SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Ultracare Topical Anaesthetic Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Benzocaine 17.9% w/w

Excipients:

Allura Red E129

Aspartame (a source of phenylalanine)

For full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Oromucosal and gingival gel

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the induction of topical anaesthesia of the oromucosa and gingiva prior to minor dental procedures.

4.2 Posology and method of administration

Sufficient gel should be applied to the desired site of action to induce anaesthesia. This will normally be between 0.2 and 0.5 ml, depending on the area over which anaesthesia is required. The required amount of gel should be extracted from the bottle with a unidose syringe onto a cotton bud applicator.

4.3 Contraindications

Do not use on patients with known hypersensitivity or allergy to benzocaine or any of the other ingredients.

Patients with methaemoglobinaemia.

Variation to extend the
in-use shelf life
Approved 04/06/2015
CC0033

4.4 Special warnings and precautions for use

Ultracare contains phenylalanine at a concentration of approximately 2.8 mg per gram. This should be taken into account in treating patients with phenylketonuria.

The colour Allura Red E129 may cause allergic reactions.

Caution should be exercised in the use of this product if there have been previous allergic reactions with other local anaesthetics or sunscreen products.

4.5 Interaction with other medicinal products and other forms of interaction

Benzocaine is hydrolysed to para-aminobenzoic acid which inhibits the antimicrobial activity of sulphonamides. Concomitant use of benzocaine and sulphonamides is not recommended.

4.6 Pregnancy and lactation

Although benzocaine has been in widespread use for many years without apparent ill consequence, there is inadequate evidence of its safety in human pregnancy. Therefore, topical benzocaine should not be used in pregnancy or lactation unless considered essential by the dental practitioner.

4.7 Effects on ability to drive and use machines

Ultracare has no effect on the ability to drive or use machinery.

4.8 Undesirable effects

Hypersensitivity reactions may occur in those patients sensitive to benzocaine. Application of benzocaine on skin and mucous membranes may result in hypersensitivity reactions (burning, stinging, pruritus, erythema, rash and oedema) and contact dermatitis

Methaemoglobinaemia may occur in patients receiving high doses or repeated applications of benzocaine-containing products.

Reporting of suspected 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

Ultracare will only be administered in the dental surgery under the direction of a dentist, and overdosage is therefore extremely unlikely. Treatment of overdose should be symptomatic and supportive.

Excessive absorption of benzocaine may produce methaemoglobinaemia in infants, children, and adults. The first clinical signs are cyanotic (greyish) skin discolouration (most notably on mucous membranes) and signs of unusual breathing or breathlessness.

Methaemoglobinaemia may be treated by the intravenous administration of 1% methylene blue.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Benzocaine is a local anaesthetic of the ester type. It produces reversible loss of sensation by preventing or diminishing the conduction of sensory nerve impulses near to the site of application. The duration of action of benzocaine on the mucous membranes ranges from 5-10 minutes. It has a short latent period for 5-30 seconds.

5.2 Pharmacokinetic properties

Benzocaine is about 80% non-ionised at pH 7.4, but its bioavailability is limited by its poor water solubility. This probably accounts for its brief duration of action, since the relatively small amount that passes into the axon quickly diffuses out when the peri-neural concentration at the site of application falls. The metabolic pathway of benzocaine in man has not been determined with certainty. It appears to be hydrolysed by esterases to aminobenzoic acid, followed by conversion to aminohippuric acid and excretion into the urine.

5.3 Preclinical safety data

No specific data are available on Ultracare, and limited toxicity data are available on benzocaine. Methaemoglobinaemia has been demonstrated to occur in most animal species. Sensitivity was variable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogols, glycerol, ethanol, aspartame, sodium saccharin, Allura red (E129), titanium dioxide (E171), flavouring.

6.2 Incompatibilities

None.

6.3 Shelf life

Unopened:

2 years.

In-use:

14 days

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Single HDPE multi-dose bottle of 30ml capacity with polypropylene cap contained within an outer carton.

6.6 Special precautions for disposal

None

7 MARKETING AUTHORISATION HOLDER

Optident Ltd
International Development Centre
Valley Drive
Ilkley
West Yorkshire
LS29 8AL
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 12139/0003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

24 August 1999

10 DATE OF REVISION OF THE TEXT

04/06/2015