

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

TCP Liquid Antiseptic
Halogenated Phenols 0.68% w/v
Phenol 0.175% w/v

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Phenol 0.175% w/v and halogenated phenols 0.68 % w/v.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous solution and concentrate for gargle.
Clear, yellow, aqueous solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

- a) A mild antiseptic for topical administration on dilution with water or, in emergencies, undiluted.
- b) For relief of sore throats, bad breath, mouth ulcers, painful gums and for topical administration in the treatment of minor wounds of the skin including cuts, grazes, stings and scalds.

4.2 Posology and method of administration

Adults, children and the elderly.

Relief of sore throat symptoms including those associated with colds and flu
Night and morning gargle with TCP diluted with 5 parts water.

DO NOT SWALLOW THIS SOLUTION.

Mouthwash

For bad breath – rinse daily after meals, diluted with 5 parts of water. For mouth ulcers – dab undiluted on the affected area three times daily. If symptoms persist for more than 14 days consult your dentist.

Cuts, grazes, bites and stings

Dilute with an equal quantity of water and apply freely. In emergencies apply undiluted.

Spots, pimples and blisters

Dab lightly every 4 hours and allow to dry.

4.3 Contraindications

Hypersensitivity to any of the active constituents.

4.4 Special warnings and precautions for use

If symptoms persist for more than 14 days a doctor should be consulted.
Use in allergic skin conditions should be avoided.
Patients should be advised to avoid contact with eyes.
Sickness, such as nausea or vomiting, can occur after accidental oral intake.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

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

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

The following convention has been utilised for the classification of undesirable effects: very common ($\geq 1/10$), common ($\geq 1/100$, $< 1/10$), uncommon ($\geq 1/1,000$, $< 1/100$), rare ($\geq 1/10,000$, $< 1/1000$), very rare ($< 1/10,000$), not known (cannot be estimated from available data).
The risk of undesirable effect is low with appropriate use.

Body System Class	Undesirable Effect	Frequency
Nervous system disorders	Mouth paresthesia, dysgeusia	Not known
Skin and subcutaneous tissue disorders	Blisters, buccal ulcer, swelling, burns, redness, pruritus, dry skin, skin necrosis, skin peeling, pain	Not known

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Serious adverse events are unlikely to result from overdosage of this product.

Accidental ingestion: If a quantity (over 30ml) of neat TCP is swallowed accidentally, drink 0.5 to 1 litre of water immediately. If discomfort persists, seek medical advice.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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 Liquid Antiseptic is for topical use only. Significant absorption from this low level dosage form is considered unlikely.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol
Concentrated phosphoric acid
Quinoline yellow (E104)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

TCP Liquid Antiseptic is stored in amber soda-lime glass bottles of 50 ml, 100 ml and 200 ml capacity which are uncoated. The cap is either a white cap of wood-filled urea formaldehyde with an expanded polyethylene wad or a white 'wadless' polypropylene cap.

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 DAC,
Treasury Building,
Lower Grand Canal Street,
Dublin 2,
Ireland

8 MARKETING AUTHORISATION NUMBER

PA1186/005/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 08 August 1986

Date of last renewal: 08 August 2006

10 DATE OF REVISION OF THE TEXT

April 2017