

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Peppermint Oil Sanofi 0.2 ml gastro-resistant soft capsules

peppermint oil

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 has 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, pharmacist or nurse. 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 2 weeks.

What is in this leaflet

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1. What Peppermint Oil Sanofi, capsules is and what it is used for

Peppermint Oil Sanofi, capsules is a herbal medicinal product which is used to relieve the symptoms of abdominal pain, minor spasms of the gastrointestinal tract (cramps), and flatulence (bloating), especially in patients with irritable bowel syndrome.

Peppermint Oil Sanofi is indicated for use in adults and adolescents 12 years of age and above (who weigh at least 40 kg).

You must talk to a doctor if you do not feel better or if you feel worse after two weeks.

2. What you need to know before you take Peppermint Oil Sanofi, capsules

Do not take Peppermint Oil Sanofi, capsules:

If you are allergic to peppermint oil or menthol or any of the other ingredients of this medicine (listed in section 6).

If you suffer from liver disease, infection of the bile duct, reduced gastric acid production, gallstones or any other biliary disorders.

If you weigh less than 40 kg (6 stone) bodyweight, because of safety concerns.

Peppermint Oil Sanofi must not be used in children under 12 years of age and adolescents with less than 40 kg (or 6 stone) bodyweight because of safety concerns.

Warnings and precautions

Talk to your doctor or pharmacist before taking Peppermint Oil Sanofi, capsules:

If you already suffer from heartburn (acid ingestion) or hiatus hernia (protrusion of the upper part of the stomach) symptoms can sometimes worsen after taking Peppermint Oil Sanofi, capsules. In this case the treatment should be discontinued.

The capsules should be swallowed whole i.e. not broken or chewed because the peppermint oil inside the capsules can cause local irritation of the mouth and gullet (oesophagus).

Check with your doctor or pharmacist immediately if unexplained abdominal pain persists or worsens, or occurs together with symptoms like fever, jaundice, vomiting, changes in bowel movement frequency, or blood in your stools.

Children and adolescents

Peppermint Oil Sanofi must not be used in children under 12 years of age and adolescents with less than 40 kg (6 stone) bodyweight because of safety concerns (see section “Do not take Peppermint Oil Sanofi, capsules”).

Other medicines and Peppermint Oil Sanofi, capsules

No interaction studies have been performed.

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

Other medicinal products used to decrease stomach acid, like histamine-2 blockers, proton pump inhibitors or antacids may cause the coating of the capsule to dissolve prematurely and should be avoided.

Peppermint Oil Sanofi, capsules with food

The capsules should be taken with liquid 30 minutes before a meal to avoid early release of the capsule content.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy

Safety during pregnancy has not been established. In the absence of sufficient human data, it is not recommended to take Peppermint Oil Sanofi capsules during pregnancy.

Breast-feeding

Clinical data have shown that 1,8 cineol, one constituent of peppermint oil, can be excreted into human breast milk. The use of Peppermint Oil Sanofi during lactation is not recommended.

Driving and using machines

No studies on the effect on the ability to drive and use machines have been performed.

Peppermint Oil Sanofi contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially “sodium-free”.

3. How to take Peppermint Oil Sanofi, capsules

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

The recommended dose is:

Adults and adolescents over 12 years of age who weigh at least 40 kg (6 stone):
One gastro-resistant capsule 3 times a day.

Use in children and adolescents:

Peppermint Oil Sanofi capsules **must not be administered** to children under 12 years of age and adolescents weighing less than 40 kg (6 stone) bodyweight (see “Do not take Peppermint Oil Sanofi, capsules”).

Method of administration

For oral use.

The capsules must be swallowed whole with liquid ie. not broken, crushed or chewed. They must be taken 30 minutes before a meal.

Duration of use

Peppermint Oil Sanofi should be taken until symptoms resolve, usually within one or two weeks. You must talk to a doctor if you feel worse, or do not feel better after two weeks.

If your symptoms persist, the capsules can be continued for periods up to 3 months per treatment course.

Special population

No data are available for a dosing instruction in case of impaired renal function.

If you take more Peppermint Oil Sanofi capsules then you should

Overdose may cause

- * severe gastro-intestinal symptoms, diarrhoea, rectal ulceration, nausea
- * epileptic convulsions, loss of consciousness, apnoea (cessation of breathing)
- * disturbances in rhythms of the heartbeat
- * lack of coordination and other problems with the central nervous system

If you take more Peppermint Oil Sanofi capsules than the recommended dose, talk to your doctor or go to a hospital straight away and take this leaflet with you.

If you forget to take Peppermint Oil Sanofi, capsules

Do not take a double dose to make up for a forgotten dose, take your usual dose at the usual time.

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.

If you experience the following effects, stop taking the capsules and seek medical help immediately:

- * allergic reactions to menthol e.g. anaphylactic shock, abnormally slow heart beat (bradycardia), red skin eruptions (erythematous skin rash), trembling (muscle tremor), lack of coordination (ataxia), and headache

Other effects that may occur include:

- * blurred vision
- * acid indigestion (heartburn), perianal burning
- * nausea and vomiting
- * menthol odour in stools and urine
- * inflammation of the glans of the penis
- * painful urination (dysuria)

The frequency of the effects occurring is not known.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance website:

www.hpra.ie.

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

5. How to store Peppermint Oil Sanofi, capsules

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

Keep blisters in the outer carton in order to protect from light.

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

6. Contents of the pack and other information

What Peppermint Oil Sanofi, capsules contains

The active substance is peppermint oil.

Each gastro-resistant soft capsule contains 0.2 ml (=181.6 mg) of *Mentha x piperita* L., aetheroleum (peppermint oil)

The other ingredients are:

Capsule shell:

gelatin
glycerol
water, purified
iron oxide yellow (E172)
brilliant blue FCF (E133)
Triglycerides, medium chain
Sunflower lecithin

Coating:

methacrylic acid – ethyl acrylate copolymer (1:1) dispersion 30 per cent
triethyl citrate
glycerol monostearate 40-55
polysorbate 80
Sodium dodecyl sulfate

What Peppermint Oil Sanofi, capsules looks like and contents of the pack

Peppermint Oil Sanofi, capsules are dull, green-coloured, oval-shaped soft capsule containing a colourless, pale yellow or pale greenish-yellow liquid

Peppermint Oil Sanofi is available in blister packs of 6, 12, 24 or 48 soft capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Sanofi

Citywest Business Campus

Dublin 24

Ireland

Manufacturer:

Dragenopharm Apotheker Pueschl GmbH

Göllstraße 1

84529 Tittmoning

Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria: Buscomint 0,2 ml Reizdarmkapseln

Germany: Buscomint bei Reizdarm 0,2 ml magensaftresistente Weichkapseln

Hungary: Entero-Spa 0,2 ml gyomornedv-ellenálló lágy kapszula

Ireland: Peppermint Oil Sanofi 0.2ml gastro-resistant soft capsules

Italy: Buscomint 0,2 ml capsule molli gastroresistenti

Poland: Olejek miętowy NO-SPA

Portugal: Buscomint 0,2 ml cápsula mole gastroresistente

Slovakia: MINTAL

Spain: Buscadol 0,2 ml capsulas blandas gastrorresistentes

United Kingdom: Buscomint Peppermint oil 0.2ml gastro-resistant capsule, soft

This leaflet was last revised in 02/2021.