SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Eczmol 1% w/w Cream
Cetraben Protect Antimicrobial 1% Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlorhexidine Gluconate 1% w/w.
(incorporated as Chlorhexidine Gluconate Solution 5.0 % v/w)

Excipient(s) with known effect

Cetostearyl alcohol 2% w/w

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Cream
A white, smooth, pourable cream

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Eczmol/Cetraben Protect Cream is an antimicrobial emollient which can also be used as an alternative to soap in the management of dry and pruritic skin conditions including eczema and dermatitis.

4.2 Posology and method of administration

For cutaneous use. For external use only.

For adults, the elderly, infants and children

For application to the skin

Apply to the affected areas as often as necessary.

For use as a soap substitute

Eczmol/Cetraben Protect Cream may also be used as a cleanser in the bath or shower, or for other toiletry purposes, instead of ordinary soap or shower gel.

4.3 Contraindications

Known hypersensitivity to the product or any of its components, especially in those with a history of possible Chlorhexidine-related allergic reactions (see section 4.4 and 4.8)

4.4 Special warnings and precautions for use

Eczmol/Cetraben Protect Cream contains chlorhexidine. Chlorhexidine is known to induce hypersensitivity, including generalised allergic reactions and anaphylactic shock. The prevalence of chlorhexidine hypersensitivity is not known, but available literature suggests this is likely to be very rare.

Eczmol/Cetraben Protect Cream must not come into contact with the eye. Serious cases of persistent corneal injury, potentially requiring corneal transplant, were reported following accidental ocular exposure to chlorhexidine containing medicinal products despite taking eye protective measures due to migration of solution beyond the intended surgical preparation area. Extreme care must be taken during application to ensure that Eczmol/Cetraben Protect Cream does not migrate beyond its intended application site into the eyes. Particular care should be taken in anaesthetised patients, who are unable to immediately report ocular exposure. If Eczmol/Cetraben Protect Cream comes into contact with the eyes, wash out promptly and thoroughly with water. An ophthalmologist's advice should be sought.

Eczmol/Cetraben Protect Cream should not be administered to anyone with a potential history of an allergic reaction to a chlorhexidine-containing compound (see sections 4.3 and 4.8).

For topical application only. Keep out of the eyes and ears and avoid contact with the brain and meninges.

Hypersensitivity to some of the ingredients of Eczmol/Cetraben Protect Cream may be more common in patients with leg ulcer or stasis dermatitis. This medicine should therefore be used in caution in these patients.

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.

This product can make skin and surfaces slippery after use. As a result, patients should be advised to take care following use, especially when entering or leaving the bath/shower.

<u>Ingredients with specified warnings</u>

This medicine contains cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).

4.5 Interaction with other medicinal products and other forms of interaction

Hypochlorite bleaches may cause brown stains to develop in fabrics which have previously been in contact with preparations containing chlorhexidine.

4.6 Fertility, pregnancy and lactation

There is no evidence of any adverse effects on the foetus arising from the use of chlorhexidine during pregnancy and lactation. Therefore no special precautions are recommended.

4.7 Effects on ability to drive and use machines

None have been reported or are known.

4.8. Undesirable Effects

Skin disorders

Frequency not known: Allergic skin reactions such as dermatitis, pruritus, erythema, eczema, rash, urticaria, skin irritation, and blisters.

Immune disorders

Frequency not known: Hypersensitivity including anaphylactic shock (see sections 4.3 and 4.4).

Eye disorders

Frequency not known: Corneal erosion, epithelium defect/corneal injury, significant permanent visual impairment*.

Cases of severe corneal erosion and permanent significant visual impairment due to inadvertent ocular exposure have been reported post-marketing, leading to some patients requiring corneal transplant (see section 4.4).

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

Accidental Ingestion

Chlorhexidine taken orally is poorly absorbed. Since there is very little absorption of chlorhexidine in the digestive tract, accidental ingestion is very unlikely to cause systemic effects. Symptoms of an overdose resemble those of alcohol intoxication (drunkenness). Nausea, vomiting, slurred speech, a staggering walk, and drowsiness may develop. In the case of massive ingestion gastro-intestinal irritation may be observed, and also hepatotoxicity. Give a glass of milk or water and employ supportive measures as appropriate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Biguanides and amidines, ATC Code: D08A C02

Chlorhexidine is effective against a wide range of Gram negative and Gram positive vegetative bacteria, yeasts, dermatophyte fungi and lipophilic viruses. It is inactive against bacterial spores except at elevated temperatures.

5.2 Pharmacokinetic properties

Because of its cationic nature, chlorhexidine binds strongly to skin mucosa and other tissues and is thus very poorly absorbed. There are, as a consequence, no general pharmacological studies on chlorhexidine available and its effects on internal organs are minimal. No detectable blood levels have been found in man following oral use and percutaneous absorption, if it occurs at all, is insignificant.

5.3 Preclinical safety data

Chlorhexidine is a drug on which extensive clinical experience has been obtained. All relevant information for the prescriber is provided elsewhere in the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetostearyl Alcohol
Macrogol Cetostearyl Ether
Isopropyl Alcohol
Liquid Paraffin
White Soft Paraffin
Purified Water

6.2 Incompatibilities

Chlorhexidine is incompatible with soap and other anionic agents.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store below 30ºC.

6.5 Nature and contents of container

250ml PP Bottle with PP/HDPE pump dispenser and tamper-evident collar
250ml HDPE shower bottle with a polypropylene cap
250ml HDPE soap dispenser pump pack
200ml polypropylene pump pack
50ml polypropylene pump pack
50ml HDPE sample pack with a polypropylene cap

6.6 Special precautions for disposal

None.

7 MARKETING AUTHORISATION HOLDER

Genus Pharmaceuticals Limited
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Huddersfield,
HD7 5QH, UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 06831/0242

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

05/01/2011

10 DATE OF REVISION OF THE TEXT

11/07/2024