SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Orajel Mouth Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Benzocaine 10% w/w

For full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Dental gel

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For temporary relief from the pain and tenderness associated with mouth ulcers and from wearing dentures.

4.2 Posology and method of administration

Adults and children over 12 years.

Directions:

- Clean and dry the affected area.
- Cut off tip of tube on score mark.
- Apply a thin layer of Orajel Mouth Gel to the areas inside the mouth which are tender or painful.
- Use up to 4 times daily, for no longer than 4 days.
- If tenderness or pain persists, consult your dentist or doctor.

Not for use in children below the age of 12 years.

4.3 Contraindications

Known sensitivity to benzocaine or any of the other ingredients.

Not to be used in those individuals suspected of lacking the normal ability to convert methaemoglobin to haemoglobin, see Section 4.4 Special warnings and precautions for use and Section 4.8 Undesirable effects.

Not for use in children below the age of 12 years.

4.4 Special warnings and precautions for use

Orajel Mouth Gel is intended for short-term use until a dentist or doctor can be consulted. Treatment with benzocaine products such as Orajel Mouth Gel may mask symptoms associated with more serious conditions and may therefore delay appropriate treatment.

Do not use continuously. Do not exceed recommended dose. The product contains sorbic acid and propylene glycol, which may cause local skin reactions, e.g. contact dermatitis.

Avoid drinking hot liquids whilst using Orajel Mouth Gel.

Do not use if there is a family history of methaemoglobinaemia.

4.5 Interaction with other medicinal products and other forms of interaction

Benzocaine, like other derivatives of para-aminobenzoic acid, inhibits the actions of sulphonamides and therefore should not be used concomitantly with any sulphonamide.

4.6 Pregnancy and lactation

There is inadequate evidence of safety of benzocaine in human pregnancy, but it has been in wide use for many years without apparent ill consequences. No clinical data are available on the use of this product during pregnancy or lactation.

4.7 Effects on ability to drive and use machines

No effect on subjects' ability to drive or operate machines.

4.8 Undesirable effects

Application of benzocaine on skin and mucous membranes has resulted in hypersensitivity reactions (burning, stinging, pruritis, erythema, rash and oedema), contact dermatitis and methaemoglobinaemia in a few cases in infants, children and adults.

If symptoms persist, or are severe, or are accompanied by fever, headache, breathlessness, nausea and vomiting, consult a doctor.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

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. Treatment of overdose should be symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Local anaesthetics, ATC code: N01BA05

Benzocaine is a local anaesthetic of the ester type, acting to produce reversible loss of sensation by preventing or diminishing the generation and transmission of sensory nerve impulses near the site of application. Depolarisation of the neuronal membrane and ion exchange are reversibly inhibited.

5.2 Pharmacokinetic properties

Benzocaine is rapidly absorbed through mucous membranes and damaged skin.

Anaesthetics of the ester type are hydrolysed by esterases in the plasma and, to a lesser extent, in the liver.

5.3 Preclinical safety data

There are no additional pre-clinical data of relevance to the prescriber.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorothymol

Eugenol

FD&C Red No. 40 (Allura Red AC): E129

Passion Fruit Flavour

Macrogol 400

Polyethylene Glycol 3350

Propylene Glycol: E1520

Purified Water

Sodium Saccharin: E954

Sorbic Acid: E200

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

No special precautions for storage.

6.5 Nature and contents of container

Low density polyethylene tube with external acrylate coating, medium density polypropylene cap. Tubes contain 5.3 g gel.

6.6 Special precautions for disposal

Not applicable.

7. MARKETING AUTHORISATION HOLDER

Church & Dwight UK Limited
Premier House, Shearway Business Park
Pent Road,
Folkestone, Kent,
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United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 00203/0229

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21 September 2000

10 DATE OF REVISION OF THE TEXT

07/05/2015