



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

04 March 2020
EMA/55625/2020

Peppermint oil

Mentha x piperita L., *aetheroleum*

This is a summary of the scientific conclusions reached by the Committee on Herbal Medicinal Products (HMPC) on the medicinal uses of peppermint oil. The HMPC conclusions are taken into account by EU Member States when evaluating applications for the licensing of herbal medicines containing peppermint oil.

This summary is not intended to provide practical advice on how to use medicines containing peppermint oil. For practical information about using peppermint oil medicines, patients should read the package leaflet that comes with the medicine or contact their doctor or pharmacist.

What is peppermint oil?

Peppermint oil is the common name for the essential oil obtained from the fresh aerial parts of the flowering plant *Mentha x piperita* L.

The HMPC conclusions only cover peppermint oil preparations that are obtained by steam distillation from the fresh aerial parts (above ground) of the flowering plant.

Herbal medicines containing these peppermint oil preparations are usually available in solid, semi-solid or liquid forms to be taken by mouth, applied to the skin, sprayed in the mouth, or inhaled.

Peppermint oil preparations may also be found in combination with other herbal substances in some herbal medicines. These combinations are not covered in this summary.

What are the HMPC conclusions on its medicinal uses?

The HMPC concluded that peppermint oil preparations that are taken by mouth can be used to relieve minor belly spasms, flatulence and belly pain, especially in patients with irritable bowel syndrome. Peppermint oil preparations for these indications should not be used in children under 8 years old. Preparations that are rubbed on the skin of the forehead and temples can be used for relief of mild headaches; they should not be used in children and adolescents under 18 years of age.

The HMPC also concluded that, on the basis of their long-standing use, peppermint oil preparations that are inhaled, sprayed in the mouth, taken by mouth or applied on the chest, the back or around the nostrils can be used to relieve symptoms in coughs and colds. In addition, preparations that are applied to the skin can be used for relieving localised muscle pain and itching when the skin is not

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union



damaged. Peppermint oil preparations must not be used in children under 2 years old and, depending on the use, they may not be recommended in older children, e.g. preparations used to relieve symptoms in colds and coughs should not be used in children aged between 2 and 11 years.

A doctor or a qualified healthcare practitioner should be consulted if symptoms persist or worsen when using these preparations.

Detailed instructions on how to take peppermint oil medicines and who can use them can be found in the package leaflet that comes with the medicine.

How does peppermint oil work as a medicine?

The way peppermint oil works is not fully known, but it is thought that it may relieve cramps by interfering with calcium ions, which are involved in the contraction of smooth muscles in the gut, thereby relaxing the muscles.

In addition, when applied on the skin, peppermint oil triggers a prolonged cold sensation, by stimulating the cold-sensitive nerves in the skin. This provides pain relief when used for headaches.

What evidence supports the use of peppermint oil medicines?

The HMPC conclusions on the use of these peppermint oil medicines for relief of gut problems and headaches are based on their 'well-established use' in these conditions. This means that there are bibliographic data providing scientific evidence of their effectiveness and safety when used in this way, covering a period of at least 10 years in the EU.

In its assessment, the HMPC considered a number of clinical studies with peppermint oil which showed that peppermint oil relieved belly pain, discomfort and bloating feeling in patients with irritable bowel syndrome. For relief of headache, a study showed that an application of 10% peppermint oil in ethanol on the forehead reduced headache intensity.

The HMPC conclusions on the use of these peppermint oil medicines for relief of symptoms of coughs and colds, muscle pain and itching are based on their 'traditional use' in these conditions. This means that, although there is insufficient evidence from clinical trials, the effectiveness of these herbal medicines is plausible and there is evidence that they have been used safely in this way for at least 30 years (including at least 15 years within the EU). Moreover, the intended use does not require medical supervision.

In its assessment, the HMPC also considered clinical studies in relief of symptoms of cough and colds. Although a possible effect in easing breathing was seen, firm conclusions could not be drawn. Therefore, the HMPC conclusions on the use of these peppermint oil medicines are based on their long-standing use.

For detailed information on the studies assessed by the HMPC, see the HMPC assessment report.

What are the risks associated with peppermint oil medicines?

Side effects with peppermint oil medicines taken by mouth include an odour of menthol in urine and stools, pain when passing urine, inflammation of the glans of the penis, allergic reactions with headache, slow heart rate, muscle tremor, inability to co-ordinate muscle movements, anaphylactic shock (sudden, severe allergic reaction), contact sensitivity on the mucosa such as the lining of the nose and mouth, and red skin rash, heartburn, burning around the anus, blurred vision, dry mouth, nausea and vomiting.

When inhaled, side effects include apnoea (interruption of breathing), broncho- and laryngo-constriction (constriction of the airways) in allergic patients.

When applied to the skin, side effects include skin rash, inflammation and irritation of the skin, eye irritation and mucosa (lining) of the nose.

For the relief of minor belly problems, peppermint oil medicines must not be used in people with achlorhydria (absence or low levels of hydrochloric acid in the stomach), liver disease, gallstones (stones in the gallbladder) and any other bile-related problems. For relief of symptoms of coughs and colds, muscle pain and itching, peppermint oil medicines must not be used in children who have had seizures (fits).

Further information on the risks associated with these peppermint oil medicines, including the appropriate precautions for their safe use, can be found in the monograph which is published on the Agency's website under the section 'Documents': ema.europa.eu/medicines/herbal/menthae-piperitae-aetheroleum.

How are peppermint oil medicines approved in the EU?

Any applications for the licensing of medicines containing peppermint oil have to be submitted to the national authorities responsible for medicinal products, which will assess the application for the herbal medicine and take into account the scientific conclusions of the HMPC.

Information on the use and licensing of peppermint oil medicines in EU Member States should be obtained from the relevant national authorities.

Other information about peppermint oil medicines

Further information on the HMPC assessment of peppermint oil medicines, including details of the Committee's conclusions, can be found in the section 'Documents' on the Agency's website: ema.europa.eu/medicines/herbal/menthae-piperitae-aetheroleum. For more information about treatment with peppermint oil medicines, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.