1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

BURNEM CREAM (ACRIFLAVINE CREAM)

Cream for topical administration

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Label claim

Each 100 gm contains:

Acriflavine BPC 0.12 gm

Excipients: Contains 9.2% w/w cetostearyl alcohol, 0.1% chlorocresol and 5 % w/w propylene glycol.

For the full list excipients, see section 6.1

3. PHARMACEUTICAL FORM

Cream for topical administration

BURNEM CREAM is available as orange yellow, smooth, homogenous, semi-solid preparation filled in 20 gm aluminium collapsible tubes.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Indicated for burns, wounds, pus formation, bruised skin and cuts, topical skin infections.

4.2 Posology and method of administration

Sufficient quantity of Burnem is applied to the cleaned affected area and rubbed in gently, is immediately absorbed. In general, its repeated use in every 6 -8 hours (thrice daily). However, a physician should be consulted in specific cases, where other medications or aliments are involved.

4.3 Contraindications

Hypersensitivity to any of the ingredients of this medicine.

4.4 Special warnings and precautions for use

Before using this drug, inform your doctor about your current list of medications, over the counter products (e.g. vitamins, herbal supplements, etc.), allergies, pre-existing diseases, and current health conditions (e.g. pregnancy, upcoming surgery, etc.). Some health conditions may make you more susceptible to the side-effects of the drug. Take as directed by your doctor or follow the direction printed on the product insert. Dosage is based on your condition. Tell your doctor if your condition persists or worsens. Important counseling points are listed below.

- Avoid contact with mucous membrane & eyes

- Avoid use in body cavities.
- Breastfeeding
- Consult with doctor for precautions.
- Do not use it for a longer period and repeatedly.
- For topical use only

BURNEM cream contains chlorocresol which may cause allergic reactions, propylene glycol may cause skin irritation and cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).

4.5 Interaction with other medicinal products and other forms of interaction

If you take other drugs or over the counter products at the same time, the effects of Burnem Cream may change. This may increase your risk for side-effects or cause your drug not to work properly. Tell your doctor about all the drugs, vitamins, and herbal supplements you are using, so that you doctor can help you prevent or manage drug interactions. Burnem Cream may interact with the following drugs and products:

- Alcohol

4.6 Fertility, pregnancy and lactation

Consult with your doctor for case-specific recommendations.

4.7 Effects on ability to drive and use machines.

If experience drowsiness, dizziness, hypotension or a headache as side-effects when using Burnem Cream medicine then it may not be safe to drive a vehicle or operate heavy machinery.

4.8 Undesirable effects

The following is a list of possible side-effects that may occur from all constituting ingredients of Burnem Cream. This is not a comprehensive list. These side-effects are possible, but do not always occur. Some of the side-effects may be rare but serious. Consult your doctor if you observe any of the following side-effects, especially if they do not go away.

- Skin Rash
- Skin Irritation
- Red or Itchy Skin
- Irritation to The Gastric Mucosa
- Rashes
- Cardiac Arrhythmias

4.9 Overdose

Do not take more than prescribed dose. Taking more medication will not improve your symptoms; rather they may cause poisoning or serious side-effects.

If you suspect that you or anyone else who may have overdosed of Burnem Cream, please go to the closest hospital or nursing home.

Do not give your medicines to other people even if you know that they have the same condition or it seems that they may have similar conditions. This may lead to overdosage.

Please consult your physician or pharmacist or product package for more information.

5.0 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Acriflavine is an antimicrobial dye structurally related to acridine. The acridine derivatives are slow-acting antiseptics. They are bacteriostatic against Gram-positive bacteria, less effective against Gram-negative bacteria, and ineffective against spores. Their activity is increased in alkaline solutions and is not reduced by tissue fluids. Acriflavine has been used in the treatment of infected wounds, burns and for skin disinfection. However, prolonged treatment may delay wound healing.

5.2 Pharmacokinetic properties

Oral absorption of Acriflavine is found to be 463.5% ±1.5.

5.3 Preclinical safety data

Not Applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Thymol, Cetostearyl Alcohol, Chlorocresol, Hard Paraffin, Borax, Stearic acid, Light Liquid Paraffin, Microcrystalline Wax, Sodium Acid Phosphate Dihydrate , Sodium Phosphate Dibasic, Propylene Glycol, Isopropyl alcohol , Purified water.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years or depending on the shelf life of API whichever is minimum.

To be used within 1 month after opening.

6.4 Special precautions for storage

Do not store above 30ºC, Protect from light.

6.5 Nature and contents of container

20 gm aluminium collapsible tube.

6.6 Special precautions for disposal and other handling

Any unused medicine or medicine waste should be disposed in accordance with local policy.

7. MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE ADDRESSES

NEM LABORATORIES PRIVATE LTD.

133, Krishna Indl. Estate,

Navghar, Vasai Road (E),

Dist. Palghar - 401 210. INDIA

8. MARKETING AUTHORIZATION NUMBER

---

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION

---

10. DATE OF REVISION OF THE TEXT

March 2022