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Patient Information Leaflet: Information for the user

Orajel Dental 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 Dental 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.

In this leaflet:

1. What is ORAJEL DENTAL GEL and what it is used for
2. Before you use ORAJEL DENTAL GEL
3. How to use ORAJEL DENTAL GEL
4. Possible side effects
5. How to store ORAJEL DENTAL GEL
6. Further information

1. What is ORAJEL DENTAL GEL and what it is used for

The name of your medicine is Orajel Dental 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 Dental Gel is used to temporarily reduce the toothache pain associated with a broken tooth or in a tooth where you may require a filling.

Church & Dwight UK Ltd



2. Before you use ORAJEL DENTAL GEL

Do not use Orajel Dental 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).
- 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 Dental 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 Dental Gel.

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

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3. How to use ORAJEL DENTAL GEL

If you are unsure, you should check with your doctor, pharmacist or dentist. Avoid taking hot drinks whilst using Orajel Dental 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 into the tooth cavity. Do not use in children below the age of 12 years. You can use Orajel Dental Gel up to a maximum of 4 times a day.

Remember:

Orajel Dental Gel is intended for short-term use until you can get to a dentist. It should not be used continuously. If the toothache persists, consult your dentist.

If you use more Orajel Dental 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 Dental 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. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store ORAJEL DENTAL GEL

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

Do not use Orajel Dental Gel if the tube or pack is damaged.

Do not use Orajel Dental Gel after the expiry date which is stated on the pack.

6. Further information

What Orajel Dental Gel contains

Orajel Dental Gel contains 10% w/w of benzocaine as the active ingredient. Orajel Dental Gel also contains macrogol 400, polyethylene glycol 3350, sodium saccharin (E954), sorbic acid (E200), natural spearmint flavor, citric acid and clove oil.

What Orajel Dental Gel looks like and contents of the pack

Orajel Dental Gel is a colourless gel. It smells like mint.

Each tube contains 5.3g of Orajel Dental Gel.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder for Orajel Dental 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 Dental Gel is Laleham Health and Beauty Limited, Mill Lane, Alton, GU34 2PR

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The leaflet was last updated in May 2019

MA Number: 00203/0227

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PROJECT #: 2036268 Wave_1

SKU JOB #: 2036269

FILE NAME: PA2036269_R1.ai

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MECHANICAL: ROUND 1

JOB INFORMATION

JOB DESCRIPTION: Orajel Dental Gel 5.3g Leaflet

BRAND: Orajel

FRONT MATERIAL #:

BACK MATERIAL #:

FRONT COPY CODE #:

BACK COPY CODE #:

UPC #:

LAST REVISION DATE: 05/29/2019

ADDITIONAL JOB INFORMATION (if available)

PRINT PROCESS: Litho PRINTER: Duncan Print Group, Welwyn Garden City, GB

SUBSTRATE: Paper

PRINTER DIE#: CHDW71

JOB SIZE: 5.3g

C&D APPROVALS

IP #: 105584MMS-1



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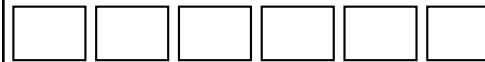


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