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Patient Information Leaflet: Information for the user

Church & Dwight UK Ltd

Orajel Extra Strength

Benzocaine 20% 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 Extra Strength 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.

2. Before you use ORAJEL EXTRA STRENGTH

Do not use Orajel Extra Strength:

- 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. This condition is very rare, see section 4 for more details.
- In children below the age of 12 years

In this leaflet:

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1. What is ORAJEL EXTRA STRENGTH and what it is used for

The name of your medicine is Orajel Extra Strength. It contains benzocaine at a concentration of 20% 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 Extra Strength is used to temporarily reduce the toothache pain associated with a broken tooth or in a tooth where you may require a filling.

Taking other medicines

Do not use Orajel Extra Strength 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 Extra Strength.

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

Please turn over

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3. How to use ORAJEL EXTRA STRENGTH

If you are unsure, you should check with your doctor, pharmacist or dentist.

Avoid taking hot drinks whilst using Orajel Extra Strength.

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 Extra Strength up to a maximum of 4 times a day.

Remember:

Orajel Extra Strength 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 Extra Strength 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 Extra Strength 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 and/or a rash)
- skin irritation

Very rare

- a condition called methaemoglobinaemia (difficulty converting a component of your blood called methaemoglobin to haemoglobin).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, pharmacist or dentist.

5. How to store ORAJEL EXTRA STRENGTH

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

Do not use Orajel Extra Strength if the tube or pack is damaged.

Do not use Orajel Extra Strength after the expiry date which is stated on the pack.

6. Further information

What Orajel Extra Strength contains

Orajel Extra Strength contains 20% w/w of benzocaine as the active ingredient.

Orajel Extra Strength also contains macrogol 400, polyethylene glycol 3350, sodium saccharin (E954), sorbic acid (E200), natural spearmint flavor, citric acid and clove oil.

What Orajel Extra Strength looks like and contents of the pack

Orajel Extra Strength is a colourless gel. It smells like mint.

Each tube contains 5.3g of Orajel Extra Strength.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder for Orajel Extra Strength is Church & Dwight UK Ltd., Premier House, Shearway Business Park, Pent Road Folkestone, Kent CT19 4RJ

The manufacturer for Orajel Extra Strength is Laleham Healthcare Ltd, Mill Lane, Alton, GU34 2PR

Is this leaflet hard to see or read?

Phone 0800 028 1454 for help.

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