



AGOG Pharma Ltd.

(WHO - GMP CERTIFIED - GOVT RECOGNISED EXPORT HOUSE)



CIN: 11-59515

Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gaurapada, 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

Brand Name : AGOSCRUB PLUS	
Generic Name : Chlorhexidine Gluconate & Cetrimide Solution	2021
Module 1	Administrative Information and Product Information
1.5	Product Information
	Confidential

1.5 PRODUCT INFORMATION

1.5.1 Prescribing Information (Summary of Products Characteristics)

1. NAME OF DRUG PRODUCT

1. Name of drug product

Chlorhexidine Gluconate & Cetrimide Solution

1.1 (Trade) name of product

AGOSCRUB PLUS

1.2 Strength

Chlorhexidine Gluconate Solution BP 20%W/V
Equivalent to Chlorhexidine Gluconate 1.5%W/V
Strong Cetrimide Solution BP Equivalent to Cetrimide 15% W/V

1.3 Pharmaceutical Dosage Form

External application



2. QUALITATIVE AND QUANTITATIVE COMPOSITIONS

2.1 Qualitative Declaration

Chlorhexidine Gluconate Solution BP 20%W/V
 Equivalent to Chlorhexidine Gluconate 1.5%W/V
 Strong Cetrimide Solution BP Equivalent to Cetrimide 15% W/V

2.2 Quantitative Declaration

Ingredients	Specification	Label Claim	Overages	Qty. / Tab.
<u>ACTIVE</u>				
Chlorhexidine Gluconate as Chlohexidine Gluconate Solution 20%W/V	BP	20% W/V	1.5%W/V 10.00%	82.500 g
Cetrimide Strong Solution 40%	BP	15% W/V	-	375.00 g
<u>NON ACTIVE</u>				
Poly Sorbate (Tween-80)	BP			1000.00 mg
Glycerine	BP			50.000 g
Colour Carmoisine Supra INH	INH		-	150.00 mg
Pine Oil	INH		-	20.00 ml

BP = British Pharmacopoeia.



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3. PHARMACEUTICAL DOSAGE FORM

HDPE Bottle of 1 Ltr.

Pink coloured clear liquid.



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4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

AGOSCRUB PLUS Which has antibacterial properties, fighting and killing bacteria. It is used for disinfecting the skin

4.2 Posology and Method of Administration

Method of administration: External application

4.3 Special Warnings and Precautions for Use

Patients are instructed to consult with their physician if they experience severe adverse reaction, they become pregnant or intend to become pregnant or they have any other questions.

For external use only

Avoid use on broken skin, the eyes, nose and lips.

4.4 Use in Pregnancy and Lactation

Patients are instructed to consult with their physician if they experience severe adverse reaction, they become pregnant or intend to become pregnant or they have any other questions.

4.5 Effects on ability to drive and operate machine

People can drive or use machines after applying **AGOSCRUB PLUS**

4.6 Overdoses

If irritation develops, use of lotion should be discontinued and appropriate therapy instituted.



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5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmaco-Kinetic Properties

Chlorhexidine gluconate

Chlorhexidine gluconate is a germicidal mouthwash that reduces bacteria in the mouth. **Chlorhexidine gluconate** oral rinse is **used to** treat gingivitis (swelling, redness, bleeding gums).

Cetrimide

Cetrimide is an antiseptic and disinfectant used topically for wound cleansing and the treatment of some skin disorders

5.2 Pharmaco-dynamic properties



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6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Poly Sorbate (Tween-80)	BP	1000.00 mg
Glycerine	BP	50.00 g
Colour Carmoisine Supra	INH	150.00 mg
Pine Oil	INH	20.00 ml

6.2 Incompatibilities

None reported

6.3 Shelf-Life

36 months from the date of manufacture.

6.4 Special Precautions for Storage

Store below 30°C.
Protect from light.

6.5 Nature and Contents of Container

HDPE Bottle of 1 Ltr.