

## **Summary of Product Characteristics for Pharmaceutical Products**

### **1. Name of the medicinal product:**

ACNEVATE Gel BP 5%W/W

### **2. Qualitative and quantitative composition**

Hydrous benzoyl peroxide equivalent to Benzoyl Peroxide 5% w/w

Excipients with known effects:

One gram of gel contains 40 mg of propylene glycol (E1520).

For the full list of excipients, see section 6.1.

### **3. Pharmaceutical form**

Topical Gel

White to off-white, smooth gel

### **4. Clinical particulars**

#### **4.1 Therapeutic indications**

Topical therapy for the treatment of acne vulgaris.

#### **4.2 Posology and method of administration**

For external use only.

##### Adults and children:

Before each application, the skin should be cleaned and dried. Apply in a thin layer once or twice daily or as directed to the affected areas. Persons with sensitive skin should be directed to apply the gel once daily before going to bed. The extent of any drying or peeling may be adjusted by modifying the dosage schedule.

#### **4.3 Contraindications**

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

#### **4.4 Special warnings and precautions for use**

For external use only.

Acnecide may cause swelling and blistering of the skin, if any of these symptoms occur, medication has to be discontinued.

A mild burning sensation will probably be felt on first application and some reddening and peeling of the skin will occur within a few days. During the first weeks of treatment a sudden increase in peeling will occur in most patients. This is not harmful and will normally subside

within a day or two if treatment is temporarily discontinued. If severe irritation occurs, patients should be directed to use the medication less frequently, to temporarily discontinue use or to discontinue use altogether.

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.

Benzoyl peroxide gel should not come into contact with the eyes, mouth, angles of the nose or mucous membranes. If the preparation enters the eye, wash thoroughly with water. Caution should be exercised when applying the drug to the neck and other sensitive areas.

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

Contact with any coloured material including hair and dyed fabrics may result in bleaching or discoloration.

Due to the risk of sensitisation, benzoyl peroxide gel should not be applied on damaged skin.

This medicine contains 40 mg of propylene glycol (E1520) in each gram, which is equivalent to 4.0 % w/w. It may cause skin irritation.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

No interaction studies have been performed; however, drugs with desquamative, irritant and drying effects should not be used concurrently with benzoyl peroxide gel.

#### **4.6 Pregnancy and Lactation**

##### Pregnancy

There is no safety concern relating to the effects of cutaneously applied benzoyl peroxide on reproductive function, fertility, teratogenicity, embryotoxicity, or peri- and post- natal development from animal data. In widespread clinical use for the cutaneous treatment of acne vulgaris, at concentrations up to 10% w/w for several decades, benzoyl peroxide has never been associated with such effects. Acnecide should only be used by a pregnant woman if clearly needed.

### Breast-feeding

It is unknown whether benzoyl peroxide/metabolites are excreted in human milk. A risk to the new-borns/infants cannot be excluded. Caution should be exercised when benzoyl peroxide is administered to a nursing woman and the preparation should not be applied on the chest to avoid accidental transfer to the infant.

### **4.7 Effects on ability to drive and use machines**

Acneate Gel has no or negligible influence on the ability to drive and use machines.

### **4.8 Undesirable effects**

The adverse reactions resulting from clinical trials are all skin disorders. They are reversible when treatment is reduced in frequency or discontinued. The following categories are used to indicate the frequency of occurrence of adverse effects:

Very common ( $\geq 1/10$ )

Common ( $\geq 1/100$  to  $<1/10$ )

Uncommon ( $\geq 1/1,000$  to  $<1/100$ )

Rare ( $\geq 1/10,000$  to  $<1/1,000$ )

Very rare ( $<1/10,000$ )

Unknown (Frequency not assessable based on the available data).

They are presented in the table below:

Skin and subcutaneous tissue disorders	Very common ( $\geq 1/10$ )	Dry skin Erythema Skin exfoliation (peeling) Skin burning sensation
	Common ( $\geq 1/100$ to $<1/10$ )	Pruritus Pain of skin (pain, stinging), Skin irritation (irritant contact dermatitis)
	Uncommon ( $\geq 1/1,000$ to $<1/100$ )	Allergic contact dermatitis

Swelling face and allergic reactions, including application site hypersensitivity and anaphylaxis (not know frequency) have been reported during post-marketing surveillance.

### Reporting of Adverse Drug Reactions

Healthcare professionals are asked to report any suspected adverse drug reactions via the Pharmacy and Poisons Board's; Pharmacovigilance-Electronic-Reporting-System(PvERS)<https://pharmacyboardkenya.org>

### **4.9 Overdose**

Benzoyl peroxide gel is a preparation indicated for topical treatment only. If the medication is applied excessively, no more rapid or better results will be obtained and severe irritation might develop. In this event,

treatment must be discontinued and appropriate symptomatic therapy should be instituted.

## **5. Pharmacological properties**

### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Anti-acne preparations for topical use, ATC Code: D10AE01

Benzoyl peroxide 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

### **5.2 Pharmacokinetic properties**

Not applicable. Acnevate is a topical preparation

### **5.3 Preclinical safety data**

In animal studies by the cutaneous route, benzoyl peroxide is associated with a minimal to moderate skin irritation potential including erythema and oedema. Phototoxic and photoallergic reactions have been reported for benzoyl peroxide therapy

## **6. Pharmaceutical Particulars**

### **6.1 List of Excipients**

Methyl paraben  
Propyl paraben  
Propylene glycol  
Purified water  
Carbomer-940  
Disodium EDTA  
Polysorbate-80(Tween 80)  
NaOH pellets  
Benzoic acid  
P.E.G. 400  
Perfume Lux Super

### **6.2 Incompatibilities**

Not applicable

### **6.3 Shelf-Life**

24 Months

### **6.4 Special Precautions for storage**

Store below 25° C. Protect from light and moisture.

### **6.5 Nature and Content of container**

Lami tubes. Pack size 30g.

**6.6 Special precautions for disposal and other handling**

Not applicable.

**7. Marketing Authorization Holder**

Dolopharma Healthcare  
P.O. BOX 102976-00101, Kenya

**8. Marketing Authorization Number**

CTD10221

**9. Date of first authorization/renewal of the authorization**

25/10/2023

**10. Date of revision of the text**

16/5/2025