

# **SUMMARY OF PRODUCT CHARACTERISTICS**

## **1 NAME OF THE MEDICINAL PRODUCT**

ORALDENE

## **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

ORALDENE contains 0.1% w/v hexetidine.

Excipients with known effect:

Ethanol (96%) 4.052g per 100ml (4.33% w/v) 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**

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

**Adults and children 12 years and over**

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

#### **Children under 12 years**

Not recommended.

#### **Method of administration**

For oromucosal 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.

Excipients with known effect:

This medicine contains 607.8 mg of alcohol (ethanol) in each 15 ml. The amount in 15 ml of this medicine is equivalent to less than 15 ml beer or 6 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

Azorubine (E122) may cause allergic reactions.

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

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](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

### **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 200 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  
50 – 100 Holmers Farm Way  
High Wycombe  
Buckinghamshire  
HP12 4EG  
UK

**8. MARKETING AUTHORISATION NUMBER**

PL: 15513/0067.

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE  
AUTHORISATION**

19/07/2004

**10 DATE OF REVISION OF THE TEXT**

10/02/2026