

MICRO LABS LIMITED, BANGALORE, INDIA							
1	Product Name	Stafofan			<div>Colours Used</div> <div><div></div> BLACK</div> <div><div></div> RED</div>		
2	Strength	20 mg/g (2% w/w) Cream					
3	Component	Leaflet					
4	Category	Export - Philippines					
5	Dimension	85 x 160 mm					
6	Artwork Code	EXG-ML01I-1256/A					
7	Pharma Code	N/A					
8	Reason for Change	Size and New Regulation					
		Prepared by (DTP)	Checked by (PD)	Approved by			
				Head CQA	Head Production/ Packing (Site)	Head QC (Site)	Head QA (Site)
Sign		Kantharaju L.					
Date		19-11-2021					

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FUSIDIC ACID

STAFOBAN

20 mg/g (2% w/w) Cream
ANTIBACTERIAL

FOR EXTERNAL USE ONLY

PRODUCT NAME:
STAFOBAN

DOSAGE FORM AND STRENGTH:
Cream, 20 mg/g (2% w/w)

PHARMACOLOGIC CATEGORY:
ANTIBACTERIAL

PRODUCT DESCRIPTION:
White smooth cream, free from black particles.

FORMULATION/COMPOSITION:
Each gram of cream contains:
Fusidic Acid BP (anhydrous)..... 20 mg

Pharmacodynamics

It is an antibiotic derived from *Fusidium coccineum*, exerts powerful antibacterial, activity against a number of gram-positive organisms. *Staphylococci*, including the strains resistant to penicillin or other antibiotics, are particularly susceptible to this cream. The therapeutic efficacy of topically applied Fusidic acid cream is due partly to the pronounced antibacterial activity of Fusidic acid cream against the organisms responsible for skin infections, and partly to the unique ability of this antibiotic intact skin.

INDICATIONS:
Fusidic acid is indicated for treatment of skin infections caused by *Staphylococci*, *streptococci*, *Corynebacterium minutissimum*. Primary skin infections that may be expected to respond to treatment with Fusidic acid applied topically include: impetigo contagiosa, superficial folliculitis, sycosis barbae, paronychia and erythrasma.

DOSAGE AND MODEL ROUTE OF ADMINISTRATION:
Fusidic Acid cream is applied to the affected area 2-3 times daily generally for a period of 7 days, or as prescribed by physician.

CONTRAINDICATIONS & PRECAUTION(S), WARNING(S)
Hypersensitivity to the active substance or any of the excipients

PRECAUTIONS AND WARNINGS:
Bacterial resistance among *Staphylococcus aureus* has been reported to occur with the use of topical Fusidic Acid. As with all antibiotics, extended or recurrent use may increase the risk of developing antibiotic resistance. Extended or recurrent use may increase the risk of developing contact sensitization.

INTERACTIONS:
No interaction studies have been performed.

ADVERSE EFFECTS:
The most frequently reported adverse reactions during treatment are various skin reactions such as pruritus and rash, followed by application site conditions such as pain and irritation, which all occurred in less than 1% of patients.

STORAGE CONDITION:
Store at temperatures not exceeding 30°C.

DOSAGE FORMS AND PACKAGING AVAILABLE:
Fusidic acid cream (stafofan) is available in Aluminum collapsible tube X 10g (Box of 1's)

INSTRUCTIONS AND SPECIAL PRECAUTIONS FOR HANDLING AND DISPOSAL (IF APPLICABLE):
Not Applicable

NAME AND ADDRESS OF MARKETING AUTHORIZATION HOLDER:
Marketing Authorization Holder
Brown & Burk Philippines Inc
U-501, 5/F., SEDCCO 1 Bldg., 120 Rada cor.,
Legaspi Sts., Legaspi Village, Makati City, Philippines

NAME AND ADDRESS OF MANUFACTURER:
MICRO LABS LIMITED
92, SIPCOT, HOSUR-635 126,
TAMIL NADU, INDIA.

CAUTION STATEMENT:
FOODS, DRUGS, DEVICES, AND COSMETICS ACT PROHIBITS DISPENSING WITHOUT PRESCRIPTION.

ADR REPORTING STATEMENT:
FOR SUSPECTED ADVERSE DRUG REACTION, REPORT TO THE FDA:
www.fda.gov.ph
Seek medical attention immediately at the first sign of Adverse Drug Reaction.

REGISTRATION NUMBER:
DRP-6185

DATE OF FIRST AUTHORIZATION:
23 June 2015

DATE OF REVISION OF PACKAGE INSERT:
May 2020

EXG-ML01I-1256/A

160 mm

85 mm

85 mm

Size: 85 (L) x 160 (H) mm
Folding size: 25 x 80 mm
Carton size: 30 x 28 x 108 mm