SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

<TRADE NAME> <STRENGTH> Cream

<REGARDING THE APPROVAL>

1. QUALITATIVE AND QUANTITATIVE COMPOSITION

Benzoyl peroxide <STRENGTH>

Excipient with known effect:

<REGARDING THE APPROVAL>

For the full list of excipients, see section 6.1.

1. PHARMACEUTICAL FORM

Cream

<REGARDING THE APPROVAL>

1. CLINICAL PARTICULARS
   1. Therapeutic indications

Benzoyl peroxide is indicated for the treatment of moderate acne vulgaris.

* 1. Posology and method of administration

Adolescents and Adults:

Apply a thin film to the whole of the affected area once or twice daily, preferably after washing and drying the skin. The patient should start with one application daily, preferably in the evening, and then gradually increase to two times daily (morning and evening) if tolerated.

If excessive dryness or peeling occurs, frequency of application should be reduced or application temporarily interrupted at the physicians instructions or according to patient tolerability.

Improvement can generally be seen after 4-6 weeks of treatment. However, longer use may be necessary.

Maximum lesion reduction may be expected after approximately eight to twelve weeks of drug use. Continued use is normally required to maintain a clinical response.

Paediatric population:

The safety and efficacy of Benzoyl peroxide has not been established in children under the age of 12 since acne vulgaris rarely presents in this age group.

* 1. Contraindications

Hypersensitivity to the active substance or to any of the excipients.

* 1. Special warnings and precautions for use

Contact with the eyes, eyelids, mouth, lips, other mucous membranes and broken skin should be avoided. In case of accidental contact, rinse well with water. Care should be taken when applying the product to the neck and other sensitive areas.

This product contains propylene glycol alginate, stearyl alcohol and cetyl alcohol. Propylene glycol alginate may cause skin irritation. Stearyl alcohol and cetyl alcohol may cause local skin reaction (e.g. contact dermatitis).

During the first weeks of treatment, a sudden increase in peeling and reddening will occur in most patients and will normally subside in a day or two if treatment is temporarily discontinued.

Patients should be advised that excessive application will not improve efficacy, but may increase the risk of skin irritation.

Concomitant topical acne therapy should be used with caution because a possible cumulative irritancy may occur, which sometimes may be severe, especially with the use of peeling, desquamating, or abrasive agents.

If severe, local irritancy occurs (e.g. severe erythema, severe dryness and itching, severe stinging/burning sensation), benzoyl peroxide should be discontinued.

As nenzoyl peroxide may cause increased sensitivity to sunlight, sunlamps should not be used and deliberate or prolonged exposure to sunlight should be avoided or minimised. When exposure to strong sunlight cannot be avoided, patients should be advised to use a sunscreen product and wear protective clothing.

The product may bleach hair and coloured or dyed fabrics. Avoid contact with hair, fabrics, furniture or carpeting.

* 1. Interaction with other medicinal products and other forms of interaction

Concomitant application of Benzoyl peroxide with tretinoin, isotretinoin, and tazarotene should be avoided since it may reduce their efficacy and increase irritation. If combination treatment is required, the products should be applied at different times of the day (e.g., one in the morning and the other in the evening).

Using Benzoyl peroxide at the same time as topical sulphonamide-containing products may cause skin and facial hair to temporarily change colour (yellow/orange).

* 1. Fertility, pregnancy and lactation

**Fertility**

There are no data on the effect of topical benzoyl peroxide on fertility.

**Pregnancy**

There are limited data on the use of topical benzoyl peroxide in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3.). No effects during pregnancy are anticipated since systemic exposure to benzoyl peroxide is very limited.

However, Benzoyl peroxide should be used during pregnancy only if the expected benefit justifies the potential risk to the foetus.

**Lactation**

Percutaneous absorption of benzoyl peroxide is very limited; however, it is not known whether benzoyl peroxide is excreted in human milk after topical application.

Benzoyl peroxide should be used during lactation only if the expected benefit justifies the potential risk to the infant.

