

For the use of Registered Medical Practitioner only

1.0 Generic Name and Brand Name

Sucralfate, Metronidazole with Lignocaine Hydrochloride Cream
CREMA- ANO™

2.0 Qualitative and Quantitative Composition

Sucralfate I.P. 7% w/w

Metronidazole I.P.1% w/w

Lignocaine Hydrochloride I.P.....4% w/w

Preservative:

Chlorocresol I.P.....0.1%w/w

In a cream base q.s.

3.0 Dosage Form and Strength:

Refer section 1 & 2

4.0 Clinical Particulars

4.1 Therapeutic Indications

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

4.2 Posology 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.

Ensure finger- nails are clipped to prevent breakage of finger glove. Wash your hands before application. Remove finger glove from the carton and Roll the finger glove on the Index finger. Uncap the tube & squeeze the recommended quantity of cream on the finger. Gently insert the finger into the anal canal. Do not push the finger past the first finger joint. Carefully apply the cream around the inner sides of the anal canal.

4.3 Contraindications:

Crema- Ano 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.

4.4 Special Warnings and Precautions for Use

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.

4.5 Drug Interactions

Version 3.0, dated 13th May 2024

Replaces Version 2.0, dated 10th Jan 2022

Drug interactions should be kept in mind when Crema- Ano is prescribed for patients who are receiving anticoagulant treatment, although they are less likely to occur with topical administration because of low absorption. Crema- Ano 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.

4.6 Effects on Ability to Drive and Use Machines

No adverse effects on the ability to drive or use machines has been reported following the topical application of Cremagel – Ano.

4.7 Use in Special Populations

Pregnancy & Lactation

Crema- Ano should not be used during pregnancy unless considered essential by the physician.

4.8 Undesirable Effects

Common (n100 to <1/10), Uncommon (1/1,000 to <1/100), Rare (n10,000 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.

4.9 Overdose

There are no reported human experiences with overdosage of Crema- Ano

5.0 Pharmacological Properties

Cremagel-H, a topical cream containing the three components, namely sucralfate, metronidazole, and lignocaine hydrochloride is a good alternative that meets all the demands of symptom management in anorectal diseases, viz., pain management, friction avoidance, wound healing, and prevention of infection.

5.1 Mechanism of Action

Sucralfate acts as a protective mechanical barrier at sites of injuries and prevents friction by forming physical a coating via enhancing mucus production. It exerts considerable anti-inflammatory and antibacterial activity and also promotes healing by enhancing PgE2 production and reducing free oxygen radicals.

Lignocaine upon topical application stabilizes the neuronal membrane and prevents the initiation and conduction of nerve impulses, thus, resulting in local anesthetic action.

Metronidazole on topical application acts by inhibiting inflammatory mediators produced by neutrophils, lymphocyte chemotaxis, and suppressing cell-mediated immunity which further resulting in the suppression of inflammatory reactions. Metronidazole also possesses an antioxidant effect by reducing reactive oxygen species (ROS) production in the skin and

scavenging for existing free radicals. Metronidazole facilitates faster wound epithelialization by promoting the growth of keratinocytes.

5.2 Pharmacodynamic Properties

Crema-Ano containing three components (sucralfate, metronidazole, and lignocaine hydrochlorid) exhibits analgesic and anti-infective actions, as well as promotes wound healing, ideal for the treatment of anorectal conditions.

5.3 Pharmacokinetic Properties

Sucralfate

There is a very limited pharmacokinetic data available for topical sucralfate. The absorption and dissolution rate of topical sucralfate is limited owing to its poor permeability. The small amount of sucralfate that is absorbed is excreted primarily through urine.

Lignocaine

Absorption: Following topical administration, lignocaine can be absorbed by mucous membranes. anesthesia usually eventuates within 1–5 min and the effect last for 15–30 min approximately.

Distribution: Plasma protein binding of lignocaine is approximately 70%. It majorly binds to alpha-1-acid glycoprotein.

Metabolism: It is metabolized extensively by the liver to a number of metabolites, such as monoethylglycinexylidide and glycinexylidide. Both of them have pharmacological activity similar to lignocaine, but with lower potency.

Excretion: Lignocaine and its metabolites are excreted by the kidneys. Less than 10% of lignocaine is excreted unchanged.

Metronidazole

Absorption: Following topical application, metronidazole is poorly absorbed systemically. Serum concentrations of metronidazole are negligible after topical application.

