SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

Fluocinolone acetonide 0.025%w/w cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Fluocinolone acetonide
Ethyl paraben
Glycerin
Hydrous wool fat
Stearic acid
Triethanolamine
Water
White Vaseline

3. PHARMACEUTICAL FORM

Fluocinolone acetonide 0.025%w/w cream

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Steroid responsive dermatoses like allergic dermatitis, atopic dermatitis, contact dermatitis, seborrheic dermatitis, eczema, skin pruritus, psoriasis, neurodermatitis.

4.2. Posology and method of administration

Apply to the affected areas 2 to 3 times a day by gentle inunction.

4.3. Contraindications

Corticosteroids have been shown to be teratogenic in animals following dermal application. As agents are absorbed percutaneously teratogenicity following topical application can not be excluded. Therefore Fluocinolone acetonide cream should not be used during pregnancy. Fluocinolone acetonide cream is contra-indicated in the treatment of herpes simplex, vaccinia or varicella. Long-term use is contra-indicated in patients with diabetes mellitus or tuberculosis. Fluocinolone acetonide cream should not be used on infants and young children.

4.4. Special warnings and special precautions for use.

Treatment should be discontinued if unfavourable reactions are seen. Regular review should be made of the necessity for continuing therapy.

If a secondary microbial skin infection is present suitable concomitant antimicrobial therapy should be instituted. Fluociinolone acetonide cream should not be used to treat infections dand ulcers of the leg. It causes delayed wound healing and increased liability to infections. Fluocinolone acetonide cream should not be applied to any skin crease area. Fluocinolone acetonide cream should be used with caution near the eyes and should be used for short course only. Application to the eyes has produced corneal ulcers, raised

intraocular pressure, and reduced visual function. The treatment of psoriasis with Fluocinolone acetonide cream may provoke the pustutar form of the disease.

4.5. Interaction with other FPPs and other forms of interaction

This product is an adrenal cortex hormone drug. It is best not to use the same product at the same time to avoid excessive dosage. If necessary, consult a physician

4.6. Pregnancy and lactation

Fluocinolone acetonide cream should not be used during pregnancy.
Long-term use is contra-indicated in patients with diabetes mellitus or tuberculosis.
Fluocinolone acetonide cream should not be used on infants or young children.

4.7. Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8. Undesirable effects

Not appropriate.

4.9. Overdose

Refer to "Side effects and Special Precautions". Treatment is supportive and symptomatic.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacological cldassification

Corticoseroids with a without anti-infective agent

5.2. Clinical pharmacology

Fluocinolone acetonide is a potent topical corticosteroid which exhibits anti-inflammatory, vasoconstrictive, anti-pruritic and anti-allergic properties when applied locally to the skin and mucosa.

5.3. Preclinical safety data

External use can constrict dermal capillaries, inhibit the proliferation or regeneration of epidermal cells, inhibit the regeneration of fibrocytes in connective tissue, stabilize intracellular lysosomal membranes, and prevent tissue damage caused by the release of lysosomal enzymes.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Fluocinolone acetonide
Ethyl paraben
Glycerin
Hydrous wool fat
Stearic acid
Triethanolamine

Water
White Vaseline

6.2. Incompatibilities
Not applicable.

6.3. Shelf life
2 years

6.4. Special precautions for storage
Do not store above 30°C

6.5. Nature and contents of container
It is contained in an aluminum tube, one tube per box.

6.6. Instructions for use and handling
Store below 30℃. Store in well closed containers. Protect from light.

7. MARKETING AUTHORISATION HOLDER
Shanghai General Pharmaceutical Co.,Ltd

8. NUMBER(S) IN THE NATIONAL REGISTER OF FINISHED PHARMACEUTICAL PRODUCTS
Application Number : 06779/REN/2018

9. DATE OF FIRST AUTHORISATION/RENEWALOF THE AUTHORISATION
Renewal date: 10-05-2021

10. DATE OF REVISION OF THE TEXT
Dec.20, 2022