SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Acea 0.75% w/w Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Metronidazole 0.75% w/w

For full list of excipients see 6.1.

3 PHARMACEUTICAL FORM

Gel

Clear very pale yellow gel

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

(i) The treatment of acute inflammatory exacerbations of rosacea.

4.2 Posology and method of administration

For cutaneous use only.

(i) For adults and the elderly. Apply the gel to the affected area of the skin in a thin film twice daily for 8 weeks. Thereafter further applications may be necessary depending on the severity of the condition.

(ii) For Children. Not recommended.

4.3 Contraindications

Known hypersensitivity to metronidazole, parabens or any of the constituents

4.4 Special warnings and precautions for use

Warnings: Avoid contact with the eyes. If contact with the eyes occurs the gel should be washed out carefully with water.

Precautions: The following statements take into account the possibility that metronidazole may be absorbed after topical application. However there is no evidence of any significant systemic concentrations of metronidazole following topical applications. Peripheral neuropathy has been reported in association with prolonged use of oral metronidazole. The elimination half-life of metronidazole remains unchanged in the presence of renal failure. Such patients, however, retain the metabolite of metronidazole. The clinical significance of this is not known at present. However in patients undergoing haemodialysis, metronidazole and its metabolites are efficiently removed.

Contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) and ethyl parahydroxybenzoate (E214), may cause allergic reactions (possibly delayed).

4.5 Interaction with other medicinal products and other forms of interaction

Patients are advised not to take alcohol during systemic metronidazole therapy because of the possibility of a disulfiram-like reaction.

Some potentiation of anti-coagulant therapy has been reported when metronidazole has been used with the warfarin type oral anticoagulants.

Patients receiving phenobarbitone metabolise metronidazole at a much faster rate than normal, reducing the half-life to 3 hours.

4.6 Pregnancy and lactation

The safety of topically applied metronidazole in pregnancy and lactation has not been adequately established and should not be used in these circumstances unless the physician considers it essential.

4.7 Effects on ability to drive and use machines

No adverse effects on the ability to drive or use machines has been reported following the topical application of metronidazole.

4.8 Undesirable effects

Dryness or irritation of the skin may be experienced after application to unbroken skin. Systemic metronidazole therapy may occasionally cause an unpleasant taste in the mouth, furred tongue, nausea, vomiting, gastro-intestinal disturbance, urticaria,

angioedema and anyphylaxis. Drowsiness, dizziness, headache, ataxia, skin rash, pruritis and darkening of urine has been reported, but rarely.

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: Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Overdose is unlikely. If necessary remove the medication by washing with warm water. If accidental ingestion occurs, an appropriate method of gastric emptying may be used if considered appropriate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: D06BX01

Metronidazole is a 5-nitroimidazole derivative with activity against anaerobic protozoa and anaerobic bacteria. It also has a radiosensitising effect of hypoxic tumour cells. Its mechanism of action is thought to involve interference with DNA by a metabolite in which the nitro group of metronidazole has been reduced. The mode of action of topical metronidazole in the treatment of rosacea is not known.

5.2 Pharmacokinetic properties

No bioavailability studies have been carried out with this formulation.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber, which have additional to those already included in other sections of the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol
Hydroxyethylcellulose
Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate (E216)
Ethyl parahydroxybenzoate (E214)
Disodium edetate
Sodium hydroxide
Potassium dihydrogen phosphate
Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months from the date of manufacture of the unopened container.
8 weeks from the date of opening

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Aluminium tube with a polypropylene screw cap.
The pack sizes are 5g, 25g and 40g. Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Not applicable

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 20685/0020

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

27/02/2004

10 DATE OF REVISION OF THE TEXT

27/07/2018