

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Viburcol®, suppository rectal

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 rectal suppository of 1,1 g contains the active substances:

Atropa bella-donna	D2	1,1mg
Calcium carbonicum Hahnemanni	D8	4,4 mg
Matricaria recutita	D1	1,1 mg
Plantago major	D3	1,1 mg
Pulsatilla pratensis	D2	2,2 mg

For the list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suppository rectal

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Conditions of restlessness and irritability with or without fever, especially in infants and children (e.g. as in teething, mild abdominal pain, sleeplessness). Symptomatic treatment of common infections.

4.2 Posology and method of administration

Posology

Unless otherwise prescribed:

Infants in the 1st year of life after consultation with a pediatrician, a maximum of 1 suppository daily.

Children from 2 to 6 years of age 1 to 2 suppositories daily.

Children from 6 to 12 years of age 1 to 3 suppositories daily.

If the symptoms improve, reduce the frequency of use.

Method of Administration:

Insert suppository into the rectum.

Duration of treatment

Like all medicines, homeopathic medicines should not be used for a long time without medical advice.

4.3 Contraindications

Known allergy to Matricaria recutita (camomile), other Compositae plants, to the active substances or to any of the excipients listed in section 6.1 .

4.4 Special warnings and precautions for use

In case of shortness of breath, fever, purulent or bloody sputum, as well as persistent unclear or newly occurring abdominal pain or abdominal pain of unknown cause, a doctor should be consulted.

In the first year of life, you should consult a doctor in case of ongoing fever above 38 °C. Toddlers should be presented to a doctor from the second day of illness at the latest.

4.5 Interaction with other medicinal products and other forms of interaction

The effect of a homeopathic medicine can be unfavourably altered by generally influencing lifestyle factors as well as by stimulants..

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

4.6 Fertility, pregnancy and lactation

Not applicable as the product is intended for children aged less than 12 years..

4.7 Effects on ability to drive and use machines

No effects on the ability to drive and use machines have been reported, and none are expected due to the homeopathic dilutions.

4.8 Undesirable effects

Like all medicinal products, this homeopathic medicinal product can cause side effects, although not everybody gets them.

In rare cases, diarrhoea or skin reactions may occur.

Notice:

When using homeopathic medicines, existing symptoms may temporarily worsen (initial worsening). In this case, you should discontinue using the medicine and consult your doctor.

4.9 Overdose

No cases of overdose have been reported, and none are expected due to the homeopathic dilutions.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: V03AX

Not applicable for homeopathic medicinal products.

5.2 Pharmacokinetic properties

Not applicable for homeopathic medicinal products.

5.3 Preclinical safety data

Not applicable for homeopathic medicinal products.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hard fat

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Keep out of the sight and reach of children.
Do not store above 25 °C.

6.5 Nature and contents of container

Moulded strip packs made of polyvinylchloride / polyethylene.
Packs containing 12 suppositories of 1,1g.

6.6 Special precautions for disposal and other handling

No special requirements.

7. MANUFACTURER / MARKETING AUTHORISATION HOLDER

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8. DATE OF REVISION OF THE TEXT

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