ESSENTIAL INFORMATION

Orajel Dental Gel (GSL). Benzocaine 10% w/w. For temporary rapid relief of toothache pain associated with presence of open carious lesions and direct exposure of a vital dental pulp. Presentation: Colorless gel. Contains benzocaine at a concentration of 10% w/w. Uses: Temporarily reduce the toothache pain associated with a broken tooth or in a tooth where you may require a filling. Dosage: Apply an amount of gel the size of a green pea into the tooth cavity. May be used up to a maximum of 4 times a day. Do not use in children below the age of 12 years. Pregnancy and lactation: 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. 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. Very rare: 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. RRP: £3.99. Legal category: GSL. PL Holder: Church & Dwight UK Ltd., Premier House, Shearway Business Park, Pent Road, Folkestone, Kent CT19 4RJ, UK. PL number 00203/0227. Date of revision: July 2014. Information about this product, including adverse reactions, precautions, contra-indications, and method of use can be found at: https://www.medicines.org.uk/emc/product/1230/smpc

Orajel Extra Strength (P). Benzocaine 20% w/w. For temporary rapid relief of toothache pain associated with presence of open carious lesions and direct exposure of a vital dental pulp. Presentation: Colourless gel. Contains benzocaine at a concentration of 20% w/w. Uses: For temporary rapid relief of toothache pain associated with presence of open carious lesions and direct exposure of a vital dental pulp. Dosage and method of use: With a clean finger or swab apply an amount of gel the size of a green pea into the tooth cavity. May be used up to 4 times a day. Do not use continuously. If toothache persists, consult your dentist. Do not use in children below the age of 12 years. Pregnancy and lactation: 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. 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, redness, rash, and/or swelling), skin irritation. Very rare: 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. RRP: £6.49 Legal category: P. PL Holder: Church & Dwight UK Ltd., Premier House, Shearway Business Park, Pent Road, Folkestone, Kent CT19 4RJ, UK. PL number 00203/0228. Date of revision: April 2015. Information about this product, including adverse reactions, precautions, contra-indications, and method of use can be found at: https://www.medicines.org.uk/emc/product/1229/smpc

ADVERSE EVENT REPORTING

Adverse events should be reported. Reporting forms and information can be found at <u>https://yellowcard.mhra.gov.uk/</u>. Adverse events should also be reported to Church & Dwight +44(0) 808 175 6410

REFERENCES

- Orajel Dental Gel. Summary of Product Characteristics. Available at: <u>https://www.medicines.org.uk/emc/product/1230/smpc</u> Accessed: November 2024
- Orajel Extra Strength. Summary of Product Characteristics. Available at: <u>https://www.medicines.org.uk/emc/product/1231/smpc</u> Accessed: November 2024
- 3. Lee, H-S. Recent advances in topical anesthesia. J Dent Anesth Pain Med. 2016;16(4):237–244.
- 4. Hersh, EV, *et al*. An evaluation of 10 percent and 20 percent benzocaine gels in patients with acute toothache. *J Am Dent Assoc*. 2013;144(5):517–526.
- 5. PAGB. OTC Directory Online. Mouth pain, toothache, teething and ulcers. Available at: <u>https://www.otcdirectory.co.uk/list/search/Mouth-Pain,-</u> <u>Toothache,-Teething,-and-Ulcers</u> Accessed: November 2024.
- PAGB. OTC Directory Online. Benzocaine. Available at: <u>https://www.otcdirectory.co.uk/list?title=Benzocaine&single=1</u> Accessed: November 2024.