

**Adverse events should be reported. Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk/>**

**Adverse events should also be reported to McNeil Products Limited on freephone 0808 238 9999.**

## **Oraldene (hexetidine) Product Information**

### **Presentation:**

A clear red solution containing 0.1% w/v hexetidine.

### **Uses:**

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.

### **Dosage:**

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.

Contraindications: Hypersensitivity to the active substance or to any of the excipients.

### **Precautions:**

For external use only. Not suitable for persistent symptoms. Azorubine (E122) may cause allergic reactions.

### **Pregnancy and Lactation:**

With the negligible systemic absorption, it is considered highly unlikely that the use of Oraldene during pregnancy will present a risk to the foetus. 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 breast milk will present any risk to the neonate/infant.

### **Side effects:**

Very rare: dysgeusia and transient anaesthesia.

Not known: hypersensitivity reactions, angioedema, ageusia, cough, dyspnoea, dry mouth, dysphagia, nausea, salivary gland enlargement, vomiting and application site reactions.

**RRP (ex VAT):** 200ml £4.17

**Legal category:** GSL

**PL Holder:** McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK

**PL Number(s):** PL 15513/0067

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