

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Care Tea Tree Oil 100%
Natures Aid Tea Tree Oil 100%

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each drop contains 100% Tea tree oil (*Melaleuca alternifolia* (Maiden and Betch) Cheel)

3 PHARMACEUTICAL FORM

Cutaneous solution / concentrate for oromucosal solution
Clear, colourless or pale yellow liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A traditional herbal medicinal product used for the treatment of small superficial wounds, insect bites, small boils (furuncles and mild acne), for the symptomatic treatment of minor inflammation of the oral mucosa and for the relief of itching and irritation in cases of mild athlete's foot, based on traditional use only.

4.2 Posology and method of administration

Adults, the elderly and children over 12 years old:

Cutaneous use:

For the treatment of small superficial wounds and insect bites

1 to 3 drops of undiluted essential oil to be applied to the affected area using a cotton Bud 1 to 3 times daily.

Duration of use

If the symptoms worsen, or persist for more than one week during the use of the medicinal product, a doctor or a qualified healthcare practitioner should be consulted.

For the treatment of small boils (furuncles and mild acne)

25 to 30 drops of essential oil stirred in 100 ml of lukewarm water to be applied as an impregnated dressing to the affected areas of the skin.

Undiluted essential oil to be applied to the boil using a cotton bud 2 to 3 times daily.

For the relief of itching and irritation in cases of mild athlete's foot

6 to 10 drops of essential oil in an appropriate volume of warm water to cover the feet. Soak feet for 5 to 10 minutes a day.

Undiluted essential oil to be applied to the affected area using a cotton bud 2 to 3 times daily.

Duration of use

Not to be used for more than one month.

If the symptoms worsen, or persist during the use of the medicinal product, a doctor or a qualified healthcare practitioner should be consulted

Oromucosal use

For the treatment of minor inflammation of the oral mucosa

6 to 10 drops of essential oil to be mixed in 100 ml of water and used as a mouth rinse or gargle 2 to 3 times daily.

Duration of use

If the symptoms worsen, or persist for more than five days during the use of the medicinal product, a doctor or a qualified healthcare practitioner should be consulted.

The use in children under 12 years of age is not recommended (see Section 4.4.'Special warnings and precautions for use.')

4.3 Contraindications

Hypersensitivity to the active substance or to colophony.

4.4 Special warnings and precautions for use

Do not exceed the stated dose.

Not to be swallowed if used as a mouth rinse or gargle.

Not to be used orally or as inhalation.

Not to be used in eyes or ears.

If a rash develops discontinue use.

For the treatment of small superficial wounds and insect bites

If fever or signs of exacerbating skin infection are observed, a doctor or qualified healthcare practitioner should be consulted.

If the symptoms worsen, or persist for more than one week during the use of the medicinal product, a doctor or a qualified healthcare practitioner should be consulted.

For the treatment of small boils (furuncles and mild acne)

In cases of severe acne, a doctor or qualified healthcare practitioner should be consulted.

If not treated adequately, acne may cause scarring. Do not use this product and consult your doctor or qualified healthcare practitioner if; you have widespread redness, oozing or infected skin sores, infected or inflamed spots, if the skin is broken, or if the affected area has suddenly become inflamed.

For the relief of itching and irritation in cases of mild athlete's foot

For the eradication of fungal infection, a doctor or qualified healthcare practitioner should be consulted.

If the symptoms worsen, or persist during the use of the medicinal product, a doctor or a qualified healthcare practitioner should be consulted

For the treatment of minor inflammation of the oral mucosa

Not to be swallowed.

If the symptoms worsen, or persist for more than five days during the use of the medicinal product, a doctor or a qualified healthcare practitioner should be consulted.

The use in children under 12 years of age has not been established due to lack of adequate data.

4.5 Interaction with other medicinal products and other forms of interaction

None reported.

4.6 Fertility, pregnancy and lactation

Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

No fertility data is available.

4.7 Effects on ability to drive and use machines

No studies on the effect on the ability to drive and use machines have been performed.

4.8 Undesirable effects

Adverse skin reactions including smarting pain, mild pruritus, burning sensation, irritation, itching, stinging, erythema, oedema (contact dermatitis) and other allergic reactions have been reported. The frequency is not known.

Burn-like skin reaction has been reported. The frequency is rare (<1: 1000).

If other adverse reactions not mentioned above occur, a doctor or a qualified healthcare practitioner should be consulted.

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.

4.9 Overdose

Cutaneous use

None reported

Oromucosal use

Accidental ingestion may cause central nervous system depression and muscle weakness. However, in adults these symptoms generally resolve within 36 hours.

If ingestion occurs, the patient should be monitored and standard supportive treatment applied as required.

In children, ingestion of tea tree oil is a medical emergency requiring immediate hospital treatment and respiratory support.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended

5.2 Pharmacokinetic properties

Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended

5.3 Preclinical safety data

Available data do not indicate a genotoxic potential of Tea tree oil.

Tea tree oil was not clastogenic using the chromosomal aberration test in human lymphocytes *in vitro* and not genotoxic in *in-vivo* mouse micronucleus test (up to 1750 mg/kg). Ames test data are incomplete.

Tests on reproductive toxicity and on carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Incompatibilities

None known.

6.3 Shelf life

Unopened:

2 years.

Opened:

Once opened, this product should be used within 3 months. After this time, discard any unused product.

6.4 Special precautions for storage

Store in the original container, protected from light and heat.

Ensure that the cap is tightly closed after each use.

Proper storage and handling are needed to avoid the formation of oxidation products which have greater potential for skin sensitisation.

6.5 Nature and contents of container

10 or 25 ml amber Type III glass bottles with plastic (polyethylene / polypropylene) child-resistant stoppers incorporating a plastic dropper.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

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

7 MARKETING AUTHORISATION HOLDER

Thornton & Ross Ltd.,
Linthwaite,
Huddersfield,
HD7 5QH,
UK

8 MARKETING AUTHORISATION NUMBER(S)

THR 00240/0399

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

30/08/2017

10 DATE OF REVISION OF THE TEXT

30/08/2017