

Front

**Mintec GR**<sup>TM</sup> *Soft Gel*  
Gastro-Resistant Capsule  
PEPPERMINT OIL 0.2 ml

منٹیک جی آر

**COMPOSITION:**

Each soft gel capsule contains:  
Peppermint oil ..... 0.2 ml.

**Product Specs.:** Manufacturer's

**DESCRIPTION:**

Mintec GR™ capsules contain a naturally occurring oil extracted from the peppermint plant which is used to relieve the symptoms of irritable bowel syndrome (IBS). Mintec GR™ relaxes spasm in the muscle of the bowel wall and helps restore normal bowel contractions. This helps to decrease the trapping of air and other bowel contents and relieves abdominal bloating, wind, discomfort and pain.

**CLINICAL PHARMACOLOGY:**

**Mechanism of Action:** Dose-dependent antispasmodic effect of peppermint oil is largely mediated by its menthol constituent. It is proposed that peppermint oil relaxes gastrointestinal smooth muscle and attenuates contractile responses by reducing the influx of extracellular calcium ions.

**Pharmacokinetics:**

**Absorption:** An open cross-over study was conducted in eight healthy volunteers, to compare the excretion pattern of menthol (the major constituent of peppermint, oil) from peppermint oil contained in gastro-resistant soft gelatin capsules (peppermint oil), and similar, uncoated capsules. In each leg of the study, each volunteer received 0.4 ml of peppermint oil as two capsules of one of the preparations. The excretion of the oil in the urine (as the glucuronide) was followed over a 24-hour period. Coated peppermint oil capsules significantly delayed the rate of excretion of menthol compared with the non-coated capsules. The maximum amounts of menthol were excreted within 0 to 2 hours following administration of uncoated capsules and between 2 to 4 hours following peppermint oil administration. There were no significant differences between treatments in terms of the maximum or total amounts of menthol excreted over the 24-hour post-dose period.

**Pharmacodynamic properties:**

**Pharmacotherapeutic group:** Drugs for functional bowel disorders.

**ATC Code:** A03A Drugs for functional bowel disorders; A02D (Anti-flatulent). Peppermint oil is an aromatic carminative which acts locally to relax gastro intestinal smooth muscle and relieve gastro-intestinal flatulence and colic. The enteric coating of the capsules is designed to delay release of the peppermint oil beyond the stomach and upper small bowel.

**Metabolism and excretion:** The predominant biliary metabolite of peppermint oil is menthol glucuronide, which undergoes enterohepatic circulation. The urinary metabolites are products of hydroxylation at the C-7 methyl group at C-8 and C-9 of the isopropyl moiety, forming a series of mono- and dihydroxymenthols and carboxylic acids, some of which are excreted in part as glucuronic acid conjugates.

Peppermint oil is eliminated mainly via the bile following oral administration, with glucuronide and sulphate metabolites predominantly. The metabolites, mainly menthol glucuronide and mono- or di-hydroxylated menthol derivatives, may also undergo approximately equal renal and fecal excretion. Renal recovery of total menthol within 24 hours was dose-dependent whereas the recovery in bile was substantially higher over 8 hours.

**Special Populations:**

**Pregnancy and breastfeeding:**

**Ask your doctor or pharmacist for advice if you:**

- are pregnant,
- think you might be pregnant,
- are thinking of becoming pregnant, before taking Mintec GR™.

**Take special care with Mintec GR™ if you:**

- are aged 40 years or over, and it is some time since your last attack
- notice your symptoms have changed
- have passed blood from the bowel
- have suffered abnormal vaginal bleeding or discharge
- have severe constipation
- have difficulty or pain in passing urine
- are suffering from nausea or vomiting
- have lost your appetite, or lost weight
- are pale and tired
- have recently had fever
- are pregnant or possibly pregnant
- have recently travelled abroad

**INDICATIONS AND USAGE:**

The symptomatic relief of minor spasms of the gastrointestinal tract, flatulence and abdominal pain, especially in patients with irritable bowel syndrome.

**Adults and elderly:**

Take one capsule three times a day, preferably before meals. Do not take the capsules immediately after food. If your symptoms are particularly severe, the dose may be increased to two capsules three times a day. Mintec GR™ should be taken until your symptoms resolve, but may be continued for up to 3 months.

**Children:**

Mintec GR™ is not recommended for use in children.

**Taking other medicines:**

Do not take Mintec GR™ immediately after food. Skin rash, slow heartbeat, or trembling and unsteadiness are rare allergic reactions which may occur when Mintec GR™ is taken with alcohol. Please ask your doctor before taking Mintec GR™.

**ADVERSE REACTIONS:**

**Heartburn may occur. If you develop this symptom, stop taking the capsules and see your doctor. Rarely, allergic reactions to Mintec GR™ have been reported, including:**

- skin rashes
- slow heartbeat
- trembling and unsteadiness.

These may also occur if Mintec GR™ is taken with alcohol.

