Oraldene

Summary of Product Characteristics Updated 08-Aug-2017 | McNeil Products Ltd

1. Name of the medicinal product

ORALDENE

2. Qualitative and quantitative composition

ORALDENE contains 0.1% w/v hexetidine.

For the full list of excipients, see section 6.1

3. Pharmaceutical form

Mouthwash.

A clear red solution.

4. Clinical particulars

4.1 Therapeutic indications

ORALDENE is indicated for use in minor mouth infections including thrush, as an aid in the prevention and treatment of gingivitis, and in the management of sore throat and recurrent aphthous ulcers. ORALDENE is also of value in the alleviation of halitosis and pre- and post-dental surgery.

4.2 Posology and method of administration

Posology

Usual dosage in adults and children 6 years and over:

Method of administration

Shake well before use. Rinse the mouth, or gargle with at least 15 ml of undiluted solution, two or three times a day. Do not swallow the solution but spit out after use.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

ORALDENE mouthwash is for external use only; the solution must therefore not be swallowed.

Not suitable for persistent symptoms.

4.5 Interaction with other medicinal products and other forms of interaction

No interactions are known.

4.6 Fertility, pregnancy and lactation

No formal studies have been conducted in man. However, on the basis of animal studies and, in theory, the negligible systemic absorption it is considered highly unlikely that the use of ORALDENE during pregnancy will present a risk to the foetus.

It is not known whether hexetidine is excreted in human breast milk, however, in view of the negligible amount of hexetidine which could be predicted to be systemically absorbed, it is unlikely that concentrations of hexetidine in the milk will present any risk to the neonate/infant.

4.7 Effects on ability to drive and use machines

ORALDENE has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

ORALDENE is generally very well tolerated with a low potential for causing irritation, or sensitisation reactions.

Prolonged use of ORALDENE is also well tolerated.

Patch testing with of hexetidine containing ointment was negative for irritation or sensitisation potential.

Adverse drug reactions (ADRs) identified during post-marketing experience with hexetidine are included in the tables below. The frequencies are provided according to the following convention:

Very common 1/10

Common 1/100 and <1/10

Uncommon 1/1,000 and <1/100

Rare 1/10,000 and <1/1,000

Very rare <1/10,000

Not known (cannot be estimated from the available data)

ADRs identified during post-marketing experience are presented by frequency category based on 1) incidence in adequately designed clinical trials or epidemiology studies, when available or 2) when incidence is unavailable, frequency category is listed as Not known.

Table 1 Adverse Drug Reactions Identified During Post-Marketing Experience with Hexetidine by Frequency Category Estimated from Clinical Trials or Epidemiology Studies:

Immune System Disorders	
Not known	Hypersensitivity reactions*; Angioedema
Nervous System Disorders	
Very rare	Dysgeusia
Not known	Ageusia
Respiratory, Thoracic and Mediastinal Disorders	
Not known	Cough; Dyspnoea**
Gastrointestinal Disorders	
Not known	Dry mouth; Dysphagia; Nausea; Salivary gland enlargement; Vomiting
General Disorders and Administration Site Conditions	
Very rare	Transient anaesthesia
Not known	Application site reactions***

*Inclusion of the PT of hypersensitivity reactions was based on cases reporting the following additional MedDRA PTs: Hypersensitivity and Urticaria.

** Observed in the context of Hypersensitivity.

*** Inclusion of the PT of Application site reactions was based on cases reporting multiple MedDRA PTs. These included Mouth and Throat mucosa irritation, Paraesthesia oral, Tongue discolouration, Tooth discolouration, Inflammation, Blistering and Ulceration.

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

Symptoms

Acute alcoholic intoxication is extremely unlikely, however, it is theoretically possible that, if a massive dose were swallowed by a small child, alcoholic intoxication may occur due to the ethanol content.

There is no evidence to suggest that repeated, excessive administration of hexetidine would lead to hypersensitivity-type

reactions.

No adverse effects have been reported in overdose other than those seen in normal use.

Hexetidine, at the strength present in ORALDENE, is unlikely to be toxic when used as directed.

Ingestion of sufficient quantities of hexetidine in alcoholic solution may lead to signs/symptoms of alcohol intoxication.

Management

Treatment of overdose is symptomatic, but rarely required. In the event of accidental ingestion of the contents of a bottle by a child, a doctor should be consulted immediately. Gastric lavage should be considered within two hours of ingestion and management should relate to treatment of alcoholic intoxication.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antiinfectives and antiseptics for local oral treatment, ATC code: A01AB12

Hexetidine is a broad spectrum antimicrobial. It is active both in vivo and in vitro, against gram positive and negative bacterium, as well as yeasts (Candida albicans) and fungi.

5.2 Pharmacokinetic properties

Specific pharmacodynamic studies have not been carried out on ORALDENE in man.

The oral retention of hexetidine to mucous membranes and dental plaque has been observed. In studies using radiolabelled hexetidine it has been shown that retention on buccal tissues can extend to between 8 and 10 hours after a single oral rinse and in some cases hexetidine has been detected on oral tissues up to 65 hours post-treatment.

No absorption studies following the topical application of ORALDENE have been performed in man.

Pharmacokinetics in renal/hepatic impairment

There have been no specific studies of ORALDENE or hexetidine in renal/hepatic impairment.

Pharmacokinetics in elderly

There have been no specific studies of ORALDENE or hexetidine in the elderly.

5.3 Preclinical safety data

Pre-clinical safety data do not add anything of further significance to the prescriber.

6. Pharmaceutical particulars

6.1 List of excipients

Polysorbate 80

Citric acid

Saccharin sodium

Levomenthol

Eucalyptus oil

Ethanol 96%

Azorubin (85%) (E122)

Sodium calcium edetate

Sodium hydroxide (E524)

Purified water

6.2 Incompatibilities

None.

6.3 Shelf life

2 years. 6 months after first opening.

6.4 Special precautions for storage

Do not store above 30°C. Keep the bottle in the outer carton in order to protect from light.

6.5 Nature and contents of container

ORALDENE is presented in a clear 100 ml, 200 ml and 30 ml glass bottles, with white aluminium ROPP cap or an HDPE plastic cap fitted with a polyterephthalate ethylene faced aluminium/expanded polyethylene laminated wad.

Not all pack sizes may be marketed

6.6 Special precautions for disposal and other handling

No special requirements for disposal. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorisation holder

McNeil Products Limited

Foundation Park

Roxborough Way

Maidenhead

Berkshire

SL6 3UG

United Kingdom

8. Marketing authorisation number(s)

PL 15513/0067

9. Date of first authorisation/renewal of the authorisation

29th April 1998

10. Date of revision of the text

26th July 2016

Company Contact Details

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