

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

TCP First Aid Antiseptic Cream.

TCP Liquid Antiseptic 25% w/w, Chloroxylenol 0.5% w/w, Triclosan 0.3% w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

TCP First Aid Antiseptic Cream contains:-

TCP Liquid Antiseptic 25% w/w, Chloroxylenol Ph. Eur. 0.5% w/w and Triclosan 0.3% w/w.

Excipients: Contains Cetyl Alcohol 4.5% w/w

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream

Smooth, white cream

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Treatment of minor cuts, grazes, scratches, insect bites and stings, spots, pimples and blisters.

TCP Cream can also be used as a first aid antiseptic hand cream.

4.2 Posology and method of administration

Adults, children and the elderly

Minor cuts, grazes, scratches, insect bites and stings

Clean wound and surrounding skin and apply the cream direct or on to a dressing.

Spots, pimples and blisters

Apply direct and rub in gently.

4.3 Contraindications

Hypersensitivity to any of the active ingredients or any of the excipients.

4.4 Special warnings and precautions for use

If symptoms persist, consult your doctor.
For external use only.
Keep out of the reach of children.
Use in allergic skin conditions should be avoided.
Cetyl alcohol may cause local skin reactions (e.g. contact dermatitis).

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

There is no experience in the use of the product in pregnancy and lactation, but the product has been widely used for many years with no adverse effects.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

No adverse events have been reported which have been causally linked to this product.

4.9 Overdose

TCP First Aid Antiseptic Cream is for topical use only and overdose is considered unlikely.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Codes: D08AE05, D08AE04, D08AE03, N02BA04.

Halogenated phenols act on all pathogenic micro-organisms similarly and to approximately the same degree - i.e. they are non-specific; and their activity is not appreciably reduced by the presence of relatively large amounts of non-living organic matter; their relatively simple chemical constitution means that their use is not liable to encourage the emergence of strains of micro-organisms adapted to resist their action.

5.2 Pharmacokinetic properties

TCP First Aid Antiseptic Cream is for topical use only. Systemic absorption from this topical dosage form is considered unlikely.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Stearic Acid
Isopropyl Palmitate
Cetyl Alcohol
Cetyl Wax Esters
Glyceryl Monostearate
Sodium Lauryl Sulphate
Carbomer
Glycerol
Sodium Edetate
Potassium Hydroxide
Demineralised Water
Fragrance EAG 5276

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25°C

6.5 Nature and contents of container

Collapsible aluminium tubes, internally lacquered, fitted with white polyethylene wadless caps.

Tubes of 30g and 60g.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Chefaro Ireland Limited
Farnham Drive
Finglas
Dublin 11.

8 MARKETING AUTHORISATION NUMBER

PA1186/005/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 07/09/1988

Date of last renewal: 07/09/2008

10 DATE OF REVISION OF THE TEXT

August 2009