).

Acnecide 10% w/w Gel is used to treat acne. Acne appears as blackheads, whiteheads, pimples and spots. Most often, the outbreaks occur on the face but can also appear on the back, chest, and shoulders. Acne of the face, chest or back may be treated with this medicine.

How does Acnecide 10% w/w Gel work?
Acnecide 10% w/w Gel contains the active ingredient benzoyl peroxide which attacks the bacteria (germs) known as *Cutibacterium acnes*, one of the main causes of acne.

How is Acnecide 10% w/w Gel used?
The pharmaceutical form of this medicine is a gel and the route of administration is topical (on the skin).

Acnecide 10% w/w Gel is for external use only.

Unless a doctor or pharmacist advises the patient otherwise, the patient should:

- Wash the affected area with a mild skin cleanser and water and gently pat their skin dry.
- Apply Acnecide 10% w/w Gel in a thin layer once a day to all the affected areas.
- Any drying or peeling which may occur to the skin may be reduced if the patient alters the number of times they apply the product, i.e. to once every two days, until their skin adjusts to the product.

The patient should try to avoid exposure to strong sunlight while using Acnecide 10% w/w Gel. If exposure is unavoidable, the patient should use a sun protection product with a protection factor of at least SPF 30 and UVA protection and they should apply Acnecide 10% w/w Gel in the evening.

How long the patient will have to use Acnecide 10% w/w Gel will depend on how quickly their condition improves. After the patient has used it for one month, they should see a doctor or pharmacist again. The pharmacist or doctor can check the improvement of the patient's skin condition.

Excessive application will not improve effectiveness, but may increase the risk of skin irritation.

Acnecide 10% w/w Gel should not be used by children less than 12 years of age.

For further information on how Acnecide 10% w/w 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 be obtained without a prescription.

The patient should always use 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 Acnecide 10% w/w Gel have been shown in studies?
Acnecide 10% w/w Gel is a line extension of the existing product Acnecide 5% w/w Gel (PL 10590/0006). The data submitted previously for Acnecide 5% w/w Gel and bibliographical studies are sufficient to demonstrate that Acnecide 10% w/w Gel shows a benefit in the indications listed.

What are the possible side effects of Acnecide 10% w/w 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.

Because Acnecide 10% w/w Gel is a line extension of the existing product Acnecide 5% w/w Gel, its benefits and possible side effects are taken as being the same as Acnecide 5% w/w Gel (PL 10590/0006).

Why was Acnecide 10% w/w Gel approved?
It was concluded that Acnecide 10% w/w Gel is effective as a topical therapy for the treatment of acne vulgaris in adults and adolescents aged 12 years and over. Furthermore, the side effects observed with use of this product are considered to be typical for this type of treatment. Therefore, the 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 Acnecide 10% w/w Gel?
As for all newly authorised medicines, a Risk Management Plan (RMP) has been developed for Acnecide 10% w/w Gel. The RMP details the important risks of Acnecide 10% w/w Gel, how these risks can be minimised, any uncertainties about Acnecide 10% w/w Gel (missing information), and how more information will be obtained about the important risks and uncertainties.

There are no safety concerns associated with use of Acnecide 10% w/w 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 Acnecide 10% w/w 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 Acnecide 10% w/w Gel
A marketing authorisation was granted in the United Kingdom (UK) on 07 July 2025.

The full PAR for Acnecide 10% w/w Gel follows this summary.

This summary was last updated in August 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 Acnecide 10% w/w Gel (PL 10590/0074) could be approved.

The product is approved for the following indication:
Topical therapy for the treatment of acne vulgaris.
Acnecide 10% w/w Gel is indicated in adults and adolescents aged 12 years and over.

The active substance is benzoyl peroxide (as hydrous benzoyl peroxide), which is an established and effective keratolytic agent with antibacterial properties. It has been shown to be effective in reducing the local population of *Cutibacterium acnes* leading to a reduction in the production of irritant fatty acids in the sebaceous glands.

This application was approved under Regulation 50 of The Human Medicines Regulation 2012, as amended (previously Article 8(3) of Directive 2001/83/EC, as amended), a full-dossier application. The application is a line extension of the existing product Acnecide 5% w/w Gel (PL 10590/0006).

As the application is a line extension to an already licensed product, a paediatric investigation plan (PIP) or a full product specific waiver are not required.

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.

