Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Peppermint Oil Sanofi 0.2 ml gastro-resistant soft capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipients with known effect: less than 1mmol (23 mg) sodium per dosage unit.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gastro-resistant capsule, soft.
Dull, green-coloured, oval-shaped soft capsule containing a colourless, pale yellow or pale greenish-yellow liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Herbal medicinal product for the symptomatic relief of abdominal pain, minor spasms of the gastrointestinal tract, and flatulence, 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).

4.2 Posology and method of administration

Posology
One gastro-resistant capsule 3 times a day for patients who weigh at least 40 kg.

Paediatric population
Peppermint Oil Sanofi is contraindicated in children under 12 years of age and adolescents who weigh less than 40 kg because of safety concerns (see 4.3 and 5.3).

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

Duration of use
The gastro-resistant capsules should be taken until symptoms resolve, usually within one or two weeks. After two weeks, the patient is instructed to seek medical advice in case of persistent or deteriorating symptoms. At times when the symptoms are more persistent, the intake of gastro-resistant capsules can be continued for periods up to 3 months per treatment course.

Method of administration
For oral use.
They must not be chewed, crushed or broken before swallowing (see 4.4).

To be taken 30 minutes before meal with plenty of liquid.

4.3 Contraindications

Hypersensitivity to the active substance, to menthol or to any of the excipients listed in section 6.1.

Patients with liver disease, cholangitis, achlorhydria, gallstones and any other biliary disorders.

Patients with less than 40 kg bodyweight because of safety concerns (see 5.3).

Children under 12 years of age and adolescents with less than 40 kg bodyweight due to safety reasons (see 5.3).

4.4 Special warnings and precautions for use

The capsules should be swallowed whole, i.e. not broken or chewed, because this would release the peppermint oil prematurely, possibly causing local irritation of the mouth and oesophagus.

Patients, who already suffer from heartburn or hiatus hernia have sometimes an exacerbation of this symptom after taking peppermint oil. Treatment should be discontinued in these patients.

In case unexplained abdominal pain persists or worsens, or occurs together with symptoms like fever, jaundice, vomiting, changes in bowel movement frequency, severe constipation, unintended weight loss or blood in stool medical advice should immediately be sought.

This medicine contains less than 1 mmol sodium (23 mg) per dosage unit.

4.5 Interaction with other medicinal products and other forms of interactions

No interaction studies have been performed.

Use of food or antacids administered at the same time could cause early release of capsule content. Other medicinal products used to decrease stomach acid, like histamine-2 blockers and proton pump inhibitors may cause premature dissolution of the enteric coating and should be avoided.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no or limited amount of data from the use of peppermint oil in pregnant women. Animal studies are insufficient with respect to reproductive toxicity (see section 5.3). In the absence of sufficient data, the use during pregnancy is not recommended.

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

Fertility
Data on human fertility have not been established.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Undesirable effects are classified into the following groups in order of frequency:
very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100),
rare (≥1/10,000 to <1/1,000), very rare (<1/10,000), not known (cannot be estimated from the available data)

Table of undesirable effects per organ system

Organ Class	**Frequency**
Immune system disorder	
Allergic reaction to menthol with anaphylactic shock	Not known
Nervous system disorders	
Muscle tremor, ataxia, and headache	Not known
Eye disorders	
Blurred vision	Not known
Cardiac disorders	

Bradycardia	Not known
Gastrointestinal disorders	
Heartburn, perianal burning, nausea and vomiting, abnormal smell of feces (odour of menthol)	Not known
Skin and subcutaneous tissue disorders	
Inflammation of the glans of the penis, erythematous skin rash	Not known
Renal and urinary disorders	
Urine odour abnormal of menthol, dysuria	Not known

If other adverse reactions not mentioned above occur, a doctor or a pharmacist should be consulted.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance website: www.hpra.ie.

4.9 Overdose

Symptoms
Overdose may cause severe gastro-intestinal symptoms, diarrhoea, rectal ulceration, epileptic convulsions, loss of consciousness, apnoea, nausea, disturbances in cardiac rhythms, ataxia and other CNS problems, probably due to the presence of menthol.

Management
In the event of overdose, the stomach should be emptied by gastric lavage. Observation should be carried out with symptomatic treatment if necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: *Other drugs for functional gastrointestinal disorders*
ATC code: A03AX15

Mechanism of action
The enteric coating delays the release of the peppermint oil until it reaches the distal small bowel, exerting local effects of colonic relaxation.

Pharmacodynamic effects
In vivo studies
Several studies in healthy subjects or patients, who underwent exposure to peppermint oil either by topical intraluminal (stomach or colon) or oral administration by single doses, result in effects, indicating a substantial spasmolytic action of peppermint oil on the smooth muscles of the gastrointestinal tract.

Peppermint oil appears to enhance production of bile. The choleretic and antifoaming effects of peppermint oil play an additional role to the antispasmodic action, decreasing the abdominal distension, as the discomfort and abdominal pain.

5.2 Pharmacokinetic properties

Absorption
Menthol and other terpene constituents of peppermint oil are fat soluble and rapidly absorbed at the proximal small intestinal tract.

Distribution
No data on distribution are available.

Biotransformation
Menthol, the main constituent of peppermint oil, is metabolized by glucuronidation.

Elimination
To some extent, they are excreted in the form of glucoronide. The peak menthol urinary excretion levels were lower and secretion delayed with the modified-release preparations, than with the immediate release preparations.
In one clinical study with peppermint oil and one clinical study with menthol, some inhibition of CYP3A4 activity has been described.

5.3 Preclinical safety data

Preclinical data concerning repeated dose toxicity are incomplete and therefore of limited informative value. Based on the long standing clinical use there is a sufficiently established safety of the usage of peppermint oil in the given posology (up to 0.6 mL daily) in humans.
A standard battery of genotoxicity studies (in-vitro bacterial reverse mutation assay, in-vitro mouse lymphoma assay, in-vivo bone marrow micronucleus assay) showed that peppermint oil has no genotoxic potential.

The recommended maximum daily intake of pulegone and menthofuran for a life-long exposure is 0.75 mg/kg bodyweight per day. For a person with at least 40 kg bodyweight the daily intake of 3 capsules of this medicinal product does not exceed this recommendation. No cases of liver damage caused by peppermint oil or mint oil were reported under this posology.
Tests on reproductive toxicity and carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

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

6.5 Nature and contents of container

The gastro-resistant soft capsules are packaged in blister packs. Folding boxes with blisters (PVC/PCTFE-aluminium) containing 6, 12, 24 or 48 capsules.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements

7 MARKETING AUTHORISATION HOLDER

Sanofi-Aventis Ireland Limited T/A SANOFI
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0540/196/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16th April 2021

10 DATE OF REVISION OF THE TEXT

August 2021