Distribution: Since, the negligible amount of metronidazole is absorbed systemically after topical application, the relevant data are not yet obtained.

Metabolism: Metronidazole is probably absorbed percutaneously in its unchanged form. The major metabolite of metronidazole is hydroxymetronidazole.

Excretion: Metronidazole is excreted through urine.

6.0 Nonclinical Properties

6.1 Animal Toxicology or Pharmacology

The results of acute, sub-chronic and chronic toxicity studies of Sucralfate, Lignocaine and Metronidazole in various species indicate that the compound has very low toxicity. Acute toxicity of lidocaine in rats, mice, dogs and monkeys may lead to CNS side-effects. Oral and subcutaneous LD50 values in mice are in the range of 200–400 mg/kg bw, while the intramuscular LD50 value of lidocaine in rats is 260 mg/kg bw.

7.0 Description

CREMA-ANO is supplied for Tropical administration, as cream base of Sucralfate, Metronidazole with Lignocaine Hydrochloride. Each mg of CREMA-ANO contains Sucralfate 7% w/w, Metronidazole 1% w/w, Lignocaine Hydrochloride 4% w/w.

8.0 Pharmaceutical Particulars

8.1 Incompatibilities

Not known

8.2 Shelf-Life

Refer pack

8.3 Packaging Information

Refer pack

8.4 Storage and Handling Instructions

Refer pack

9.0 Patient Counselling Information

a) Appropriate treatment

Sucralfate IP 7% w/w, Metronidazole IP 1% w/w, Lignocaine Hydrochloride IP 4% w/w.

It is indicated for the treatment of bedsores, hemorrhoids, fistulae and anal fissures. Clean the affected area with mild soap & warm water. Rinse thoroughly and pat dry. Wear the finger cot on the index finger. Apply 0.5 FTU (Finger Tip Unit) cream over the affected area. Remove the finger cot after using and discard. Repeat the process two - three times daily. Keep the product out of reach of children.

Duration of therapy: As per physician discretion

b) Interactions

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

c) Warning 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.

10. Details of Manufacturer

Refer pack for Manufacturer details.

Marketed By:

Abbott India Limited

Angel Space, Lifestyle Bldg. No. D-4,
Gala No. 7 to 10 & 17 to 20 Ground Floor,
107 to 110 & 117 to 120 First Floor,
Pimplas Village, Dist. Thane,
Bhiwandi - 421 302, India

TM-Trademark of Abbott GMBH

11. Details of Licence Number

Refer Pack for Permission/License details.

12. Date of Revision

Version 3.0, dated 13/05/2024

For product complaints and queries please write to webmasterindia@abbott.com

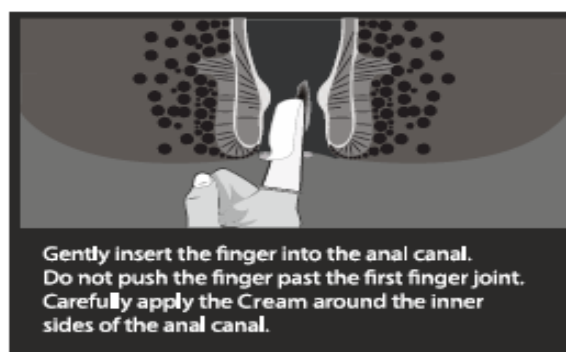
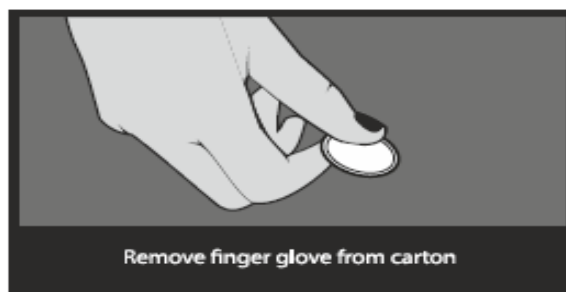
Source:

1. *EMA report (Lignocaine)*
2. *LMX4 Lidocaine 4% Cream PI (Ferndale Pharmaceuticals Pvt. Ltd.)*
3. *Published article on Metronidazole toxicity studies*

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User Guide



*Sucralfate, Metronidazole with Lignocaine Hydrochloride Cream
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(distal skin-crease to the tip of the index finger of an adult)