JAMXONE CREAM
(HYDROCORTISONE CREAM BP 1.0% W/W)

1.3.1 Summary of Product Characteristics (smpc)

1. Name of the medicinal product

1.1 (Invented) name of the medicinal product

JAMXONE CREAM

INN (GENERIC NAME)

HYDROCORTISONE CREAM BP 1.0% W/W

1.2 Strength:- 1.0% W/W

1.3 Pharmaceutical form:- Cream

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2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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Composition:
- Hydrocortisone BP (1.0 % W/W)
- Cream Base: (- QS)

4000X 15g TUBES: 60 kg

Sr. No.	Ingredients	Specification	Mg/tube	Label Claim % w/w	Overages (%)	Required Qty.(kg)
1	Hydrocortisone	BP	153	1	2	0.612
2	Cetostearyl Alcohol	BP	1050	--	--	4.2
3	Cetomacrogol 1000	BP	300	--	--	1.2
4	Light Liquid Paraffin	BP	750	--	--	3
5	White soft Paraffin(White petroleum jelly)	BP	3000	--	--	12
6	Propyl paraben	BP	3.75	--	--	0.015
7	Methyl paraben	BP	37.5	--	--	0.150
8	Butylated Hydroxy Toluene	BP	37.5	--	--	0.150
9	Propylene Glycol	BP	450	--	--	1.800
10	Glyceryl Monostearate	IP	81	--	--	0.324
11	Disodium Edetate (Disodium E.D.T.A.)	BP	15	--	--	0.06
12	Ess.Lavender	IHS	37.5	--	--	0.150
13	Purified Water	BP	9084.75	--	--	36.339kg

BP = British Pharmacopoeia
IH = In-House Specification
IP = Indian Pharmacopoeia

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3. PHARMACEUTICAL FORM. :

A smooth white colour cream.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications:

Hydrocortisone has topical anti-inflammatory activity of value in the treatment of irritant dermatitis, contact allergic dermatitis, insect bite reactions and mild to moderate eczema.

4.2 Posology and method of administration:

Posology

Use sparingly over a small area once/twice a day for a maximum period of one week. If the condition has not improved, or worsens, consult your doctor.

This product should not be recommended for use on children under 10 years of age without medical advice.

Method of administration

For cutaneous use.

4.3 Contraindications:

Bacterial (e.g. impetigo), viral (e.g. Herpes simplex) or fungal (e.g. candidal or dermatophyte) infections of the skin.

Hypersensitivity to the active substance.

Use on the eyes and face, Ano-genital region, Broken or infected skin including cold sores, acne and athlete's foot.

4.4 Special warnings and precautions for use:

Remarks on indications

1. There is no good evidence that topical corticosteroids are efficacious against immediate (Type 1) allergic skin reactions or short-lived weal and flare reactions from other causes.

2. Topical corticosteroids are ineffective in granulomatous conditions and other inflammatory reactions involving the deeper regions of the dermis.

3. Topical corticosteroids are not generally indicated in psoriasis excluding widespread plaque psoriasis provided that warnings are given.

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Topical corticosteroids may be hazardous in psoriasis for a number of reasons including rebound relapses following development of tolerance, risk of generalised pustular psoriasis, and local and systematic toxicity due to impaired barrier function of the skin. Careful patient supervision is important.

Although generally regarded as safe, even for long-term administration in adults, there is potential for overdosage in infants and children. Extreme caution is required in dermatoses of infancy especially napkin eruption where the napkin can act as an occlusive dressing and increase absorption . In infants and children, courses of treatment should therefore not normally exceed 7 days.

Appropriate antimicrobial therapy should be used whenever treating inflammatory lesions, which have become infected. Any spread of infection requires withdrawal of topical corticosteroid therapy, and a systemic administration of antimicrobial agents.

As with all corticosteroids, prolonged application to the face is undesirable.

Do not use under an occlusive dressing.

This medicinal product contains chlorocresol, which may cause allergic reactions.

