PROFESSIONAL INFORMATION
SPASMOPEP® PEPPERMINT OIL SOFTGEL CAPSULES softgel capsules.

- Complementary Medicine.
- D33.6 Discipline-Specific Traditional Claims – Western Herbal Medicine.
- This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS
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1. NAME OF THE MEDICINE
SPASMOPEP® PEPPERMINT OIL SOFTGEL CAPSULES (softgel capsules)
2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each softgel capsule contains:

Active ingredients	Per softgel capsule	Per maximum daily dose (3 softgel capsules)
Mentha x piperita L. (pro. sp.) (Peppermint) essential oil	0,2 ml	0,6 ml

Spasmopep® Peppermint Oil is sugar and preservative free.
For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Gastro-resistant softgel capsule.
Spasmopep® Peppermint Oil softgel capsules are green, opaque, oblong softgel capsules filled with a clear liquid that has a minty odour.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
Spasmopep® Peppermint Oil softgel capsules can support the body in the symptomatic relief of minor spasms of the gastrointestinal tract, flatulence and abdominal pain, especially in patients with irritable bowel syndrome. Peppermint oil and its major component, menthol, have carminative, anti-spasmodic and choleretic properties.
Efficacy of support may vary between users.
4.2 Posology and method of administration
The recommended daily dosage is
Adults and Children 8 years and older:
One (1) softgel capsule three (3) times per day, 30 minutes before meals taken whole with a glass of water.
Advise patients not to bite or chew (softgel capsules must be swallowed whole with water).
Spasmopep® Peppermint Oil softgel capsules should be taken until symptoms resolve, usually within one (1) or two (2) weeks. At times when the symptoms are more persistent, the intake can be continued for periods of no longer than three (3) months per course.
Advise the patient to not take dosage at the same time as other medications (see **4.5**).
4.3 Contraindications
- Must not be given to patients that are hypersensitive (allergic) to peppermint oil, menthol or salicylates.
- Must not be given to patients with known hypersensitivity to any of the ingredients of Spasmopep® Peppermint Oil (see section 6.1 List of excipients). Patients should be advised to consult their medical practitioner if in doubt.
- Must not be given to patients with symptoms of gastro-oesophageal reflux disease (GORD) or hiatus hernia.
- Must not be given to patients with gallbladder or bile duct obstruction, cholangitis or a history of gall or kidney stones and any other biliary disorders.
- Must not be given to patients with severe liver disease.
- Must not be given to patients that have achlorhydria (achlorydia increases gastric pH, which may result in premature dissolution of the softgel coating).
- Patients taking any chronic medication should not use this product without consulting their medical practitioner.

4.4 Special warnings and precautions for use
- Advise patients not to bite or chew the capsules as this would release the peppermint oil prematurely and could possibly cause local irritation of the mouth and oesophagus.
- Patients who suffer from heartburn may have exacerbation of this symptom after taking peppermint oil. Treatment should be discontinued in these patients.
- Avoid the use of other medicinal products during use of the product.
- Use with caution in patients that have diarrhoea as increased intestinal motility may cause unabsorbed menthol in the anal mucosa and anal burning.
- Use with caution in patients with iron-deficiency anaemia as peppermint oil may inhibit iron absorption.
- Advise patients to consult a healthcare practitioner if symptoms persist or worsen.
- Do not exceed the daily recommended dose.
- Do not use after the date of expiry.
- Products containing herbal ingredients may interact with some medication.

Porphyria
Safety has not been established.
4.5 Interaction with other medicinal products and other forms of interactions
No interaction studies have been performed on Spasmopep® Peppermint Oil softgel capsules, see below interactions with individual ingredients.

Active ingredient	Medicine	Description
Peppermint oil	Antacids (e.g., magnesium hydroxide), proton-pump inhibitors (e.g., omeprazole), histamine-2 blockers (e.g., cimetidine)	Medication that decrease stomach acid and raise gastric pH can cause premature dissolution of softgel capsules. Take these medications at least two (2) hours before or after Spasmopep® Peppermint Oil softgel capsules.
Peppermint oil	Iron supplements	Concomitant use of peppermint with iron may inhibit iron absorption.

