

125 mm

168 mm

R_x **Sucralfate, Metronidazole with Lignocaine Hydrochloride Cream**

ANO-metrogylTM

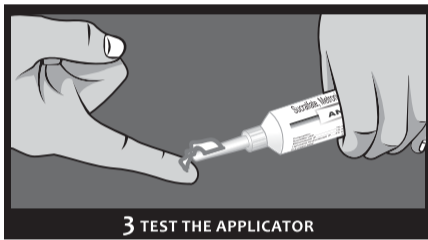
User Guide



1 WASH YOUR HANDS



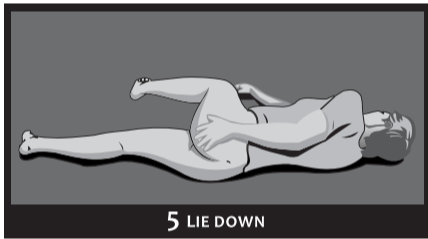
2 PUNCTURE THE FOIL AND ATTACH THE APPLICATOR



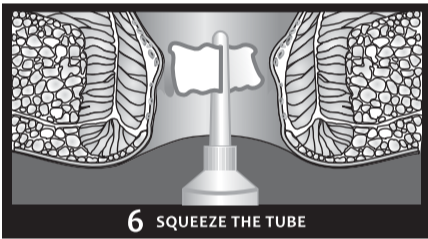
3 TEST THE APPLICATOR



4 LUBRICATE THE APPLICATOR



5 LIE DOWN



6 SQUEEZE THE TUBE

128198

For the use of Registered Medical Practitioner or a Hospital or a Laboratory
R_x **Sucralfate, Metronidazole with Lignocaine Hydrochloride Cream**
ANO-metrogylTM

COMPOSITION:

Sucralfate IP7% w/w
Metronidazole IP1% w/w
Lignocaine Hydrochloride IP4% w/w
In a cream baseq.s.

DOSAGE FORM:

Cream.

INDICATIONS:

It is indicated for the treatment of bedsore, hemorrhoids, fistulae and anal fissures.

DOSE AND METHOD OF ADMINISTRATION:

As directed by physician depending on the severity of the condition.

Directions for use:

FOR EXTERNAL USE ONLY

Route of administration: Topical.

Clean the affected area with mild soap & warm water. Rinse thoroughly and pat dry. Apply the cream with the special applicator. Cleanse the applicator thoroughly after use. Keep the product out of children's reach.

USE IN SPECIAL POPULATIONS:

Pregnancy & Lactation

ANO-metrogyl Cream should not be used during pregnancy unless considered essential by the physician.

CONTRA-INDICATIONS:

ANO-metrogyl cream is contraindicated in patients with a history of hypersensitivity to metronidazole, amide-type local anaesthetics, sucralfate or to any other ingredient in the formulation. Caution is recommended in lactating females.

250 mm

Applicable Only for Front Panel

Generic Name Font and Size : CG Omega 20 pt.

Brand Name Font and Size : CG Omega 18 pt.

| | | | | |
|---|-----------------------------------|---|-----------------------------------|-----------------------------|
| SAP Code: 128198 | Country : Domestic (India) | Mfg. Location : Alaina Healthcare Pvt. Ltd. | Product Name : Ano-Metrogyl Cream | |
| Packaging Material : Leaflet | Existing / Reference Art : 124052 | Version No.: 2 | Date : 07.01.2020 | |
| Dimension : (L) 250 x (B) 168 mm (Tolerance ± 1 mm) | | Size After Folding : (L) 125 x (B) 21 mm | Core Dia : NA | |
| Reel Dia : NA | Varnish / Lamination : NA | Folding Pattern : 1 vertical + 3 Horizontal Folds | Print Repeat Length : NA | |
| Specification : White Maplitho Paper | | Pantone : Black | | |
| Grammage: 56 ± 5% gm/m ² | | | | |
| Thickness : NA | | | | |
| Other Test : NA | | | | |
| Reason for Change : Change in Marketed by Lekar address | | | | |
| File Path : X:\Artworks\Kiran\AS PER DCGI GUIDELINE\Ano-metrogyl V-1\open file\128198 Anometrogyl Leaflet - AS PER DCGI GUIDELINE.cdr | | | | |
| Artist : Gajanan Khade | Initiated by | Checked by | Approved by | Approved by |
| Sign & Date | | | | |
| Designation | Executive - PDD | Manager - PDD | Regulatory Affairs | V. P. (Supply Chain) |

125 mm

168 mm

WARNINGS AND PRECAUTIONS:

Avoid contact with eyes. If eye contact occurs, immediately wash out the eye with water or saline and protect the eye until sensation returns.

Do not apply to irritated skin or if excessive irritation develops. Dermal application may cause transient local blanching followed by transient erythema.

DRUG INTERACTIONS:

Drug interactions should be kept in mind when ANO-metrogyl cream is prescribed for patients who are receiving anticoagulant treatment, although they are less likely to occur with topical administration because of low absorption. ANO-metrogyl cream should be used with caution in patients receiving Class I anti-arrhythmic drugs (such as tocainide and mexiletine) since the toxic effects are additive and generally synergistic.

UNDESIRABLE EFFECTS:

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 ($< 1/10,000$), Not known (cannot be estimated from available data).

Skin and subcutaneous tissue disorders:

Common-Dry skin, erythema, pruritus, skin discomfort (burning, pain of skin/stinging), skin irritation, redness, itching, rash, urticaria worsening of rosacea. Unknown frequency- Contact dermatitis, swelling face, skin exfoliation.

Nervous system disorders:

Uncommon- Hypoesthesia, paraesthesia, dysgeusia (metallic taste).

Gastrointestinal disorders:

Uncommon- Nausea.

In rare cases local anesthetics have been associated with allergic reactions including anaphylactic shock. Corneal irritation after accidental eye exposure.

OVERDOSE:

There are no reported human experiences with overdosage of ANO-metrogyl cream.

PACKAGING INFORMATION:

Tube of 10gm / 20gm.

STORAGE AND HANDLING INSTRUCTIONS:

Store at a temperature not exceeding 30°C.

Do not freeze.

Manufactured in India by:

Alaina Healthcare Pvt. Ltd.

Khasra No. 127-132, 707/133,
685/608/32, Village Jharmajri,
Baddi, Dist. – Solan (H.P.) - 174 103.

Marketed by:

Lekar Pharma Ltd.

Neelam Centre, 'B' Wing, 3rd Floor,
Hind Cycle Road, Worli, Mumbai – 400 030, India

™ Trade Mark

250 mm