

GEL FOR OROMUCOSAL APPLICATION

Pansoral

CHOLINE SALICYLATE • CETALKONIUM CHLORIDE

Composition: Choline salicylate 8,7 g, Cetalkonium chloride 0,01 g, Excipients s.q.f. 100 g (alcohol 96% v/v, glycerol, hydroxyethylcellulose, star anise oil, medicinal solution of sodium hydroxyde at 32%, purified water). Alcohol content: 37%. Oromucosal gel: 15 g tube.

Pharmaco-therapeutic classification: PREPARATIONS FOR STOMATOLOGY/OTHER AGENTS FOR LOCAL TREATMENT (A 01 AD11) (A: digestive system and metabolism).

Name and address of marketing authorization holder in France: PIERRE FABRE MEDICAMENT.

Distributed in France by: **Pierre Fabre Oral Care**

Manufactured by: PIERRE FABRE MEDICAMENT PRODUCTION Rue du lycée, Gien - France.

Indications: This medication is recommended as a short-term adjunctive treatment of the pain associated with inflammatory and ulcerous conditions of the mucus membranes of the mouth.

Warning: WHEN NOT TO USE THIS MEDICATION

This medication SHOULD NOT BE USED in the following cases:

- known allergy to medical products containing salicylates (aspirin...),
- in children and patients below 18 years of age.

IF IN DOUBT, YOU MUST SEEK THE ADVICE OF YOUR DENTIST.

SPECIAL PRECAUTIONS: THIS MEDICATION IS FOR ADULT USE ONLY.

Consult your dentist if no improvement is noticed after a few days. Gum irritation caused by dentures could mean that they need adjustment, in which case treatment with PANSORAL should be seen as a temporary solution only.

NOTE: THIS PRODUCT CONTAINS 39 g OF ALCOHOL AT 96% PER 100 g.

Precautions for use: IN DOUBT, YOU MUST SEEK THE ADVICE OF YOUR DENTIST.

Drug interactions and other interactions: TO AVOID POSSIBLE INTERACTIONS BETWEEN MEDICATIONS, ALWAYS INFORM YOUR DENTIST OR STOMATOLOGIST OF ANY OTHER MEDICATION YOU ARE USING.

Pregnant women and nursing mothers: IN GENERAL, PREGNANT WOMEN AND NURSING MOTHERS SHOULD ALWAYS INFORM THEIR DENTIST OR STOMATOLOGIST OF THEIR CONDITION BEFORE USING ANY MEDICATION.

Excipient with known effect: Alcohol.

Dosage and directions for use: This medication is for adult use only. Strictly for local application only. For application to the gums. Thoroughly clean and dry dentures before application. On average 1 to 4 applications (a nut-sized amount) per day. For permanent dentures: put a pea-sized amount onto the affected area, usually at incisor or molar level.

For temporary dentures: put the gel onto the part of the denture in contact with the affected area.

Once inside the mouth, the warmth and movements when chewing ensure that the gel spreads uniformly.

Undesirable effects: LIKE ANY ACTIVE PRODUCT, THIS MEDICATION CAN HAVE SIDE EFFECTS OF VARYING SEVERITY IN CERTAIN PATIENTS:

- hypersensitivity reactions to medical products containing salicylates,
- risk of irritation due to the presence of alcohol.

DO NOT HESITATE TO SEEK THE ADVICE OF YOUR DENTIST AND INFORM HIM OR HER OF ANY UNDESIRABLE EFFECT NOT MENTIONED IN THIS PATIENT INFORMATION LEAFLET.

Storage: DO NOT EXCEED THE SELL-BY DATE MARKED ON THE OUTER PACKAGING. Store below 25 °C.

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Made in **France**



Pierre Fabre

Consumer Health Care

UNE DIVISION PIERRE FABRE MÉDICAMENT