



Package leaflet: information for the patient

Sinolpan® 100 mg gastro-resistant capsules, soft

For adults and children from 6 years

Active substance: Cineole

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

Always take 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 Sinolpan® is and what it is used for
2. What you need to know before you take Sinolpan®
3. How to take Sinolpan®
4. Possible side effects
5. How to store Sinolpan®
6. Contents of the pack and other information

1. What Sinolpan® is and what it is used for

Sinolpan® contains the active substance cineole.

Sinolpan® is an anti-inflammatory and expectorant medicine that is used as adjunctive treatment for conditions affecting the respiratory tract.

For the treatment of symptoms of bronchitis and common cold.

Also indicated as adjunctive therapy in the treatment of chronic and inflammatory conditions affecting the respiratory tract e.g. of the paranasal sinuses (sinusitis).

The medicinal product is indicated for use in children (aged 6 – 11 years), adolescents (aged 12 – 17 years) and adults.

2. What you need to know before you take Sinolpan® ?

Do not take Sinolpan®

- if you are allergic to cineole or any of the other ingredients of this medicine (listed in section 6),
- in the event of whooping cough or pseudocroup,
- in infants or children younger than 6 years of age.

Sinolpan® contains soya lecithin. If you are allergic to peanut or soya, do not use this medicinal product.

Warnings and precautions

Talk to your doctor or pharmacist before taking Sinolpan®.

Special care is needed when taking Sinolpan® :

- In conditions that are accompanied by marked respiratory tract hypersensitivity.
- Bronchial asthma and COPD are to be treated with Sinolpan® solely under medical supervision, as the benefits and risks of treatment need to be weighed up against each other on an individual basis.
- You should go and see a doctor in the event of symptoms that last for longer than a week, shortness of breath, fever or discharge containing pus or blood.

Sinolpan® contains 10.90 mg sorbitol in each capsule

Children

Owing to the limited amount of scientific data available, Sinolpan® should be used in children under the age of 8 solely under medical supervision.

Other medicines and Sinolpan®

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

In animal experiments, cineole leads to the induction of metabolising enzymes in the liver. It cannot, therefore, be ruled out that the effect of other medicinal products is weakened and/or shortened by high doses of cineole. Such an effect has not, however, yet been able to be observed in humans following the correct use of cineole.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy:

There are no scientific studies on the use of Sinolpan® in pregnant women. If you are pregnant, you should not use Sinolpan® until you have spoken to your doctor.

In animal experiments performed on rats, cineole, the active substance in Sinolpan®, passes through the placenta, thereby reaching the foetus. The currently available data from animal experiments do not, however, indicate any malformations.

Breast-feeding:

Owing to the fat-soluble properties of the active substance, excretion thereof in breast milk cannot be ruled out. There are, however, no systematic studies on this, especially with regard to the possible occurrence of adverse drug reactions. Essential oils can alter the taste of breast milk and lead to drinking problems. You should not use Sinolpan® whilst you are breast-feeding until you have spoken to your doctor.

Driving and using machines

Sinolpan® has no or negligible influence on the ability to drive and use machines.

Sinolpan® contains sorbitol.

Sinolpan® contains 10.90 mg sorbitol in each capsule.

3. How to take Sinolpan®

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Ask your doctor or pharmacist if you are not sure.

Unless otherwise prescribed by your doctor, the recommended dose is:

Age	Single dose	Total daily dose
Adults and adolescents aged 12 years and above	2 capsules (equivalent to 200 mg of cineole)	4–8 capsules (equivalent to 400 – 800 mg of cineole)
Children aged 8 years and above – below 12 years of age (approx. 25 – 43 kg)	1 capsule (equivalent to 100 mg of cineole)	3 capsules (equivalent to 300 mg of cineole)
Children aged 6 years and above – below 8 years of age (approx. 20 – 24 kg)	1 capsule (equivalent to 100 mg of cineole)	3 capsules (equivalent to 300 mg of cineole)

The medicinal product is indicated in children (aged 6 – 11 years), adolescents (aged 12 – 17 years) and adults. Adults and adolescents aged 12 and above take 2 capsules 3 times daily. In particularly stubborn cases, 2 capsules 4 times daily. 2 capsules 2 times daily are generally sufficient for further and maintenance treatment. Children between the ages of 6 and 11 take 1 capsule 3 times daily.

Before taking Sinolpan® it should be assured that children are generally able to swallow capsules.

Method of administration:

The medicinal product is for oral use.

Swallow Sinolpan® unchewed with an ample amount of fluid that is not too hot (preferably a glass of drinking water [200 ml]), if possible, half an hour prior to eating. If you have a sensitive stomach, it is recommended that you take Sinolpan® during meals.

The duration of time that the capsules are to be taken is determined by the nature, severity and course of the condition being treated.

You should go and see a doctor in the event of symptoms that last for longer than a week, shortness of breath, fever or discharge containing pus or blood.

Talk to your doctor or pharmacist if you think that the effects of Sinolpan® are too strong or too weak.

If you take more Sinolpan® than you should

To date, there have been no reports of poisoning following the use of Sinolpan®.

If you suspect that you have taken too many Sinolpan®, tell your doctor. He/She will be able to decide what measures possibly need to be taken based on the severity of your symptoms of poisoning. Possible symptoms of a Sinolpan® overdose are effects on the central nervous system such as a clouding of consciousness, tiredness, weakness in the limbs, excessive constriction of the pupils (miosis) of the eyes and, in serious cases, coma and breathing problems.

If you forget to take Sinolpan®

Do not take a double dose to make up for a forgotten dose. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Information about the frequency of side effects is based on the following categories:

Gastro-intestinal symptoms (nausea, diarrhoea) may occur in uncommon cases (may affect up to 1 in 100 people). Hypersensitivity reactions (facial oedema, itching, shortness of breath, coughing) and swallowing difficulties are rare (may affect up to 1 in 1,000 people).

Sinolpan® may not be taken again at the first signs of a hypersensitivity reaction.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sinolpan®

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the blister after „Expiry date“. The expiry date refers to the last day of that month.

Store in the original package, in order to protect the capsules from moisture.

Do not store above 30°C.

Do not throw away any medicines via wastewater < or household waste>. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Sinolpan® contains

The active substance is: cineole.

Each gastro-resistant capsule, soft contains 100 mg of cineole.

The other excipients are:

Capsule content: Medium chain triglycerides,
Capsule shell: Gelatin, Methacrylic acid-ethylacrylate copolymer (1:1) dispersion 30%, Sorbitol liquid 70% (non crystallising) (E420), Soya lecithin (E 322), Glycerol (85 per cent), Propylene glycol, Glycerol monostearate 40–55, Polysorbate 80, Sodium dodecyl sulfate

What Sinolpan® looks like and contents of the pack

Sinolpan® are oval and colourless gastro-resistant capsules, soft. Pack sizes: 21, 50, 100 gastro-resistant capsules, soft. Not all pack sizes may be marketed.

Marketing authorisation holder and manufacturer

Engelhard Arzneimittel GmbH & Co. KG
Herzbergstraße 3
61138 Niederdorfelden
Tel.: 06101 / 539 – 300
Fax: 06101 / 539 – 315
Internet: www.engelhard.de
E-Mail: info@engelhard.de

This medicinal product is authorised in the Member States of the EEA under the following names:
Austria: Sinolpan forte® 200 mg magensaftresistente Weichkapseln
Germany: Sinolpan forte® 200 mg magensaftresistente Weichkapseln

This leaflet was last revised in Februar 2018.

