Drugfield Pharmaceuticals Limited

SUMMARY OF PRODUCT CHARACTERISTICS

(SmPC)

HYDROCORTISONE CREAM 1%W/W B.P

1. NAME OF THE MEDICINALPRODUCT

HYDROCORTISONE CREAM 1%W/W B.P

2. QUALITATIVE AND QUANTITATIVECOMPOSITION

Each 1 gram of the cream contains 10 mg of hydrocortisone (i.e. 1 %w/w).

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cream (semi-solid)

4. Clinical particulars

4.1 Therapeutic indications

Hydrocortisone cream is indicated in inflammatory disorders of the skin such as contact eczema, atopic eczema, psoriasis seborrhoeal eczema, intertrigo, non-specific pruritis, e.t.c.

This medication is used to treat a variety of skin conditions (e.g., insect bites, poison oak/ivy, eczema, dermatitis, allergies, rash, itching of the outer female genitals, anal itching). Hydrocortisone reduces the swelling, itching, and redness that can occur in these types of conditions.

4.2 Posology and method of administration

Posology

Important Dosage and Administration Instructions

- For itching of skin irritation, inflammation, and rashes:
- Adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily and for children under 2 years of age: do not use, ask a doctor.
- For external anal and genital itching, adults:
- when practical, clean the affected area with mild soap and warm water and rinse thoroughly
- gently dry by patting or blotting with toilet tissue or a soft cloth before applying apply to affected area not more than 3 to 4 times daily Children under 12 years of age: ask a doctor.
- Spread the cream in a thin layer over the area of irritated skin.
- Carefully smooth it into your skin in the direction the hair grows until it disappears.
- Be careful not to get the cream into broken skin or cuts.
- Wash your hands afterwards (unless it's your hands that you're treating).

- Use the cream on all the irritated skin, not just the worst areas.

Initial Dosage

The dose of this medicine will be different for different patients. Follow your doctor's orders or the directions on the label. The following information includes only the average doses of this medicine. If your dose is different, do not change it unless your doctor tells you to do so.

The amount of medicine that you take depends on the strength of the medicine. Also, the number of doses you take each day, the time allowed between doses, and the length of time you take the medicine depend on the medical problem for which you are using the medicine.

For redness, itching, and swelling of the skin:

For topical dosage form (cream):

Adults—Apply to the affected area of the skin two or three times per day.

Children—Apply to the affected area of the skin two or three times per day.

Method of administration

Topical administration

4.3 Contraindications

Hydrocortisone skin cream isn't suitable for some people. **Tell your pharmacist or doctor before starting the medicine if you:**

- have had an allergic reaction to hydrocortisone or any other medicine in the past
- have a skin infection (including eye infections)
- are trying to get pregnant, are already pregnant or you're breastfeeding

4.4 Special warnings and precautions foruse

For external use only

Do not use

 in the genital area if you have a vaginal discharge. Ask a doctor. for the treatment of diaper rash. Ask a doctor.

When using this product

- avoid contact with the eyes
- do not use more than directed unless told to do so by a doctor
- do not put directly into the rectum by using fingers or any mechanical device or applicator

Stop use and ask a doctor if

- condition worsens
- symptoms persist for more than 7 days or clear up and occur again within a few days, and do not begin use of any other hydrocortisone product unless you have asked a doctor
  - rectal bleeding occurs

Keep out of reach of children.

4.5 Interaction with other medicinal products and other forms ofinteraction

Don't put on hydrocortisone at the same time as other creams or ointments such as your, or your child's, usual moisturiser. Wait at least 10 minutes between using hydrocortisone and any other product. Ideally, use different skin products at different times of the day.

If you're using a dressing like a bandage or plaster, wait at least 10 minutes after putting hydrocortisone on. This helps to prevent side effects.

It's very unlikely that other medicines - either prescribed or ones you buy from a pharmacy or shop - will interfere with the way hydrocortisone skin products work.

4.6 Pregnancy and Lactation

Pregnancy

Risk Summary

Mild hydrocortisone creams that you buy from a pharmacy are safe to use during pregnancy. There is inadequate evidence of safety in human pregnancy. Topical administration of topical corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intra-uterine growth retardation. There may therefore be a very small risk of such effects in the human foetus. **Lactation**

Mild hydrocortisone creams that you buy from a pharmacy are safe to use during breastfeeding.

As a precaution, if you're breastfeeding, wash off any cream you put on your breasts before feeding your baby.There is no evidence against use in lactating women. However, caution should be exercised when Hydrocortisone Cream is administered to nursing mothers. In this event, the product should not be applied to the chest area. There is theoretical risk of infant adrenal function impairment if maternal systemic absorption occurs.

