Medicines & Healthcare products
Regulatory Agency

Public Assessment Report

National Procedure

Adapalene + Benzoyl Peroxide 0.1% + 2.5% Gel
Adapalene + Benzoyl Peroxide 0.3% + 2.5% Gel

adapalene; benzoyl peroxide, hydrous

PL 00289/2643 - 2644

TEVA UK LIMITED

LAY SUMMARY

Adapalene + Benzoyl Peroxide 0.1% + 2.5% Gel
Adapalene + Benzoyl Peroxide 0.3% + 2.5% Gel
adapalene; benzoyl peroxide, hydrous

This is a summary of the Public Assessment Report (PAR) for Adapalene + Benzoyl Peroxide 0.1% + 2.5% Gel and Adapalene + Benzoyl Peroxide 0.3% + 2.5% Gel. It explains how these products 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 these products.

These products will be referred to as Adapalene + Benzoyl Peroxide Gel in this lay summary for ease of reading.

These products have been authorised by Medicines and Healthcare products Regulatory Agency (MHRA) for the United Kingdom. This procedure takes into account the outcome of decentralised (DC) procedures in European Union Member States (and/or Iceland, Liechtenstein, Norway) on 26 November 2024 (NL/H/6176/001-002/DC). This is known as the MR/DC Reliance Procedure.

These applications 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 Adapalene + Benzoyl Peroxide Gel, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

What is Adapalene + Benzoyl Peroxide Gel and what are these products used for?
These applications are for hybrid medicines. This means that the medicine is similar to reference medicines already authorised, called Epiduo 0.1%/2.5% Gel and Epiduo 0,3%/2,5% Gel.

Adapalene + Benzoyl Peroxide 0.1% + 2.5% Gel is used for the treatment of acne. This medicinal product is only intended for use in adults, adolescents and children aged 9 years and over.

Adapalene + Benzoyl Peroxide 0.3% + 2.5% Gel belongs to a group of medicines called “anti-acne preparation for topical use”. It is used for the treatment of acne vulgaris, when comedones (blackheads, whiteheads), numerous papules and pustules (inflammatory pimples) are present. This medicinal product should only be used in adults and adolescents aged 12 years and over.

How do Adapalene + Benzoyl Peroxide Gel products work?
This gel combines two active ingredients, adapalene and benzoyl peroxide which work together but in different ways. Adapalene belongs to a group of products known as retinoids and acts specifically on the skin processes that cause acne. Benzoyl peroxide, the other active ingredient, works as an antimicrobial agent and by softening and peeling the outer layer of the skin.

How are Adapalene + Benzoyl Peroxide Gel products used?
The pharmaceutical form of these medicines is gel and the route of administration is cutaneous (onto the skin). This medicine is for external use only.

Adapalene + Benzoyl Peroxide products must not be used if the patient is pregnant or planning to have a baby. The patient's doctor can give them more information. If patients become pregnant while using this medicinal product, the treatment must be discontinued and patients should inform their doctor as soon as possible for a further follow-up.

Due to the differing strengths and level of detail in the usage instructions, it is best to refer directly to the PILs and Summaries of Product Characteristics (SmPCs) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website, for information on how the Adapalene + Benzoyl Peroxide Gel products are used.

These medicines 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 Adapalene + Benzoyl Peroxide Gel have been shown in studies?
No additional studies were needed as Adapalene + Benzoyl Peroxide Gel products contain the same active substance as the reference medicine, and satisfactory data to justify the differences have been provided.

What are the possible side effects of Adapalene + Benzoyl Peroxide Gel?
For the full list of all side effects reported with these medicines, see Section 4 of the PILs or the SmPCs 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 Adapalene + Benzoyl Peroxide Gel are generic medicines and are comparable to the reference medicines, their benefits and possible side effects are considered to be the same as the reference medicines.

Why were Adapalene + Benzoyl Peroxide Gel approved?
It was concluded that, Adapalene + Benzoyl Peroxide Gel products have been shown to be comparable to the reference medicines. Therefore, the MHRA decided that, as for the reference medicine, the benefits are greater than the risks and recommended that it can be approved for use.

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

The following safety concerns have been recognised for Adapalene + Benzoyl Peroxide Gel:

Summary of safety concerns	
Important identified risks	• None
Important potential risks	• Teratogenicity
Missing information	• None

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 Adapalene + 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 these applications and are satisfactory.

Other information about Adapalene + Benzoyl Peroxide Gel
Marketing authorisations were granted in the United Kingdom on 16 April 2025.