If used during lactation, Benzoyl peroxide should not be applied to the breast area to avoid accidental ingestion by the infant..

* 1. Effects on ability to drive and use machines

Not relevant.

* 1. Undesirable effects

Adverse reactions are classified by System Organ Class. Adverse reactions that occurred either during clinical studies or that were spontaneously reported are presented below.

Frequencies were defined as follows:

Very common ≥1/10

Common ≥1/100 to <1/10

Uncommon ≥1/1000 to <1/100

Rare≥1/10000 to <1/1000

Very rare <1/10000

Not known (cannot be estimated from the available data)

***Immune System Disorders***

Not known: Allergic reactions, including application site hypersensitivity and anaphylaxis

***Skin and subcutaneous tissue disorders***

Very Common: Peeling, application site erythema

Common: Dryness, pruritus and contact sensitisation reactions

Uncommon: Burning sensation

Not known: Application site rash

***General Disorders and Administration Site Conditions***

Not known: Application site discoloration and application site reactions such as irritation and pain.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Health Product Vigilance Center; HPVC

* 1. Overdose

Topically applied benzoyl peroxide is not generally absorbed in sufficient amounts to produce systemic effects.

Excessive application may result in severe irritation. In this event, discontinue use and wait until the skin has recovered.

Cold compresses can provide relief from irritation due to excessive application.

Accidental ingestion of topical benzoyl peroxide should be managed clinically or as recommended by the National Poisons Centre, where available.

1. PHARMACOLOGICAL PROPERTIES
   1. Pharmacodynamic properties

Pharmacotherapeutic group: Benzoyl peroxide, ATC Code: D10A E01

**Mechanism of action**

Benzoyl peroxide is a highly lipophilic, oxidising agent with keratolytic and bacteriocidal effects.

**Pharmacodynamic effects**

The effectiveness of benzoyl peroxide in the treatment of acne vulgaris is primarily attributable to its antibacterial activity, especially with respect to Propionibacterium acnes. The antibacterial activity of benzoyl peroxide is due to the release of active or free-radical oxygen capable of oxidising bacterial proteins. Benzoyl peroxide is also believed to be effective in the treatment of acne on account of its anti-inflammatory and mild keratolytic properties.

* 1. Pharmacokinetic properties

Radio-labelled studies have shown that absorption of benzoyl peroxide through the skin can only occur following its conversion to benzoic acid. Following topical application, less than 5% of the dose enters systemic circulation as benzoic acid. Benzoyl peroxide is excreted as benzoic acid in the urine.

* 1. Preclinical safety data

In animal toxicity studies, benzoyl peroxide was well tolerated when applied topically.

Although high doses of benzoyl peroxide have been shown to induce DNA strand breaks, the available data from other mutagenicity studies, carcinogenicity studies and a photo co-carcinogenicity study indicate that benzoyl peroxide is not a carcinogen or a photocarcinogen.

Benzoyl peroxide (250, 500, or 1000 mg/kg/day) administered orally to male rats for 29 days and female rats for 41-51 days did not affect mating period, mating rate, conception rate, delivery rate, birth rate, pregnancy period, luteinisation number, implantation number and the rate of losing embryos and fetuses after implantation. In pups, body weight was significantly decreased in the high-dose group.

1. PHARMACEUTICAL PARTICULARS
   1. List of excipients

<REGARDING THE APPROVAL>

* 1. Incompatibilities

Not applicable.

* 1. Shelf life

<REGARDING THE APPROVAL>

* 1. Special precautions for storage

<REGARDING THE APPROVAL>

* 1. Nature and contents of container

<REGARDING THE APPROVAL>

* 1. Special precautions for disposal

<REGARDING THE APPROVAL>

1. MARKETING AUTHORISATION HOLDER

<REGARDING THE APPROVAL>

1. MARKETING AUTHORISATION NUMBER(S)

<REGARDING THE APPROVAL>

1. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<REGARDING THE APPROVAL>

1. DATE OF REVISION OF THE TEXT1

<REGARDING THE APPROVAL>