

Orajel[®] Extra Strength

Benzocaine 20% w/w

Please read this leaflet carefully before you take this medicine. This leaflet provides a summary of the information available on your medicine. If you have any queries about this medicine, or are not sure about anything, ask your doctor, dentist or pharmacist. Keep this leaflet until you have finished your medicine.

ABOUT YOUR MEDICINE

The name of your medicine is Orajel[®] Extra Strength. The dental gel contains Benzocaine at a concentration of 20% w/w.

Other ingredients are used in the manufacture of the gel. They are Polyethylene Glycol, Sodium Saccharin (E954), Spearmint Flavour, Sorbic Acid (E200) and Clove Oil. The gel is packaged in a tube containing 5.3g.

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

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

The Marketing Authorisation Holder for Orajel[®] Extra Strength is Church & Dwight UK Ltd., Peninsular House, Whitfield Court, Honeywood Close, White Cliffs Business park, Dover CT16 3PX. The gel is manufactured by Laleham Healthcare Ltd, Mill Lane, Alton, GU34 2PR.

WHAT DOES ORAJEL[®] EXTRA STRENGTH DENTAL GEL DO?

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.

BEFORE TAKING YOUR MEDICINE

Make sure it is safe for you to apply Orajel[®] Extra Strength. Do not take this medicine 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).
- You have been told by your doctor that you have difficulty converting a component of your blood called methaemoglobin to haemoglobin. Please don't be worried. Most people taking this medicine will not experience any problems.

Tell your pharmacist, doctor or dentist if:

- You are taking antibiotics called sulphonamides, for example co-trimoxazole, as benzocaine may prevent them from working well.
- You are pregnant or breast feeding.

HOW TO TAKE YOUR MEDICINE

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. You can use the gel up to a maximum of 4 times a day.

This medicine is not for use by children below the age of 12 years.

Remember:

Orajel® Extra Strength 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 toothache persists, consult your dentist.

IF YOU APPLY OR SWALLOW TOO MUCH GEL

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.

ARE THERE ANY UNWANTED EFFECTS FROM THIS MEDICINE?

Like other medicines, this gel may cause some side effects. If this happens to you, stop using the gel. An allergic reaction (burning, stinging, itching and/or a rash) or skin irritation may occasionally occur. Very, very rarely a condition called methaemoglobinaemia may occur. If you experience any other unusual or unexpected symptoms, you should consult your doctor, dentist or pharmacist.

STORAGE AND DISPOSAL OF YOUR MEDICINE

- Keep your medicine out of the sight and reach of children.
- There are no special precautions for storage.
- Do not use your medicine if the tube or pack is damaged or after the expiry date printed on the pack.

Remember:

The information in this leaflet provides a summary of the information available on Orajel® Extra Strength. Further information is available from your doctor, dentist or pharmacist.

Date of preparation of this leaflet: 1st August 2009.

MA Number: 00203/0228

Distributor in UK:

Church & Dwight UK Ltd., Peninsular House, Whitfield Court, Honeywood Close, White Cliffs Business Park, Dover, Kent CT16 3PX.

Component Code: IN-37003-01