

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Dentokind

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 tablet (100 mg) contains:

Active substances:

Belladonna trit. D6	15.00 mg
Chamomilla trit. D6	15.00 mg
Ferrum phosphoricum trit. D6	15.00 mg
Hepar sulfuris trit. D12	15.00 mg
Pulsatilla trit. D6	15.00 mg

Excipient with known effect: lactose monohydrate

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Teething symptoms such as irritability, restlessness, earaches, painful gums, mild fever and softened stools in infants and children.

4.2 Posology and method of administration

Posology

Children under 1 year of age:

For acute complaints, 1 tablet is administered every hour, up to a maximum of 6 tablets per day. When the complaints improve, 1 tablet is administered 3 times per day.

Children aged 1 to 6 years:

For acute complaints, 2 tablets are administered every hour, up to a maximum of 12 tablets per day. When the complaints improve, 2 tablets are administered 3 times per day.

Method of administration

Tablets should be allowed to dissolve slowly in the mouth. For small children, tablets can be dissolved in a little bit of water.

An interval of at least half an hour to meals should be kept.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

This medicinal product contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicinal product.

A reassessment of the therapy is necessary

- if the child is poorly responding to Dentokind,
- if additional complaints arise.

4.5 Interaction with other medicinal products and other forms of interaction

Interactions with other medicinal products have not been observed. The use of this homeopathic medicinal product does not exclude the use of other medicinal products.

Parents are advised to consult a doctor if their child is taking, has recently taken or might take any other medicinal products.

4.6 Pregnancy and lactation

This medicinal product is meant for children.

4.7 Effects on ability to drive and use machines

This medicinal product is meant for children.

4.8 Undesirable effects

No side effects are known up to present.

If any side effects are noticed, appropriate measures have to be taken.

Note: Existing complaints may temporarily become worse when homeopathic medicines are taken (initial homeopathic aggravation). In such cases, patients are advised to discontinue the medication and consult a doctor.

4.9 Overdose

No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Homeopathic medicinal product

Homeopathic therapy differs markedly from conventional medicine with regard to the understanding of disease and the use of medicinal substances. Homeopathic remedies stimulate the organism's own defence mechanisms and thereby activate its self-healing power. The response of the organism to a homeopathic remedy is highly individual. For these reasons dose-specific pharmacological effects, pharmacodynamic or pharmacokinetic data can not be determined.

5.1 Pharmacodynamic properties

Not applicable.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable. Dentokind tablets as a homeopathic pharmaceutical have not gone through preclinical testing.

6. PHARMACEUTICAL PROPERTIES

6.1 List of excipients

Cellulose microcrystalline, lactose monohydrate, magnesium stearate, talc.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

5 years.

Do not use after the expiration date indicated on the package

6.4 Special precautions for storage

Store at a temperature not exceeding 25 ° C. Store out of reach and sight of children.

6.5 Nature and contents of container

150 tablets in bottle; 1 bottle and PIL in carton box.

6.6 Special precautions for disposal

No special requirements.

7. MANUFACTURER

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8. MARKETING AUTHORISATION HOLDER

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9. MARKETING AUTHORISATION NUMBER(S)

[To be completed]

10. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

17/07/2018

11. DATE OF REVISION OF THE TEXT

October 2023

