SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

Hydrocortisone Acetate Cream, 1%, 15g

2. QUALITATIVE AND QUANTITATIVECOMPOSITION

For product Hydrocortisone Acetate cream, it contains 0.15g Hydrocortisone Acetate per tube.

For excipients, see 6.1.

3. PHARMACEUTICAL FORM

Cream

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Hydrocortisone Acetate Cream is a topical anti-inflammatory indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. Hydrocortisone Acetate Cream used in the treatment of:

•irritant dermatitis (inflammation of the skin)

•contact allergic dermatitis

•insect bite reactions

•mild to moderate eczema (inflammation of the skin)

4.2 Posology and method of administration

Always use Hydrocortisone Acetate Cream as directed by your doctor. Check the label on the medicine for exact dosing instructions.

Apply a small amount of medicine to the affected area. Gently rub it in until it is evenly distributed. Wash your hands after applying Hydrocortisone Acetate Cream, unless your hands are part of the treated area.

Do not bandage or wrap the affected area unless directed otherwise by your doctor.

Do not Hydrocortisone Acetate Creamon your face, groin, or underarms unless your doctor tells you otherwise.

If you miss a dose of hydrocortisone cream, apply it as soon as possible. If it is almost time for your next dose, skip the missed doseand go back to your regular schedule. Do not use 2 doses at once.

4.3 Contraindications

Topical corticosteroids are contraindicated in those patients with a history

ofhypersensitivity to any of the components of thepreparation.

4.4 Special warnings and special precautions for use

WARNINGS:

For external use only.Do not apply to eyes for complicated infection caused by bacteria or virus, it should be used with antibiotics. Over absorption of this cram may cause undesirable reaction all over the body.

PRECAUTIONS

Systemic absorption of topical corticosteroids has produced reversible hypothalamicpiturary-adrenal(HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and Glucose urea in some patients. Conditions which augument systemic absorption includes the application of more potent steroids, use3 over large surface areas, prolonged use, and the additions of occlusive dressing. Therefore patients receiving a large dose of potent topical steroids applied to a large surface area, or under an occlusive dressing, should be evaluated for evidence of HPA axis suppression.

4.5 Interaction with other FPPs and other forms of interaction

If drug interactions with other medications may occur, consult your physician or pharmacist for details.

4.6 Pregnancy and lactation

Pregnancy and breast-feeding

Should not be used in pregnancy and breastfeeding without medical advice.

4.7 Effects on ability to drive and use machines

None reported.

4.8 Undesirable effects

Like all medicines, Hydrocortisone Cream can cause side effects, although not everybody gets them.

Hydrocortisone preparations are usually well tolerated, but if any signs of hypersensitivity appear, application should stopimmediately;this may includeallergic contact dermatitis (rash which may be red, itchy and burning) or worsening of your condition.

Other side effects:

- Stretch marks may occur in areas where the skin may rub, for example at the joints and at folds in the skin.

- Thinning of the skin, changes in skin pigmentation (color) and hair growth.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

4.9 Overdose

Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects. Of over, please apply for the medical attention.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Glucocorticoid

External use as: anti-inflammatory, anti-allergic, anti-proliferative, antipruritic and reducing exudative effects; can reduce and prevent tissues from responding to inflammation, can eliminate local fever, redness and swelling caused by non-infectious inflammation, thereby reducing inflammation Performance; immunosuppressive effect: prevent or suppress the immune response mediated by cells, delayed allergic reactions, and reduce the expansion of the primary immune response.

5.2 Pharmacokinetic properties

This product can be absorbed through the skin, especially faster on the damaged skin. This product is mainly metabolized and transformed by the liver, most of the metabolites are combined into glucuronide, and a small amount is excreted by the prototype through the urine.

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings.

Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids. Thus, occlusive dressings may be a valuable therapeutic adjunct for treatment of resistant dermatoses.

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolized primarily in the liver and are then excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted into the bile.

5.3 Preclinical safety data

Topical corticosteroids share anti-inflammatory, antipruritic and vasoconstrictive actions.

The mechanism of anti-inflammatory activity of the topical corticosteroids is unclear. Various laboratory methods, including vasoconstrictor assays, are used to compare and predict potencies and/or clinical efficacies of the topical corticosteroids. There is some evidence to suggest that a recognizable correlation exists between vasoconstrictor potency and therapeutic efficacy in man.

Carcinogenesis, Mutagenesis, and Impairment of Fertility

Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of topical corticosteroids.
Studies to determine mutagenicity with prednisolone and hydrocortisone have revealed negative results.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydrocortisone Acetate
Benzyl Alcohol
Ethyl Paraben
Glycerin
Glycerin monostearate
Liquid Paraffin
SorbitanMonosrearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 25 °C. Sealed well and protect from sunlight. Keep out of reach of children.

6.5 Nature and contents of container

It is sealed Aluminium tube with a cap, and kept cream inside. One Aluminium tube in one box.

6.6 Instructions for use and handling

Local external use only. Apply appropriate amount of the product to the affected areaandgently rub for a while2-3 times a day.Occlusive dressings may be used for the management of psoriasis or recalcitrant conditions. If an infection develops, the use of occlusive dressings should be discontinued and appropriate antimicrobial therapy instituted.Do not use Hydrocortisone Acetate Cream after the expiry date stated on the carton.Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required.

7. MARKETING AUTHORISATION HOLDER

Shanghai General Pharmaceutical Co.,Ltd.

8. NUMBER(S) IN THE NATIONAL REGISTER OF FINISHED PHARMACEUTICAL PRODUCTS

05906/07287/REN/2020

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Renewal on 03-05-2021

10. DATE OF REVISION OF THE TEXT

Dec.21, 2022