Females and Males of Reproductive Potential

No sufficient studies

4.7 Effects on ability to drive and usemachines

Hydrocortisone does not affect the ability to drive and use machines.

4.8 Undesirableeffects

Your skin can absorb topical medicine, which may cause steroid side effects throughout the body. Stop using hydrocortisone topical and call your doctor if you have: weight gain (especially in your face or your upper back and torso);

slow wound healing, thinning skin, increased body hair; irregular

menstrual periods, changes in sexual function; or muscle weakness,

tired feeling, depression, anxiety, feeling irritable.

Children can absorb larger amounts of this medicine through the skin and may be more likely to have side effects.

Common side effects may include:

acne, skin redness; mild burning,

tingling or prickly feeling; changes in

skin color; or dryness or cracking of

treated skin.

4.9 Overdose

Clinical Presentation

Data regarding acute overdoses of glucocorticoids are rare. Chronic high doses of glucocorticoids can lead to the development of cataract, glaucoma, hypertension, water retention, hyperlipidemia, peptic ulcer, pancreatitis, myopathy, osteoporosis, mood changes, psychosis, dermal atrophy, allergy, acne, hypertrichosis, immune suppression, decreased resistance to infection, moon face, hyperglycemia, hypocalcemia, hypophosphatemia, metabolic acidosis, growth suppression, and secondary adrenal insufficiency. Overdose may be treated by adjusting the dose or stopping the corticosteroid as well as initiating symptomatic and supportive treatment.

Treatment of Overdose

Overdose may be treated by adjusting the dose or stopping the corticosteroid as well as initiating symptomatic and supportive treatment.

5. PHARMACOLOGICALPROPERTIES

5.1 Pharmacodynamics properties

Pharmacotherapeutic group: Benzomorphan derivatives}, ATC code: NO2ADO1

Mechanism of Action

The short term effects of corticosteroids are decreased vasodilation and permeability of capillaries, as well as decreased leukocyte migration to sites of inflammation. Corticosteroids binding to the glucocorticoid receptor mediates changes in gene expression that lead to multiple downstream effects over hours to days.

Glucocorticoids inhibit neutrophil apoptosis and demargination; they inhibit phospholipase A2, which decreases the formation of arachidonic acid derivatives; they inhibit NF-Kappa B and other inflammatory transcription factors; they promote anti-inflammatory genes like interleukin-10.

Lower doses of corticosteroids provide an anti-inflammatory effect, while higher doses are immunosuppressive. High doses of glucocorticoids for an extended period bind to the mineralocorticoid receptor, raising sodium levels and decreasing potassium levels.

Pharmacodynamics

Hydrocortisone binds to the glucocorticoid receptor leading to downstream effects such as inhibition of phospholipase A2, NF-kappa B, other inflammatory transcription factors, and the promotion of anti-inflammatory genes. Hydrocortisone has a wide therapeutic index8 and a moderate duration of action. Patients should stop taking the medication if irritation or sensitization occurs.

5.2 Pharmacokinetic properties

Absorption

Hydrocortisone is absorbed through skin, particularly in denuded areas.

Distribution

Corticosteroids are rapidly distributed to all body tissues. They cross the placenta to varying degrees and may be excreted in small amounts in breast milk. Corticosteroids in the circulation are usually extensively bound to plasma proteins, mainly to globulin and less so to albumin.

Metabolism

Hydrocortisone is metabolised in the liver and most body tissues to hydrogenated and degraded forms such as tetra hydrocortisone and tetrahydrocortisol.

Excretion

The metabolites are excreted in the urine mainly conjugated as glucuronides, together with a very small proportion of unchanged hydrocortisone.

5.3 Preclinical safety data

Not applicable

6. PHARMACEUTICALPARTICULARS

6.1 List of excipients

Benzyl Alcohol
Cetomacrogol
Emulsifying Ointment
Purified Water

6.2 Incompatibilities

None have been reported or are known

6.3 Shelflife

36 Months

6.4 Special precautions for storage

Store below 30^{o}C in tight container protected from light and moisture.

6.5 Nature and contents of container and special equipment for use, administration or implantation

It is presented as an homogenous white cream in a collapsible aluminum tube sealed with aluminum and covered with a white plastic screw cap. Packed in 15 grams in a hardboard-box properly labeled.

6.6 Special precautions for disposal and other handling

No special requirements.

7. APPLICANT/MANUFACTURER

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