4.6 Fertility, pregnancy and lactation
Pregnancy
Safety for use during pregnancy has not been established therefore this product should not be used in patients who are pregnant.
Breastfeeding
Safety for use during lactation (breastfeeding) has not been established (see **4.3**), therefore this product should not be used if patients are lactating (breastfeeding).
Fertility
There are no known effects of Spasmopep® Peppermint Oil softgel capsules on fertility.
4.7 Effects on the ability to drive and use machines.
Based on the side effect profile, Spasmopep® Peppermint Oil softgel capsules should not affect your ability to drive or operate machinery.
It is not always possible to predict to what extent Spasmopep® Peppermint Oil softgel capsules may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which Spasmopep® Peppermint Oil softgel capsules affects them.
4.8 Undesirable effects
Spasmopep® Peppermint Oil softgel capsules are generally well tolerated with the occurrence of adverse events unknown.
Patients experiencing any side effects or sensitivity to any of the ingredients, should discontinue use.
Adverse reactions reported in the literature are listed below, by system organ class and frequency. Frequencies are defined as:
- 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)

System Organ Class	Frequency	Adverse Event
Immune system disorders	Not known	Hypersensitivity reactions or anaphylaxis, symptoms include difficulty breathing or swallowing, angioedema, itchy throat, urticaria itching, headache, bradycardia, muscle tremor and ataxia which are exacerbated if taken in conjunction with alcohol.
Gastrointestinal disorders	Not known	Abdominal pain, anal/perianal burning, belching, diarrhoea, dry mouth, heartburn , nausea and vomiting.
Skin and subcutaneous tissue disorders	Not known	Hypersensitivity reaction (skin rash and itching).

If symptoms persist, or if any adverse reactions occur, advise the patient to consult a healthcare provider.
Reporting of suspected adverse reactions
Reporting of suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicine.
Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form,**" found online at: https://www.sahpra.org.za/Publications/Index/8 or via the "**Adverse drug reaction and product quality reporting**" website found online at: https://www.sahpra.org.za/Publications/Index/8.
4.9 Overdose
Symptoms
See 4.8 Undesirable effects
In overdose, side effects can be precipitated and/or be increased.
There is no evidence that this product can lead to an overdose when used as recommended.
Treatment
If an accidental overdose occurs, treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Category and class: D.33.6 Complementary Medicines: Discipline- Specific Traditional Claims
Pharmacotherapeutic classification: Western Herbal Medicine
ATC code A03AX. Antispasmodic and carminative.
Peppermint oil
The principal pharmacodynamic effect of peppermint oil is a dose-related antispasmodic effect on the smooth muscles of the gastrointestinal tract. Peppermint oil is slowly released as the matrix passes along the gut, exerting colonic relaxation by interfering with the movement of calcium across the cell membrane. Peppermint oil also appears to promote bile production. The choleretic and antifoaming effects of peppermint oil play an additional role to the antispasmodic action, decreasing abdominal distension and abdominal pain.
5.2 Pharmacokinetic properties
Peppermint oil
Absorption: Menthol and other terpene constituents of peppermint oil are fat soluble and are relatively rapidly absorbed in the proximal intestine after oral administration of enteric coated peppermint formulations.
Metabolism: The primary biliary metabolite of peppermint oil, menthol, is metabolized by glucuronidation.
Excretion: Peppermint oil metabolites are excreted (mainly as menthol glucuronide) via the urine and minor quantities are excreted in faeces.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Bovine gelatine capsule
Colourants (C818/S, C814/S, C148/S)
Glycerine
Soybean oil
6.2 Incompatibilities
None known
6.3 Shelf life
24 months
6.4 Special precautions for storage
- Store in a dry place at or below 25 °C.
- Protect from light and moisture.
- Do not use after the expiry date printed on the carton.

6.5 Nature and contents of container
Spasmopep® Peppermint Oil softgel capsules are green, and oblong. Spasmopep® Peppermint Oil softgel capsules is available in a blister pack with one (1) strip of 10 softgel capsules and is packaged in a printed unit carton that includes a patient information leaflet.
Spasmopep® Peppermint Oil softgel capsules is also available in a blister pack with three (3) strips of 10 softgel capsules each and is packaged in a printed unit carton that includes a patient information leaflet.
6.6 Special precautions for disposal and other handling
No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION
Nativa (Pty) Ltd
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8. REGISTRATION NUMBER(S)
To be allocated

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
To be allocated

10. DATE OF REVISION OF THE TEXT
March 2024

PPIL002/02