This medicinal product also contains cetostearyl alcohol in the excipient cetomacrogol emulsifying wax, and may cause local skin reactions (e.g., contact dermatitis).

Topical steroid withdrawal syndrome :

Long term use of topical steroids can result in the development of rebound flares after stopping treatment (topical steroid withdrawal syndrome). A severe form of rebound flare can develop which takes the form of a dermatitis with intense redness, stinging and burning that can spread beyond the initial treatment area. It is more likely to occur when delicate skin sites such as the face and flexures are treated. Should there be a reoccurrence of the condition within days to weeks after successful treatment a withdrawal reaction should be suspected. Reapplication should be with caution and specialist advise is recommended in these cases or other treatment options should be considered.

The label will state mild steroid.

4.5 Interaction with other medicinal products and other forms of interaction:

None known.

4.6 Pregnancy and lactation:

Pregnancy

There is inadequate evidence of safety in human pregnancy. Topical administration of 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.

Breastfeeding

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.

4.7 Effects on ability to drive and use machines:

None known.

4.8 Undesirable Effects:

Hydrocortisone preparations are usually well tolerated, but if any signs of hypersensitivity appear, application should stop immediately.

Striae may occur especially in intertriginous areas.

Skin and Subcutaneous Tissue Disorders: Not known (cannot be estimated from available data)

Withdrawal reactions - redness of the skin which may extend to areas beyond the initial affected area, burning or stinging sensation, itch, skin peeling, oozing pustules.

4.9 OVERDOSE:

Not applicable.

5 Pharmacological Properties:

5.1 Pharmacodynamic properties:

Pharmacotherapeutic group: Corticosteroids, mild (group I); ATC code: D07A A02

Hydrocortisone is an anti-inflammatory steroid. Its anti-inflammatory action is due to reduction in the vascular component of the inflammatory response and reduction in the formation of inflammatory fluid and cellular exudates. The granulation reaction is also decreased due to the inhibition effect of Hydrocortisone on connective tissue. Stabilisation of most cell granules and lysomal membranes decreases the mediators involved in inflammatory response and reduces release of enzymes in prostaglandin synthesis. The vasoconstrictor action of Hydrocortisone may also contribute to its anti-inflammatory activity.

5.2 Pharmacokinetic properties:

Absorption: Topically applied steroids are absorbed to a significant extent only if applied to broken skin, to very large areas, or under occlusive dressings.

Distribution: Corticosteroids are rapidly distributed to all body tissues. They cross the placenta and may be excreted in small amounts in breast milk

Metabolism: Hydrocortisone is metabolised mainly in the liver, but also the kidney, to various degraded and hydrogenated forms such as tetrahydrocortisone.

Elimination: Hydrocortisone is excreted in the urine, mostly conjugated as glucuronides. Only very small amounts of unchanged hydrocortisone are excreted.

5.3 Preclinical safety data:

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Adverse effects of Hydrocortisone are due to its effects on electrolyte balance, metabolism and particularly adrenal suppression. Topical use of Hydrocortisone has only rarely been associated with systemic side effects.

6 Pharmaceutical Particulars

6.1 List of excipients

1Cetostearyl Alcohol BP
2 Cetomacrogol1000 BP
3 LightLiquid Paraffin BP
Whitesoft Paraffin (White petroleumjelly) BP
4 Propylparaben BP
5 Methylparaben BP
6 ButylatedHydroxy Toluene BP
7 PropyleneGlycol BP
8 Glyceryl Monostearate IP DisodiumEdetate (Disodium E.D.T.A.)BP
9 Ess.Lavender IHS
10 PurifiedWater

6.2 Incompatibilities
Not Applicable

6.3 Shelf life
3 Years

6.4 Special precaution for storage
Do not store above 30*C
Do not freeze

6.5 Nature of container
Laminated tbe

6.6 Special precaution for disposal
Not applicable

7 Applicant:Jamin International Company Ltd.
26 Basden street, Fegge Onitsha

8. Manufacturer: Medico Remedies Limited,
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Lomanya Nagar, Palgar (West), Thane 401404
Maharashtra State, India