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

This summary was last updated in June 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 applications for Adapalene + Benzoyl Peroxide 0.1% + 2.5% Gel and Adapalene + Benzoyl Peroxide 0.3% + 2.5% Gel (PL 00289/2643 - 2644) could be approved.

The products are approved for the following indications.

Adapalene + Benzoyl Peroxide 0.1% + 2.5% Gel
This medicinal product is indicated for cutaneous treatment of Acne vulgaris when comedones, papules and pustules are present. Adapalene + Benzoyl Peroxide Gel is indicated in adults, adolescents and children aged 9 years and above.

Adapalene + Benzoyl Peroxide 0.3% + 2.5% Gel
This medicinal product is indicated for cutaneous treatment of Acne vulgaris when comedones, papules and pustules are present. Adapalene + Benzoyl Peroxide Gel is indicated in adults and adolescents aged 12 years and over.

For more information on the indications and usage of these medicines, please refer to the Summaries of Product Characteristics available on the MHRA website.

Adapalene + Benzoyl Peroxide Gel combines two active substances, which act through different, but complementary, mechanisms of action.

Adapalene is a chemically stable, naphthoic acid derivative with retinoid-like activity. Biochemical and pharmacological profile studies have demonstrated that adapalene acts in the pathology of Acne vulgaris: it is a potent modulator of cellular differentiation and keratinization, and it has anti-inflammatory properties. Mechanistically, adapalene binds to specific retinoic acid nuclear receptors. Current evidence suggests that topical adapalene normalizes the differentiation of follicular epithelial cells resulting in decreased microcomedone formation. Adapalene inhibits the chemotactic (directional) and chemokinetic (random) responses of human polymorphonuclear leucocytes in in vitro assay models; it also inhibits the metabolism of arachidonic acid to inflammatory mediators. In vitro studies have shown inhibition of the AP-1 factors and the inhibition of the expression of toll like receptors 2. This profile suggests that the cell mediated inflammatory component of acne is reduced by adapalene.

Benzoyl peroxide has been shown to have antimicrobial activity; particularly against Cutibacterium acnes, which is abnormally present in the acne-affected pilosebaceous unit. The mechanism of action of Benzoyl peroxide has been explained by its highly lipophilic activity, enabling its penetration through the epidermis into bacterial and keratinocyte cell membranes of the pilosebaceous unit. Benzoyl peroxide is recognized as a very effective broad-spectrum antibacterial agent in the treatment of acne vulgaris. It has been demonstrated to exert bactericidal effect by generating free radicals that oxidize proteins and other essential cellular components in the bacterium wall. The minimum inhibitory concentration of benzoyl peroxide is bactericidal and has demonstrated effectiveness on antibioticsensitive and antibiotic-resistant C. acnes strains. Additionally, benzoyl peroxide has demonstrated exfoliative and keratolytic activities.

These products have been authorised by Medicines and Healthcare products Regulatory Agency (MHRA) for the United Kingdom. This procedure takes into account the outcome of decentralised (DC) procedures in European Union Member States (and/or Iceland, Liechtenstein, Norway) on 26 November 2024 (NL/H/6176/001-002/DC). This is known as the MR/DC Reliance Procedure.

For the scientific discussion of the quality, non-clinical and clinical assessment conducted during the MR and/or DC procedures, 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.

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

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

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

Marketing authorisations were granted on 16 April 2025.

II. PRODUCT INFORMATION

Summaries of Product Characteristics (SmPCs)

The SmPCs are in line with current guidelines and are satisfactory.

PATIENT INFORMATION LEAFLET (PIL)

The PILs are in line with current guidelines and is satisfactory.

LABEL

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

III. QUALITY ASPECTS

MHRA considered that the quality data submitted for these applications is satisfactory. The grant of marketing authorisations were recommended.

IV. NON-CLINICAL ASPECTS

Pharmacodynamic, pharmacokinetic and toxicological properties of adapalene and benzoyl peroxide are well known. As adapalene and benzoyl peroxide are widely used, well-known active substances, overview based on literature review is considered appropriate.

The grant of marketing authorisations were recommended.

V. CLINICAL ASPECTS

MHRA considered that the clinical data submitted for these applications is satisfactory. The grant of marketing authorisations were 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

Full colour mock-ups of the Patient Information Leaflets (PILs) were provided with the applications in accordance with legal requirements, including user consultation.

VIII. OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION

The quality of the products is acceptable, and no new non-clinical or clinical safety concerns have been identified. The benefit/risk balance is, therefore, considered to be positive.

The Summaries of Product Characteristics (SmPCs), Patient Information Leaflets (PILs) and labelling are satisfactory.

In accordance with legal requirements, the current approved UK versions of the SmPCs and PILs for these products 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**