Advice was sought from the Commission on Human Medicines (CHM) on 22 February 2024 and 23 January 2025. Following the provision of additional data by the applicant, the CHM were reassured regarding the quality of the product.

A marketing authorisation for Acnecide 10% w/w Gel was granted in the United Kingdom (UK) on 07 July 2025.

II QUALITY ASPECTS

II.1 Introduction

This product consists of a gel. Each gram of gel contains 100 mg (10%) benzoyl peroxide (as hydrous benzoyl peroxide).

In addition to hydrous benzoyl peroxide, this product also contains the following excipients:
Docusate sodium
Disodium edetate
Poloxamer
Carbomer
Propylene glycol (E1520)
Acrylates copolymer
Glycerol
Colloidal anhydrous silica
Purified water
Sodium hydroxide (for pH adjustment)

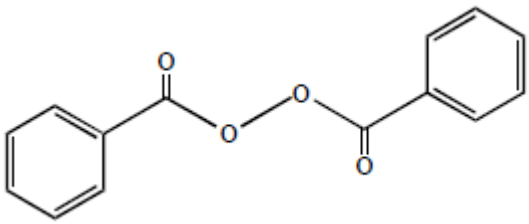
The finished product is packaged in a white low density polyethylene tube in a pack size of 30 g and 40 g. Not all pack sizes may be marketed.

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

II.2 ACTIVE SUBSTANCE

rINN: Benzoyl peroxide (as hydrous benzoyl peroxide)

Chemical Name: Dibenzoyl peroxide
Molecular Formula: $C_{14}H_{10}O_4$
Chemical Structure:



Molecular Weight: 242.2
Appearance: White or almost white, amorphous or granular powder
Solubility: Sparingly soluble in water and alcohol. Soluble in benzene, acetone, chloroform and ether.

The information related to the active substance was provided in an Active Substance Master File (ASMF). The Active substance is the subject of a Ph.Eur. 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 specifications are in place for all starting materials and reagents, and these are supported by relevant Certificates of Analysis.

Appropriate proof-of-structure data have been supplied for the active substance. All potential known impurities have been identified and characterised.

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. Batch analysis data are provided and comply with the proposed specification. Satisfactory Certificates of Analysis have been provided for all working standards.

Suitable specifications have been provided for all packaging used. The primary packaging has been shown to comply with current regulations concerning materials in contact with food.

Appropriate stability data have been generated supporting a suitable retest period when stored in the proposed packaging.

II.3 DRUG PRODUCT

Pharmaceutical development

A satisfactory account of the pharmaceutical development has been provided.

All excipients comply with either their respective European/national monographs, or a suitable in-house specification. Satisfactory Certificates of Analysis have been provided for all excipients.

No excipients of animal or human origin are used in the finished product.

This product does not contain or consist of genetically modified organisms (GMO).

Manufacture of the product

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

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

Finished Product Specifications

The finished product specifications at release and shelf-life are satisfactory. The test methods have been described and adequately validated. Batch data have been provided that comply with the release specifications. Certificates of Analysis have been provided for any working standards used.

Stability

Finished product stability studies have been conducted in accordance with current guidelines, using batches of the finished product stored in the packaging proposed for marketing. Based on the results, a shelf-life of 2 years, with the storage conditions ‘Do not store above 25ºC’, is acceptable.

After first opening, the shelf life is 3 months.

II.4 Discussion on chemical, pharmaceutical and biological aspects

The grant of a marketing authorisation is recommended.

III NON-CLINICAL ASPECTS

III.1 Introduction

The pharmacology, pharmacokinetics and toxicology of the active substance are well known. As such, no new non-clinical studies have been conducted in support of this application and none are required.

III.2 Pharmacology

No new pharmacology data were provided and none were required for this application.

III.3 Pharmacokinetics

No new pharmacokinetic data were provided and none were required for this application.

III.4 Toxicology

No new toxicology data were provided and none were required for this application.

III.5 Ecotoxicity/Environmental Risk Assessment

An Environmental Risk Assessment (ERA) was submitted with this application. No increased environmental exposure to the active substance is anticipated on introduction of this product to the market.

III.6 Discussion on the non-clinical aspects

The grant of a marketing authorisation is recommended.

IV CLINICAL ASPECTS

IV.1 Introduction

As this application is for a line extension of the existing product Acnecide 5% w/w Gel (PL 10590/0006), the clinical efficacy data are identical to those submitted previously. Clinical development evaluated the safety of Acnecide 10% w/w Gel, but not its efficacy. Following a literature review, the applicant has provided bibliographical studies in support of the efficacy of Acnecide 10% w/w Gel.

