Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Oraldene Icemint 0.1% w/v Gargle/Mouthwash Hexetidine

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.
For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Gargle/mouthwash

A clear, blue-green coloured liquid for use as a gargle, mouthwash and oromucosal solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Oraldene Icemint 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 Icemint 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 Icemint should not be taken internally.
Oraldene Icemint 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 or 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.

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 Icemint 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 ≥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
Not known Ageusia; Dysgeusia

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
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 MedDRAPTs. 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 HPRA 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 60
Citric acid monohydrate
Saccharin sodium
Quinoline yellow (70%)
Patent blue V (85%)
Mint flavour
Ethanol (96 per cent)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Do not store above 25°C. Keep the bottle in the outer carton in order to protect from light.

6.5 Nature and contents of container

200 ml Type 3 glass bottle, white aluminium ROPP cap fitted with PE- Alu- PET wad or with a HDPE plastic cap fitted with a PE-Alu-PET wad.

400 ml PET bottle with aluminium ROPP cap fitted with PE-Alu-PET wad, or with a HDPE plastic cap fitted with a PE-Alu-PET wad.

Each bottle fitted with own propylene measuring cup.

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

Johnson & Johnson (Ireland) Limited
Airton Road
Tallaght
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0330/024/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19 April 2002

Date of last renewal: 19 April 2007

10 DATE OF REVISION OF THE TEXT