

Oraldene® 0.1% w/v Gargle/Mouthwash

Hexetidine

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you.

- Keep this leaflet. You may need to read it again.
- This medicine is used to relieve throat and mouth infections.
- This medicine is for use by adults and children aged 6 years and over.
- Ask your pharmacist if you need more information or advice.
- If you get any side-effects, talk to your doctor, pharmacist or nurse. This includes any side-effects not listed in this leaflet. See section 4 ►
- **Do not use this medicine:**
 - If you have had a **bad reaction** to Oraldene or any of the ingredients in it. See section 6 ►
- **Follow the dosage instructions carefully.**

1 What the medicine is for

The mouthwash contains hexetidine, which is an antibacterial and antifungal and is used to help treat throat and mouth infections, including mouth ulcers, thrush, sore or bleeding gums (called gingivitis), bad breath (halitosis) or sore throat. It can also be used before and after dental surgery to help prevent infections.

2 Before using this medicine

This medicine is suitable for most people, but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist.



❌ Do not use this medicine...

- If you have ever had a **bad reaction** (e.g: hypersensitivity or allergic reaction) to Oraldene or any of its ingredients
- If there is evidence of increased inflammation, the treatment should be stopped.

If the above applies to you, **get advice from your doctor or pharmacist without using Oraldene.**

⚠️ If you are pregnant or breast-feeding

- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

⚠️ Some of the ingredients can cause problems

- 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.
- Azorubin (E122) can cause allergic reactions, including asthma. Reactions are more common in people who are allergic to aspirin.

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

3 How to use this medicine

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

Check the table below to see how much medicine to use.

Oraldene is for topical use only, which means that it should not be swallowed or taken internally.

ⓘ Children under 6 years old

Oraldene is not recommended for children under 6 years of age.

ⓘ Adults and Children aged 6 years and over

Age	Dose
Adults and children aged 6 years and over	Rinse mouth or gargle with at least 15 ml (about 1 tablespoon) of solution two to three times a day or as otherwise directed.

- Do not dilute.
- Do not swallow but spit out after use.
- An adult should supervise use in children.

⚠️ If anyone accidentally swallows this product

If anyone accidentally swallows this product, contact a doctor or your nearest Accident and Emergency department (Casualty) taking this leaflet and pack with you.

⚠️ If you forget to use the medicine

Use the next dose as soon as you remember unless it is time to use it again. **Do not** use two quantities in one go.

4 Possible side-effects

Like all medicines this medicine can cause side-effects, although not everybody gets them.

If you experience the following, stop using the medicine and talk to your doctor:

- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- Allergic reactions including itchy rash
- Irritation, tingling or numbness of the tongue and/or tissues inside the mouth
- Shortness of breath
- Cough
- Dry mouth
- Feeling sick (nausea)
- Sickness (vomiting)
- Salivary gland enlargement
- Taste disturbance or loss of taste
- Pain, swelling, redness or heat
- Tongue or tooth discolouration
- Blistering or ulceration.

Reporting of side-effects

If you get any side-effects, talk to your doctor, pharmacist or nurse. This includes any possible side-effects not listed in this leaflet. You can also report side-effects directly via HPRA Pharmacovigilance, website: www.hpra.ie. By reporting side-effects you can help provide more information on the safety of this medicine. You can also report side effects directly in Malta via: ADR Reporting at: www.medicinesauthority.gov.mt/adrportal

5 Storing this medicine

Do not store above 30°C.

Keep the bottle in the outer carton in order to protect from light.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

6 Further information

What's in this medicine?

The active ingredient is: The mouthwash contains 0.1 g/100 ml (0.1% w/v) of the active ingredient Hexetidine.

Other Ingredients are: Polysorbate 80, Citric acid, Saccharin sodium, Levomenthol, Eucalyptus oil, Ethanol 96%, Azorubin (85%) (E122), Sodium calcium edetate, Sodium hydroxide (E524) and Purified water.

What the medicine looks like

Oraldene is a clear red solution available in 100 ml or 200 ml bottles. Not all pack sizes are marketed. It contains 0.1 g of the active ingredient in every 100 ml of medicine. Each pack contains a 15 ml measuring cup.

Product Authorisation Holder:

JNTL Consumer Health I (Ireland) Ltd.
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Manufacturer:

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This leaflet was revised September 2023.

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Oral Health Guide

A healthy mouth, teeth and gums are everyone's aim. Not only do they look good, but they also feel good. But no matter how thorough your oral hygiene routine is, the mouth can still be prone to infection from time to time. The result is swelling, inflammation, painful mouth ulcers, and an uncomfortable mouth generally.

Regular trips to your dentist are an essential part of looking after your mouth and so is eating a healthy diet. Flossing and brushing your teeth well on a regular basis are also vital, and there is considerable scientific evidence to show that antiseptic mouthwashes are an effective element in good oral hygiene.

Listed below are some common oral health complaints and their symptoms. Remember to consult your dentist or doctor if the problem persists or the symptoms worsen.

Sore or bleeding gums (gingivitis)

Gingivitis is inflammation of the gums (the gingivae), caused usually by a build up of dental plaque. Plaque is a living colony of bacteria that accumulate in pits or fissures where the gums meet the teeth and between the teeth. If plaque is not removed regularly by toothbrushing and flossing, the bacteria grow and produce substances which cause gum inflammation and some bleeding.

Mouth ulcers

Mouth ulcers are shallow, usually painful, erosions of the lining of the mouth or gums which may occur singly or in crops and may be recurrent. Many ulcers are caused by bacterial, viral and fungal infections associated with stress, underlying illness, certain foods, stopping smoking, or menstruation. They may also be caused by repeated rubbing from badly fitting dentures. Mouth ulcers generally last between 10-14 days. The pain lasts three to five days, then healing starts to take place. However, if an ulcer lasts for more than 14 days, go and see your doctor.

Like mouth ulcers, sore throats can have many causes, for example, they may accompany colds or flu. Remember that some sore throats result from serious infections. You should consult your doctor if a sore throat persists or is particularly troublesome.

Bad breath (halitosis)

Bad breath has two main causes: strong smelling or spicy foods or drink; or bacteria normally present in the mouth can digest food particles to produce smelly, sulphur-containing compounds. Good oral hygiene can combat the growth of bacteria that produce bad smells. Bad breath may also be caused by other medical conditions such as a digestive disorder.

Please consult your doctor or dentist if you feel your bad breath does not improve with good oral hygiene.

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