

bonjela
Oromucosal Gel
Choline salicylate 8.714%
Cetalkonium chloride 0.010%

PACKAGE LEAFLET: INFORMATION FOR THE USER

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 Bonjela 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 if your symptoms worsen or do not improve after 7 days. 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 Bonjela is and what it is used for
2. Before you use Bonjela
3. How to use Bonjela
4. Possible side effects
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1. WHAT BONJELA IS AND WHAT IT IS USED FOR

Bonjela is a clear gel, which is applied to the inside of the mouth or gums. It contains choline salicylate (a pain killer and anti-inflammatory) which soothes the sore areas in the mouth, and antiseptic called cetalkonium chloride, which kills bacteria and helps prevent infection. Bonjela can be used to relieve pain and reduce inflammation and help fight infection in infant teething, mouth ulcers, cold sores, and sore spots due to dentures in adults and orthodontic devices in children.

2. BEFORE YOU USE BONJELA

Do not use Bonjela:

- if you are allergic (hypersensitive) to the active ingredients or any of the ingredients listed in section 6.
- if you are currently taking aspirin or other salicylate, except under direction of a doctor
- in children under 4 months
- if you have active or a history of recurrent stomach ulcer
- if you are currently suffering from chicken pox or flu particularly in children and adolescents under 16 years of age

Take special care with Bonjela

- if you are pregnant or breastfeeding, please consult your doctor before use
- if there is no improvement after 7 days, consult your doctor
- especially in children, as frequent application may give rise to salicylate poisoning.

Taking other medicines

Salicylates may enhance the effect of blood thinning medicines (anticoagulants) and can decrease the effect of medicines to treat gout (uricosurics) such as probenic acid.

Please tell your doctor or pharmacist 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, planning to become pregnant, or breastfeeding, speak to your doctor or your pharmacist.

Important information about some of the ingredients of Bonjela

This medicine contains 46.83 mg of alcohol (ethanol) in each dose.

The amount in each dose of this medicine is equivalent to less than 2 ml beer or 1 ml of wine.

The small amount of alcohol in this medicine will not have any noticeable effects.

It may cause burning sensation on damaged skin.

This medicine contains less than 1 mmol sodium (23 mg) in each dose, that is to say essentially 'sodium-free'.

This medicine contains fragrance with d-Limonene, anisyl alcohol and linalool. D-Limonene, anisyl alcohol and linalool may cause allergic reactions.

3. HOW TO USE BONJELA

Bonjela is for oral topical use on the mouth and gums. Check that the cap seal is unbroken before first using this product. Apply with a clean finger.

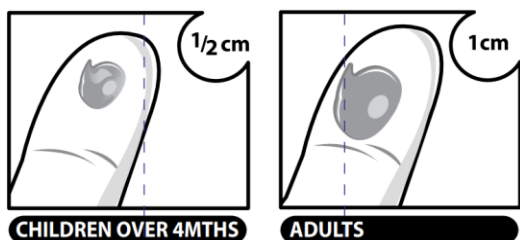
Children (from 4 months) – massage a pea sized amount of gel onto the sore area, not more than once every 3 hours. Do not apply more than six times in 24 hours.

Adults – Massage approximately 1cm of the gel onto the sore area, not more than once every 3 hours.

Orthodontic Devices – Apply to sore area as described above, not more than once every 3 hours.

Dentures Irritation – Apply to the gums and leave at least 30 minutes before re-insertion of the dentures. Do not apply directly to the dentures.

DO NOT EXCEED THE STATED DOSE



If your symptoms do not improve after 7 days of treatment you should contact your doctor.

If you use more Bonjela than you should

Contact your doctor or pharmacist. Symptoms of overdose include nausea, vomiting, fever and disorientation. It is especially important in infants to follow the dosage instructions carefully.

If you forget to use Bonjela

Apply a new dose as described above. Do not take a double dose to make up for a forgotten dose. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Bonjela can cause side effects, although not everybody gets them. Allergic reactions to salicylates such as an asthma attack or breathing difficulties may occur. Other reactions such as inflammation, burns, numbing or stinging of the mouth or gums may occur. There have been post-marketing reports of cases of suspected Reyes syndrome and possible salicylate toxicity in children who had a history of use of choline salicylate gels but causality has not been established.

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 nurse. You can report side effects directly via HPRa Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie

5. HOW TO STORE BONJELA

Keep out of the reach and sight of children.

Do not store above 25°C. Do not use Bonjela after the expiry date which is stated on the carton and tube. Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Bonjela contains

The active ingredients are choline salicylate 8.714% w/w and cetalkonium chloride 0.01% w/w. The other ingredients are ethanol, glycerol, levomenthol, hypromellose 4500, star anise oil (d-Limonene, anisyl alcohol, linalool), saccharin sodium and purified water.

What Bonjela looks like and contents of the pack

Each pack contains a 15g tube of clear, aniseed flavoured, oromucosal gel.

Marketing Authorisation Holder and Manufacturer

PA Holder: RB Ireland Ltd., 7 Riverwalk, Dublin 24, IE.

Manufacturers: RB Healthcare UK Ltd, Hull, HU8 7DS, UK and RB NL Brands B.V. Schiphol Blvd 207, 1118 BH Schiphol, NL. For product queries please call: 01-6305429

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