All studies were conducted in line with current Good Clinical Practice (GCP).

IV. 2 Pharmacokinetics

The applicant has described adequately the pharmacokinetics of Acnecide 10% w/w Gel.

Benzoyl peroxide applied topically is metabolised in the skin to benzoic acid before systemic penetration. Benzoic acid is widely used in food, cosmetic and pharmaceutical applications and consumer exposure occurs by the oral and dermal route. The acceptable daily intake for benzoic acid and its salts was established by the Joint FAO/WHO Expert Committee on Food Additives at 5 mg/kg/day of benzoic acid equivalent.

Percutaneous absorption figures *in vivo* were reported in non-clinical studies with benzoyl peroxide applied topically as a 10% aqueous emulsion and with benzoyl peroxide applied topically as a 5% gel. The studies showed that 4.5% and 4.3% of benzoyl peroxide penetrated the skin, respectively, reaching the systemic circulation as benzoic acid.

The applicant notes that for a patient treated with 2.5 g of benzoyl peroxide 2.5%, 5% or 10% gel, the exposure to benzoic acid would represent 10% or less of the acceptable daily intake of benzoic acid as established for food additives.

The applicant further provides a clinical study to support this (Study SRE.27122). Within the framework of the development of a fixed-combination of adapalene and benzoyl peroxide 2.5% aqueous gel, the applicant conducted a single-centre, randomised, evaluator-blinded, vehicle-controlled study in Japanese adult healthy males to evaluate the local tolerability of the combination and of benzoyl peroxide monads (2.5% and 5% aqueous gels), and to investigate the systemic exposure to adapalene and benzoyl peroxide after 5-day repeated topical application to the face.

A total of 40 subjects received study treatment, 10 in each treatment group (Combination aqueous Gel, benzoyl peroxide 2.5% aqueous Gel monad, benzoyl peroxide 5% aqueous Gel monad, and aqueous Gel Vehicle). With a benzoic acid-controlled diet, endogenous levels of benzoic acid in subjects were well controlled and demonstrated to be non-quantifiable (<20 ng/mL) in the Vehicle group and in all subjects (except one subject at baseline) before study drug application.

After 5 days of topical treatment with the fixed-dose combination with adapalene or monads, benzoic acid levels were quantifiable in most subjects. Nonetheless, the benzoic acid levels in the combination and benzoyl peroxide monad 2.5% groups remained at a level close to the lower limit of quantification (LOQ, 20 ng/mL) with no accumulation observed throughout the treatment period. Benzoyl peroxide monad 2.5% and combination groups demonstrated similar exposure levels to benzoic acid throughout the study duration. Thus, adapalene did not increase the level of benzoic acid in the plasma when formulated in a fixed-dose combination with benzoyl peroxide. The benzoyl peroxide monad 5% group exhibited slightly higher benzoic acid systemic exposure compared to the 2.5% monad group (mean values of 25 to 30 compared to 21 to 22 ng/mL).

The applicant notes that these results confirm that systemic penetration of benzoyl peroxide, assessed through measurement of the benzoic acid metabolite is extremely limited. The efficacy of benzoyl peroxide relies on local activity at the skin surface and does not depend on systemic absorption.

IV.3 Pharmacodynamics

The applicant has provided an adequate review of the pharmacodynamics of Acnecide 10% w/w Gel. The antibacterial activity of benzoyl peroxide 10% formulation is well-established and supported by evidence.

Benzoyl peroxide is a peroxide. Its main properties are antibacterial, keratolytic and comedolytic. It also has anti-inflammatory and wound healing activity. Benzoyl peroxide has been shown to be effective in reducing the local population of *Cutibacterium acnes*. Investigations into the penetration of topically applied benzoyl peroxide through the skin and its systemic disposition have shown limited penetration as unchanged material in the stratum corneum, followed by diffusion into the epidermis and dermis with conversion into benzoic acid, and elimination of unchanged benzoate in the urine.

The antibacterial activity of benzoyl peroxide 2.5%, 5% and 10% formulations has been extensively evaluated. The three concentrations all have highly potent antibacterial activity against C. acnes as demonstrated in open trials after C. acnes sampling of the pilosebaceous unit or the skin surface. The applicant has provided an overview of in-house studies for the 5% strength product (SUM.0325, SRE.105041, SRE.2585) as well as a literature review covering 2.5%, 5% and 10% strengths.

