

1. NAME OF THE MEDICINAL PRODUCT

DENTIBABY – Teething gel, in tube.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Camomile flower extract 5 %, Valerian root extract 5 %, Propolis extract 5 %, Excipients q.s. 100%.

3. PHARMACEUTICAL FORM

Gingival Gel.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

“DENTIBABY – Teething gel, in tube” should be used in the event of gum pain related to teething in babies.

4.2 Posology and Method of Administration

Wash your hands thoroughly. Apply a small amount of gel to a finger and lightly massage the painful gum for 2 to 3 minutes.

You can repeat the application until 5 times a day.

4.3 Contraindications

Not relevant.

4.4 Special Warnings and Precautions for Use

Close the tube tightly after use.

In the event that symptoms linked to teething continue (e.g. temperature, pain, red cheeks, nappy rash), consult your doctor.

Do not use in the event of hypersensitivity to one of the components

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

4.5 Interaction with other Medicinal Products and other Forms of Interaction

No interaction studies have been performed.

4.6 Pregnancy and Lactation

None.

4.7 Effects on Ability to Drive and Use Machines

Not relevant.

4.8 Undesirable Effects

Not relevant.

4.9 Overdose

No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Other agent for local gingival treatment,

ATC code: A01AD11

5.2 Pharmacokinetic Properties

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5.3 Preclinical Safety Data

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6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Chamomilla recutita extract, Propolis cera extract, Valeriana officinalis extract, Sodium Alginate, Sodium saccharinate, Sodium cyclamate, Methyl parahydroxybenzoate (Methylparaben), Potassium sorbate, Propyl parahydroxybenzoate (Propylparaben), Aroma caramel, Purified water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

36 months.

6.4 Special Precautions for storage

Store below 30°C.

Do not use after the expiry date stated on the tube.

6.5 Nature and contents of container

Tube of 25 mL, made of medium-density polyethylene.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Any unused product or waste material should be disposed in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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