Patient Information Leaflet: Information for the user

Orajel™ Mouth Gel

Benzocaine 10% w/w

Read all of this leaflet carefully because it contains important information for you.
This medicine is available without prescription. However, you still need to use Orajel™ Mouth Gel carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor or dentist if your symptoms worsen or do not improve.
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

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1. What is ORAJEL™ MOUTH GEL and what it is used for

The name of your medicine is Orajel™ Mouth Gel. It contains benzocaine at a concentration of 10% w/w.

Benzocaine belongs to a group of medicines called local anaesthetics. It provides rapid relief by numbing the area and therefore reducing the pain.

Orajel™ Mouth Gel is used to temporarily reduce the pain, tenderness and discomfort of mouth ulcers and from wearing dentures.

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2. Before you use ORAJEL™ MOUTH GEL

Do not use ORAJEL™ MOUTH GEL:

- If you have had an allergic reaction to benzocaine or any of the ingredients in the gel particularly sorbic acid. An allergic reaction may include a rash, stinging, swelling or itching. This product contains sorbic acid, which may cause local skin reactions (eg contact dermatitis) and propylene glycol, which can cause skin irritation.
- If you have been told by your doctor that you have difficulty converting a component of your blood called methaemoglobin to haemoglobin. See section 4 for more details.
- In children below the age of 12 years

Taking other medicines

Do not use Orajel™ Mouth Gel if you are taking any antibiotics called sulphonamides, for example co-trimoxazole, as benzocaine may prevent them from working well.

Please tell your doctor, pharmacist or dentist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, make sure it is safe for you to apply Orajel™ Mouth Gel.

If you are unsure, talk to your pharmacist, doctor or dentist.

Please turn over

3. How to use ORAJEL™ MOUTH GEL

If you are unsure, you should check with your doctor, pharmacist or dentist.
Avoid taking hot drinks whilst using Orajel™ Mouth Gel.
For adults and children 12 years and over, remove cap, cut open tip of tube and with a clean finger apply an amount of gel the size of a green pea to the affected area.
Do not use in children below the age of 12 years. You can use Orajel™ Mouth Gel up to a maximum of 4 times a day.
Remember:
Orajel™ Mouth Gel is intended for short-term use until you can get to a dentist. It should not be used continuously. Do not use for more than 4 days at a time. If the pain persists, consult your dentist.
If you use more Orajel™ Mouth Gel than you should
Contact your nearest hospital casualty department, doctor or dentist immediately. Take this leaflet and any remaining gel with you to show the doctor or dentist.

4. Possible side effects

Like all medicines, Orajel™ Mouth Gel can cause side effects, although not everybody gets them.
Stop using the gel and contact your doctor or dentist immediately if any of the following occur:

- an allergic reaction (burning, stinging, itching, redness, rash and/or swelling)
- skin irritation
- a condition called methaemoglobinaemia (difficulty converting a component of your blood called methaemoglobin to haemoglobin).

If symptoms persist, or are severe, or are accompanied by fever, headache, breathlessness, nausea and vomiting, consult a doctor.

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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store ORAJEL™ MOUTH GEL

Keep this medicine out of the reach and sight of children.
Do not use Orajel™ Mouth Gel if the tube or pack is damaged.
Do not use Orajel™ Mouth Gel after the expiry date which is stated on the pack.

6. Further information

What Orajel™ Mouth Gel contains
Orajel™ Mouth Gel contains 10% w/w of benzocaine as the active ingredient.
Orajel™ Mouth Gel also contains macrogol 400, polyethylene glycol 3350, propylene glycol, sodium saccharin (E954), chlorothymol, eugenol, passion fruit flavour, sorbic acid (E200), and FD&C Red No 40.
What Orajel™ Mouth Gel looks like and contents of the pack
Orajel™ Mouth Gel is a pink gel. It smells fruity.
Each tube contains 5.3g of Orajel™ Mouth Gel.
Marketing Authorisation Holder and Manufacturer
The Marketing Authorisation Holder for Orajel™ Mouth Gel is Church & Dwight UK Ltd., Premier House, Shearway Business Park, Pent Road, Folkestone, Kent CT19 4RJ
Orajel™ is a trademark of Church & Dwight Co., Inc.
The manufacturer for Orajel™ Mouth Gel is Laleham Health and Beauty Limited, Mill Lane, Alton, GU34 2PR
For Medical Enquiries please call +44 (0) 808 175 6410

Is this leaflet hard to see or read? Phone 0808 175 6410 for help.

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