After two weeks of daily treatment, Benzoyl peroxide 10% once daily decreases the amount

of C. acnes in pilosebaceous follicles by 98% (n=9), Benzoyl peroxide 5% twice daily reduces the number of C. acnes on the skin surface by 98% (n=9) and Benzoyl peroxide 2.5% twice daily decreases the number of C. acnes on the skin surface by 99% (n=10). A one year-long study did not show changes in the drug sensitivity to antibiotics of Benzoyl peroxide 2.5% and 5% Gels.

Lipophilic properties of benzoyl peroxide enhance its penetration into the pilosebaceous duct. Benzoyl peroxide has demonstrated exfoliative and keratolytic properties. Due to its irritant effect, benzoyl peroxide increases turnover rate of epithelial cells, thereby peeling the skin, thus preventing the plugging and fostering the unplugging of pilosebaceous glands. Benzoyl peroxide also has anti-inflammatory and wound-healing properties, which are beneficial in the treatment of acne. How benzoyl peroxide affects sebum secretion rate remains a point of debate.

IV.4 Clinical efficacy

Following a literature review, the applicant has provided the following bibliographical studies in support of the efficacy of Acnecide 10% w/w Gel:

Comparison of a Benzoyl peroxide 10% gel with a Benzoyl peroxide 5% gel

A recent Cochrane review pooled the results of two Chinese efficacy and safety trials comparing 10% benzoyl peroxide with 5% benzoyl peroxide for treating acne.

These studies were:

- a randomised, controlled, parallel-design study in 103 patients with grade 1 to 3 facial acne, treated twice daily for 6 weeks with Benzoyl peroxide 2.5% gel (n= 34), Benzoyl peroxide 5% gel (n=35) or Benzoyl peroxide 10% gel (n=34)
- a randomised, controlled, parallel-group, single centre study in 118 patients with grade 1 to 3 facial acne vulgaris, treated for 6 weeks with Benzoyl peroxide 10% cream twice daily (n=67) or Benzoyl peroxide 5% gel twice daily (n=51).

Neither of the trials reported the change in lesion counts from baseline, but trial authors pooled lesion counts at the end of the 6 weeks of treatment for the two studies. Compared with 5% Benzoyl peroxide, the mean difference in Inflammatory Lesion counts at week 6 was -0.62 and the mean difference in Non-Inflammatory Lesion counts was -7.56, in favour of 10% Benzoyl peroxide.

Comparison of a Benzoyl peroxide 10% gel with a Benzoyl peroxide 2.5 % gel

A recent Cochrane review reviewed the results of two studies comparing 10% Benzoyl peroxide gel with 2.5% Benzoyl peroxide gel for treating acne.

These studies were:

- (as above) a randomised, controlled, parallel-design study in 103 patients with grade 1 to 3 facial acne, treated twice daily for 6 weeks with Benzoyl peroxide 2.5% gel (n= 34), Benzoyl peroxide 5% gel (n=35) or Benzoyl peroxide 10% gel (n=34)

Trial authors presented lesion counts at week 6, rather than the change in lesion counts from baseline, suggesting that both Inflammatory Lesion and Non-Inflammatory Lesion counts were fewer in the 10% benzoyl peroxide group than in the 2.5% group (Mean Difference -3.80 and -3.70 respectively).

- a double-blind study in patients with mild to moderately severe acne vulgaris treated twice daily for 8 weeks with Benzoyl peroxide 2.5% gel (n=24) and Benzoyl peroxide

10% gel (n=24). The percent reduction of Inflammatory lesions was comparable at week 8: (44.7% for 10% benzoyl peroxide versus 46.7% for 2.5% benzoyl peroxide).

Summary of Clinical Efficacy

The clinical evidence base supporting the efficacy of Acnecide 10% w/w Gel is limited to small studies from the literature comparing different formulations of Benzoyl peroxide 10% gel with Benzoyl peroxide 2.5% and 5% gel formulations. No vehicle-controlled studies were presented. The data indicate that trial participants using Benzoyl peroxide 10% gel formulations had on average fewer inflammatory and non-inflammatory lesions compared with lower Benzoyl peroxide gel strengths at the end of follow-up.

IV.5 Clinical safety

Safety data were collected in 10 clinical studies including 4 Phase 1 dermal safety studies, 1 Phase 1 study with efficacy assessments, and 5 post-market studies investigating the clinical safety of several benzoyl peroxide topical formulations.

