

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Oraldene 0.1% w/v Gargle/Mouthwash

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains Hexetidine 0.10% w/v

Excipients with known effect: contain 4.052g Ethanol (96%) per 100ml i.e.: up to 0.6078g ethanol per 15ml dose
Azorubine (E122)

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Gargle/mouthwash

A clear, red coloured liquid for use as a gargle or mouthwash.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Oraldene is recommended as a topical antiseptic in the management of superficial infections of the oropharynx and in their prophylaxis in the preoperative period of dental surgery or pharyngeal surgery in geriatric nursing. Oraldene can also be used as an adjunct to systemic therapy of oropharyngeal infections.

4.2 Posology and method of administration

Posology

Adults and children 6 years and over

Rinse the mouth or gargle with at least 15 ml of solution two to three times daily or as directed. Do not swallow the solution but spit out after use. An adult should supervise use in children to ensure that product is administered correctly.

Elderly

As for adults.

Children **under 6 years**: Not recommended

Method of administration

For oromucosal use only. Do not swallow.

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 should not be taken internally.

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

This medicine contains 607.8 mg of alcohol (ethanol) in each 15 ml dose. The amount in 15 ml of dose of this medicine is equivalent to 15 ml beer, 6 ml wine.

If swallowed, the amount of alcohol in this medicine is not likely to have an effect in adults and adolescents, and its effects in children are not likely to be noticeable. It may have some effects in younger children, for example feeling sleepy.

If swallowed, the alcohol in this medicine may alter the effects of other medicines. Talk to your doctor or pharmacist if you are taking other medicines.

If you are pregnant or breast-feeding, talk to your doctor or pharmacist before taking this medicine.

If you are addicted to alcohol, talk to your doctor or pharmacist before taking this medicine.

Azorubine (E122) may cause allergic reaction.

This medicine contains less than 1 mmol sodium (23 mg) per 15 ml dose, that is to say essentially 'sodium-free'.

If there is evidence of increased inflammation, the treatment should be stopped.

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

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 $\geq 1/10$

Common $\geq 1/100$ and $< 1/10$

Uncommon $\geq 1/1,000$ and $< 1/100$

Rare $\geq 1/10,000$ 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
<i>Not known</i> Hypersensitivity reactions*; Angioedema
Nervous System Disorders
<i>Not known</i> Ageusia; Dysgeusia
Respiratory, Thoracic and Mediastinal Disorders
<i>Not known</i> Cough; Dyspnoea**

Gastrointestinal Disorders	
<i>Not known</i>	Dry mouth; Dysphagia; Nausea; Salivary gland enlargement; Vomiting
General Disorders and Administration Site Conditions	
<i>Not known</i>	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 HPRC Pharmacovigilance, website: www.hpra.ie

4.9 Overdose

Symptoms

Hexetidine is a bactericide and fungicide.

No adverse events have been reported in overdose other than those seen in normal use. There are no reports of alcoholic intoxication from overdose with hexetidine.

Hexetidine, at the strength present in hexetidine products is non-toxic. 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.

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

5.2 Pharmacokinetic properties

Little is known about the pharmacokinetics of hexetidine. The compound absorbs to buccal and gingival mucosae.

5.3 Preclinical safety data

Extensive toxicological studies have been carried out in animals which have predicted a very safe profile for clinical use.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polysorbate 80
Citric acid monohydrate
Saccharin sodium
Levomenthol
Eucalyptus oil
Ethanol 96%
Azorubin (85%) (E122)
Sodium calcium edetate
Sodium hydroxide (E524)
Purified Water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months

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

Clear glass bottles with white aluminium roll-on-pilfer-proof caps and PE-Alu-PET wad or with a plastic HDPE cap fitted with a PE-Alu-PET wad, containing 100 or 200 ml.
Each bottle is provided with a 15ml polypropylene measuring cap.

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

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8 MARKETING AUTHORISATION NUMBER

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9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26th March 1990

Date of last renewal: 26th March 2010

10 DATE OF REVISION OF THE TEXT

October 2023