



**AGOG Pharma Ltd.**

(WHO - GMP CERTIFIED - GOVT RECOGNISED EXPORT HOUSE)



CIN: 11-09015

Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gauraipada, Vasai (E), Dist. Thane - 401 208. INDIA.  
Tel. : 95250 - 2455801 / 2452714 / 2453525 • Fax : 95250 - 2452074 (0091 - 250 - 2452074) • Email : agog@vsnl.net & agogpharma@rediffmail.com

<b>Brand Name</b> : AGOSCAB APPLICATION	2021
<b>Generic Name</b> : (Benzyl Benzoate Application BP 25% W/V)	
<b>Module 1</b> Administrative Information and Product Information	<b>Confidential</b>
<b>1.5</b> Product Information	

## 1.5 PRODUCT INFORMATION

### 1.5.1 Prescribing Information (Summary of Products Characteristics)

#### 1. NAME OF DRUG PRODUCT

#### 1. Name of drug product

Benzyl Benzoate Application BP 25% W/V

#### 1.1 (Trade) name of product

AGOSCAB APPLICATION

#### 1.2 Strength

Each ml contains:  
Benzyl Benzoate BP 250 mg.

#### 1.3 Pharmaceutical Dosage Form

Semi-Solid dosage form



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## 2. QUALITATIVE AND QUANTITATIVE COMPOSITIONS

### 2.1 Qualitative Declaration

Benzyl Benzoate Application BP 25% W/V

### 2.2 Quantitative Declaration

Ingredients	Specification	Label Claim	Overages	Qty. / unit (ml.)
<b><u>ACTIVE</u></b>				
Benzyl Benzoate	BP	250 mg	5.00 %	26.250 g
<b><u>NON ACTIVE</u></b>				
Simethicone Emulsion 30% USP	USP	-	-	3.000 mg
Perfume gardenia 4535	INH	-	-	44.000 mg
Emulsifying wax	BP	-	-	2.000 g
Xanthane gum	BP	-	-	100.000 mg

BP = British Pharmacopoeia.



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### **3. PHARMACEUTICAL DOSAGE FORM**

PET Clear Bottle of 100 ml.  
White uniform emulsion.



## 4. CLINICAL PARTICULARS

### Benzyl Benzoate

Benzyl benzoate is one of the older preparations used to treat scabies. Scabies is a skin infection caused by the mite *Sarcoptes scabiei*. It is characterised by severe itching (particularly at night), red spots, and may lead to a secondary infection. Benzyl benzoate is lethal to this mite and so is useful in the treatment of scabies. It is also used to treat lice infestation of the head and body. Benzyl benzoate is not the treatment of choice for scabies due to its irritant properties.

#### Indication

Used to kill lice and the mites responsible for the skin condition scabies.

#### Associated Conditions

- Lice
- Scabies

- **Pharmacodynamics**

- Benzyl benzoate is one of the older preparations used to treat scabies. Scabies is a skin infection caused by the mite *Sarcoptes scabiei*. It is characterised by severe itching (particularly at night), red spots, and may lead to a secondary infection. Benzyl benzoate is lethal to this mite and so is useful in the treatment of scabies. It is also used to treat lice infestation of the head and body. Benzyl benzoate is not the treatment of choice for scabies due to its irritant properties.

- **Mechanism of action**

- Benzyl benzoate exerts toxic effects on the nervous system of the parasite, resulting in its death. It is also toxic to mite ova, though its exact mechanism of action is unknown. In vitro, benzyl benzoate has been found to kill the *Sarcoptes* mite within 5 minutes.

- **Absorption**

- No data are available on percutaneous absorption of benzyl benzoate. Some older studies have suggested some percutaneous absorption, however the amount was not quantified.

- **Volume of distribution**

- Not Available

- **Protein binding**

- Not Available

- **Metabolism**

- Rapidly hydrolyzed to benzoic acid and benzyl alcohol, which is further oxidized to benzoic acid. The benzoic acid is conjugated with glycine to form hippuric acid.

- **Route of elimination**

- Not Available

- **Half-life**

- Not Available

- **Clearance**

- Not Available



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- **Adverse Effects**
- **Toxicity**
- Oral, rabbit: LD<sub>50</sub> = 1680 mg/kg; Skin, rabbit: LD<sub>50</sub> = 4000 mg/kg. Symptoms of overdose include blister formation, crusting, itching, oozing, reddening, or scaling of skin; difficulty in urinating (dribbling); jerking movements; sudden loss of consciousness.
- **Pathways**
- Not Available

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- **Pharmacogenomic Effects/ADRs**
- 
- Not Available

## • INTERACTIONS

- **Drug Interactions**
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- This information should not be interpreted without the help of a healthcare provider. If you believe you are experiencing an interaction, contact a healthcare provider immediately. The absence of an interaction does not necessarily mean no interactions exist.
- Not Available

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- **Food Interactions**
- Not Available



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## 5. PHARMACOLOGICAL PROPERTIES

### Benzyl Benzoate

#### 5.1 Pharmacodynamic properties

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#### 5.2 Pharmacokinetic properties

Benzyl benzoate exerts toxic effects on the nervous system of the parasite, resulting in its death. It is also toxic to mite ova, though its exact mechanism of action is unknown. In vitro, benzyl benzoate has been found to kill the *Sarcoptes* mite within 5 minutes.

No data are available on percutaneous absorption of benzyl benzoate. Some older studies have suggested some percutaneous absorption, however the amount was not quantified.

Rapidly hydrolyzed to benzoic acid and benzyl alcohol, which is further oxidized to benzoic acid. The benzoic acid is conjugated with glycine to form hippuric acid



## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of Excipients

Simethicone Emulsion 30% USP	USP	3.000 mg
Perfume gardenia 4535	INH	44.000 mg
Emulsifying wax	BP	2.000 g
Xanthane gum	BP	100.000 mg

### 6.2 Incompatibilities

None reported

### 6.3 Shelf-Life

36 months from the date of manufacture.

### 6.4 Special Precautions for Storage

Store under normal storage condition (15°C -30°C)  
Protect from light.

### 6.5 Nature and Contents of Container

PET Clear Bottle of 100 ml.