

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

CALADIN Lotion (Calamine Lotion BP)

2. Qualitative and quantitative composition

Composition:

Calamine BP

Zinc Oxide BP

Bentonite BP

Sodium Citrate BP

Phenol BP

Glycerin BP

Excipients

Purified water BP

3. Pharmaceutical form

Topical Lotion

4. Clinical particulars

4.1 Therapeutic indications

CALADIN Lotion (Calamine Lotion BP) is used in eczemas, specially where the surface is red and tender, to alleviate discomfort. CALADIN Lotion (Calamine Lotion BP) cools the skin by evaporation and is useful in reducing the pain and swelling of sunburn.

Can be used for temporarily relief from pain and itching occurred due to rashes, insectbites, minor skin irritation and minor cuts.

4.2 Posology and method of administration

Adults and Children 2 years of age and older. Apply the lotion 3 to 4 times a day to the affected area.

Childern under 2 years of age: As directed by physician.

4.3 Contraindications

None.

4.4 Special warnings and precautions for use

Patients are instructed to consult with their physician if they experience adverse reactions. Protect from light. Keep out of reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

None

4.6. Fertility, pregnancy and lactation

Not Known.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

No reaction or side effects have been reported.

4.9 Overdose

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

5. Pharmacological properties

5.1 Pharmacodynamic properties

CALADIN Lotion (Calamine Lotion BP) has no systemic pharmacologic effects. It has, however, local effects on the skin and astringent, antiperspirant, antipruritic, and mild antiseptic activities. These are probably related to the ability of the zinc ion to precipitate protein but other mechanisms may also be involved in its actions against bacteria.

5.2 Pharmacokinetic properties

No information available.

5.3 Preclinical safety data

None.

6. Pharmaceutical particular

6.1 List of excipients

Zinc Oxide	BP
Bentonite	BP
Magnesium Aluminium Silicate	USP
Xanthan Gum	BP
Sodium Citrate	BP
Phenol	BP
Glycerin	BP
Purified Water	BP

6.2 Incompatibilities

None known.

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store below 30°C. Protect from light. Keep the bottle tightly closed. Keep out of reach of children.

6.5 Nature and contents of container

Caladin Lotion (calamine Lotion) is available in 100 ml, 200 ml, 500 ml and 1000 ml pack.

6.6 Special precautions for disposal and other handling

No special requirements.

7. Marketing authorisation holder

Galentic Pharma (India) Pvt. Ltd.

Samruddhi Venture Park, 4th Floor,
MIDC Central Road, Andheri (East),
Mumbai 400 093.

Telephone no: 00 91 22 2838 2233 / 34 / 35 / 36

E-mail address: info@galentic.com

8. Marketing authorization number

04351/06809/REN/2018

9. Date of authorization

Mar 20, 2019

10. Date of revision

Mar 20, 2019