Phase 1 dermal tolerance studies in healthy subjects using benzoyl peroxide AC gels 2.5%, 5% and 10% or AC wash 5%, showed good local tolerance. In addition, analyses of adverse events (AEs) in clinical studies in healthy subjects and patients with *acne vulgaris* indicated that benzoyl peroxide topical formulations caused mainly mild to moderate, transient and local AEs including irritation, erythema, scaling, dryness, stinging/burning, pruritus and tightness.

Overall, AEs related to benzoyl peroxide AC Gel 5% led to the discontinuation of 4 subjects and AEs related to benzoyl peroxide AC 5% Wash led to the discontinuation of 2 subjects. All are well known and expected AEs with benzoyl peroxide topical formulations. No serious adverse events (SAEs) related to benzoyl peroxide formulations and no AE of special interest (including suspected sensitisation reactions) was reported during the clinical development program.

The literature review identified 4 prospective randomised studies evaluating the safety of benzoyl peroxide 10% gels. In pooled data of two comparative studies, no significant difference was found in the withdrawals due to adverse effects; it occurred in 1/93 participants treated with 10% benzoyl peroxide and 5/164 participants in the 5% benzoyl peroxide group. No significant difference was found for pooled data in the percentage of participants experiencing any adverse event.

When comparing Benzoyl peroxide 10% gel with a Benzoyl peroxide 2.5 % gel (pooled data of two comparative studies), none of the participants discontinued treatment due to adverse events, whichever the group. In one of the studies, more participants in the 10% benzoyl peroxide group experienced adverse events than in the 2.5% benzoyl peroxide group (20/33 versus 11/31, respectively). The other study reported a significantly higher frequency and severity of erythema, peeling, and burning in those receiving 10% benzoyl peroxide than in those receiving 2.5% benzoyl peroxide at all follow-up visits.

Overall, the literature review indicates that although application site irritation was more pronounced with the Benzoyl peroxide 10% gels compared with the lower concentrations, no significant difference was found in withdrawals due to adverse effects.

Post-marketing experience

Because this product is administered topically, an accurate market exposure is very difficult to estimate. The following method was used to evaluate the number of patients exposed to

benzoyl peroxide during the latest periodic safety update report (PSUR) review period [March 2019 to February 2021]: considering that a patient uses 1g per day of benzoyl peroxide gel for three months and 3g per day of benzoyl peroxide solution or wash (used on body) for three months, the amount of benzoyl peroxide used by a patient is 90g of gel, or 270g or ml of wash/lotion. From 1998, cumulatively, the estimated number of patients exposed to benzoyl peroxide for all available formulations is 60,139,660 patients.

The safety information regarding benzoyl peroxide up to February 2021 is consistent with the known safety profile of topical benzoyl peroxide. The overall risk profile remains stable.

One signal 'pigmentation disorder', which was opened during the periodic benefit risk evaluation reports (PBRER) (February 2016 to February 2017) and categorised as a non-important potential risk, remains under monitoring. One important identified risk of type I hypersensitivity has not raised any new safety concern up to February 2021.

Summary of Clinical safety
The safety profile of topical benzoyl peroxide is well characterised. The safety information presented is consistent with the known safety profile of topical benzoyl peroxide. The overall risk profile remains stable.

The cumulative review of the important identified risk of type I hypersensitivity did not raise any new safety concern. The signal 'pigmentation disorder', which has been opened from the period of February 2016 to February 2017, was closed and classified as potential risks not categorised as important and will continue to be closely monitored as non-important potential risk. The analysis of the cases in post-marketing surveillance did not allow the identification of a clear profile of patients or circumstances of occurrence.

There was one safety signal for topical benzoyl peroxide for face oedema which was closed in 2017. Face oedema is consistent with the known safety profile of benzoyl peroxide.

The majority of adverse events reported with benzoyl peroxide formulations represent local skin reactions. Local skin reactions as well as allergic contact dermatitis, swelling of the face, allergic reactions, including application site hypersensitivity and anaphylaxis are included in section 4.8 of the SmPC.

IV.6 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.

IV.7 Discussion on the clinical aspects
The grant of a marketing authorisation is recommended for this application.

V 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.

VI OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

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

The Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and labelling are satisfactory, and in line with current guidelines.

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

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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 SmPC and/or PIL available on the MHRA website.

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