SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Zenoxone®
Hydrocortisone Cream
Hydrocortisone 1% Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Hydrocortisone BP 1.0%w/w

BAN rINN: Hydrocortisone
Trivial name: Cortisol

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Aqueous cream

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the relief of irritant contact dermatitis, allergic contact dermatitis, insect bite reactions and mild to moderate eczema.

4.2 Posology and Method of Administration

To be applied topically.

Adults and elderly: To be applied sparingly once or twice daily for a maximum period of one week.

Children: To be applied as above. Do not use for children under 10 years of age without medical advice.

4.3 Contraindications

Hypersensitivity to hydrocortisone or to any of the excipients listed in section 6.1.

Zenoxone® should not be used on the eyes, face, the ano-genital region or on broken or infected skin such as; cold sores, athlete's foot, acne or chicken pox.

4.4 Special Warnings and Precautions for Use

Visual disturbance:
Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

Do not use under an occlusive dressing.

Contains Hydrocortisone. Do not use on the eyes, face or ano-genital region, broken or infected skin. Do not use in pregnancy without medical advice. Do not use for children under 10 without medical advice. Stop treatment if symptoms of hypersensitivity occur. If the condition does not improve consult a doctor.

Hydrocortisone Cream contains **Chlorocresol** which may cause allergic reactions.

Instruct patients not to smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard.
Washing clothing and bedding may reduce product build-up but not totally remove it.

4.5 Interaction with other Medicinal Products and other Forms of Interaction

None known.

4.6 Fertility, pregnancy and Lactation

This product should not be used without medical advice.

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.

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

Striae may occur especially in intertriginous areas.

Treatment with hydrocortisone is usually well tolerated but treatment should be stopped if symptoms of hypersensitivity occur.

Eye disorders:
Frequency Not known: Vision, blurred (see also section 4.4 'special warnings and precautions for use').

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard, or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

No special procedures or antidote are likely to be needed.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Hydrocortisone is a mild, topical corticosteroid. 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

a) General characteristics: and b) Characteristics in patients:

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

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

White Soft Paraffin BP
Cetomacrogol Emulsifying Wax BP
Liquid Paraffin BP
Chlorocresol BP
Purified Water BP

6.2 Incompatibilities

None known.

6.3 Shelf-Life

3 years.

6.4 Special Precautions for Storage

Store at a temperature not exceeding 25°C, do not freeze.

6.5 Nature and Content of Container

Internally-lacquered aluminium tube fitted with a polythene cap.
Pack Size: 15g
Pack Size: 10g

6.6 Special Precautions for Use, Handling and Disposal

Wash hands before and after applying hydrocortisone but if applying to the hands do not wash after application.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

TEVA UK Limited
Brampton Road
Hampden Park
Eastbourne
East Sussex
BN22 9AG

8. MARKETING AUTHORISATION NUMBER

PL 00289/0759

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

08/01/2006

10. DATE OF REVISION OF THE TEXT

17/05/2019

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