choline salicylate, cetalkonium chloride

INFORMATION FOR THE USER

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have

- told you. - Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.
- What is in this leaflet:
- 1. What bonjela is and what it is used for 2. What you need to know before you use bonjela
- 3. How to use boniela 4. Possible side effects
- 5. How to store boniela
- 6. Contents of the pack and further information

1. WHAT BONJELA IS AND WHAT IT IS USED FOR

boniela is used to

- relieve the pain and discomfort of common mouth ulcers and cold sores.
- aid healing of sore spots and ulcers due to

bonjela is a clear, almost colourless gel, which is applied to the inside of the mouth or gums. It

contains choline salicylate (a pain killer and anti-inflammatory) which soothes sore areas in the mouth and an antiseptic called cetalkonium chloride, which kills bacteria and helps prevent

bonjela is intended for adults and children over the age of 16.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE BONJELA

Do not give to children or adolescents under 16 years of age. This is because there is a possible link between salicylates and Reye's syndrome when given to children. Reye's syndrome is a very rare disease which affects the brain and liver and can be fatal.

Do not use if you are

- suffering from a stomach ulcer allergic to salicylates, Asprin or other NSAIDs
- (e.g. ibuprofen), or to any other ingredients in this product (see section 6)

Warnings and precautions

This product contains salicylates. Talk to your doctor before taking this product with Aspirin or other salicylates.

Other medicines and bonjela

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Salicylates may increase the effect of blood thinning medicines (anticoagulants) and can decrease the effect of medicines to treat gout (uricosurics) such as probenic acid,

Pregnancy and breast-feeding

If you are pregnant, planning to become pregnant, or breast-feeding, speak to your doctor or pharmacist.

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Important information about some of the

- ingredients in 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
- This medicine contains fragrance with d-Limonen anisyl alcohol and linalool. d-limonene, anisyl alcohol and linalool may cause allergic reactions.

3. HOW TO USE BONJELA

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

For adults and children over the age of 16 years only. - Mouth ulcers and sores

- using a clean finger
 Massage approximately one centimetre (half an inch) of
 bonjela onto the sore area. This can be repeated after 3 hours.
- Denture sores Massage approximately one centimetre of bonjela onto the sore area, and leave at least 30 minutes
- before reinserting the dentures. Do not apply bonjela directly onto the dentures. Do not take more medicine than the label or leaflet tells you to as salicylate
- toxicity may occur as a result. If your symptoms do not go away after 7 days of treatment, you should see your doctor or dentist. In the case of a missed dose, simply apply a new dose and follow the instructions
- described above. In the event of an overdose, seek medical advice If you have any further questions on the use of this product, ask Ink & Varnish Free

your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS Like all medicines, bonjela can cause side effects, although not everybody gets them.

- STOP taking this product and seek immediate medical help if you experience:

 unexplained wheezing or coughing, asthma, shortness of breath, difficulty breathing, itching, face, tongue or throat swelling, which can be signs of serious allergic reactions.

 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 nore information on the safety of this medicine.

5. HOW TO STORE BONJELA

Keep out of the sight and reach of children. Do not use bonjela after the expiry date which is stated on the carton and on the tube. The expiry date refers to the last day of that month. Do not store above 25°C.

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. CONTENTS OF THE PACK AND FURTHER INFORMATION

What bonjela contains
The active ingredients (which make the medicine work) are choline salicylate 8.714% w/w, cetalkonium chloride 0.01 % w/w. The other ingredients are ethanol, glycerol, levomenthol, hypromellose 4500, star anise oil, sodium saccharin and water. What bonjela looks like and contents of the pack Each tube contains 15g of clear, aniseed flavoured oral gel. Marketing Authorisation holder/Manufacturer: Reckitt Benckiser Healthcare (UK) Limited, Hull HU8 7DS Licence number: PL 00063/0121
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