**DRUG INTERACTIONS:**

Acenocoumarol	The serum concentration of Acenocoumarol can be increased when it is combined with Peppermint oil.
Alfuzosin	The metabolism of Alfuzosin can be decreased when combined with Peppermint oil.
Alprazolam	The metabolism of Alprazolam can be decreased when combined with Peppermint oil.
Aripiprazole	The metabolism of Aripiprazole can be decreased when combined with Peppermint oil.
Aripiprazole lauroxil	The metabolism of Aripiprazole lauroxil can be decreased when combined with Peppermint oil.
Atorvastatin	The metabolism of Atorvastatin can be decreased when combined with Peppermint oil.
Cilostazol	The metabolism of Cilostazol can be decreased when combined with Peppermint oil.
Colchicine	The metabolism of Colchicine can be decreased when combined with Peppermint oil.
Eliglustat	The metabolism of Eliglustat can be decreased when combined with Peppermint oil.
Eszopiclone	The metabolism of Eszopiclone can be decreased when combined with Peppermint oil.
Fentanyl	The metabolism of Fentanyl can be decreased when combined with Peppermint oil.
Finerenone	The serum concentration of Finerenone can be increased when it is combined with Peppermint oil.
Haloperidol	The serum concentration of Haloperidol can be increased when it is combined with Peppermint oil.
Ibrutinib	The metabolism of Ibrutinib can be decreased when combined with Peppermint oil.
Iloperidone	The metabolism of Iloperidone can be decreased when combined with Peppermint oil.
Levamlodipine	The serum concentration of Levamlodipine can be increased when it is combined with Peppermint oil.
Lovastatin	The metabolism of Lovastatin can be decreased when combined with Peppermint oil.
Midazolam	The serum concentration of Midazolam can be increased when it is combined with Peppermint oil.
Prucalopride	The metabolism of Prucalopride can be decreased when combined with Peppermint oil.
Retapamulin	The metabolism of Retapamulin can be decreased when combined with Peppermint oil.
Roflumilast	The serum concentration of Roflumilast can be increased when it is combined with Peppermint oil.
Ropinirole	The risk or severity of adverse effects can be increased when Peppermint oil is combined with Ropinirole.
Tacrolimus	The serum concentration of Tacrolimus can be increased when it is combined with Peppermint oil.
Tofacitinib	The metabolism of Tofacitinib can be decreased when combined with Peppermint oil.
Tramadol	The metabolism of Tramadol can be decreased when combined with Peppermint oil.
Vardenafil	The metabolism of Vardenafil can be decreased when combined with Peppermint oil.
Voxelotor	The serum concentration of Voxelotor can be increased when it is combined with Peppermint oil.
Warfarin	The serum concentration of Warfarin can be increased when it is combined with Peppermint oil.
Zolmitriptan	The metabolism of Zolmitriptan can be decreased when combined with Peppermint oil.
Zopiclone	The metabolism of Zopiclone can be decreased when combined with Peppermint oil.

**OVERDOSAGE:**

Oral LD50 value in rat is 2426 mg/kg MSDS. In fasted mice, the LD50 following oral administration was 2410 mg/kg. Higher doses of peppermint oil has the potential to induce menstruation, bronchospasm, tongue spasms, and, possibly, respiratory arrest in addition to potential hepatotoxicity and nephrotoxicity.

Overdose may cause severe gastrointestinal 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. In the event of overdose, the stomach should be emptied by gastric lavage. Observation should be carried out with symptomatic treatment if necessary. A near fatal case of high dose peppermint oil ingestion was reported, the overdose was characterized by comatose and reduced heart rate.

**INSTRUCTIONS:**

- Store below 30°C.
- Protect from heat, sunlight & moisture.
- Keep out of the reach of children.
- To be sold on the prescription of a registered medical practitioner only.

**USUAL ADULT DOSAGE:** As directed by the physician.

*For mild and proactive gut-health support in IBS:*

Take one capsule three times a day.

*Moderate & Severe Cases of IBS:*

Two capsules three times a day for 4 to 6 weeks.

**NOTE:**

- Do not exceed eight capsules per day.
- Capsule should be swallowed whole, not chewed.
- Preferably capsule should be taken 30 to 90 minutes before meal.

**PRESENTATION:**

**Mintec GR™ Soft Gel Capsule** : Pack of 3 x 10 capsules.

ہدایات:  
۳۰ درجہ سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔

گرمی، دھوپ اور نمی سے بچائیں۔

بچوں کی پہنچ سے دور رکھیں۔

صرف مستند ڈاکٹر کے نسخے پر فروخت کریں۔

خوراک بالغ کیلئے:

ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

معتدل کیفیت میں: ایک کپسول دن میں تین بار لیں۔

شدید کیفیت میں: دو کپسول دن میں تین بار ۴ سے ۶ ہفتوں تک لیں۔

نوٹ:

ایک دن میں آٹھ سے زیادہ کپسول نہ لیں۔

پورا کپسول بغیر چبائے نگل لیں۔

ترتیبی طور پر کپسول کو کھانے سے ۳۰-۹۰ منٹ پہلے لیں۔

Manufactured by:  
SHMZ Labs & Pharmaceuticals  
101 Sundar Industrial Estate, Lahore, Pakistan.

Distributed by:  
Nexpharm Healthcare (Pvt.) Ltd.  
65 Industrial Estate, Kot Lakhpat, Lahore, Pakistan.

FOR FURTHER INFORMATIONS PLEASE CONTACT:



Manufactured for:  
CCL Pharmaceuticals (Pvt.) Ltd.  
62 Industrial Estate, Kot Lakhpat, Lahore, Pakistan.

