

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1 NAME OF THE MEDICINAL PRODUCT**

Mintec Capsules

### **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each capsule contains 0.2ml peppermint oil.  
For a full list of excipients, see section 6.1.

### **3 PHARMACEUTICAL FORM**

Gastro-resistant capsules, soft (for oral use).  
Size no. 4, one half of capsule is green, the other half is white.

### **4 CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

Symptomatic relief of irritable bowel or spastic colon syndrome.

## **4.2 Posology and method of administration**

Adults: one capsule orally three times a day, preferably before meals with a small quantity of water, but not immediately after food. The capsules must not be broken or chewed.

When symptoms are more severe, the dose may be increased to two capsules three times a day.

Mintec should be taken until symptoms resolve, but may be continued for up to 2 to 3 months.

Elderly: Dose as for adults.

Paediatric patients: Mintec is not recommended for children.

## **4.3 Contraindications**

Hypersensitivity to peppermint oil, salicylates or to any other excipients of Mintec..

## **4.4 Special warnings and precautions for use**

If this is the first occurrence of these symptoms, a doctor should be consulted before self medication begins, to confirm the appropriateness of the treatment. Before beginning self medication, a doctor should be consulted if:

The patient is over 40 years old and it is some time since the last attack of irritable bowel or spastic colon syndrome, or the symptoms have changed; blood has been passed from the bowel; the patient has experienced nausea or vomiting, loss of appetite or loss of weight, paleness and tiredness, severe constipation, fever, abnormal vaginal bleeding or discharge, difficulty or pain in passing urine.

If the patient has recently travelled abroad, or is pregnant or possibly pregnant, they should consult their doctor prior to self medication.

If there are new symptoms or worsening of the condition or failure to improve over two weeks of treatment, the patient should consult their doctor.

In patients with pre-existing heartburn, symptoms may be exacerbated.

Mintec capsules contain sorbitol (E420) therefore, patients with rare hereditary problems of fructose intolerance should not take this medicine.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

None known.

#### **4.6 Fertility, Pregnancy and lactation**

The usual precautions concerning the administration of any drug during pregnancy should be observed.

#### **4.7 Effects on ability to drive and use machines**

Mintec has no known influence on the ability to drive and use machines.

#### **4.8 Undesirable effects**

Heartburn, and rarely allergic reactions including erythematous skin rash, bradycardia, muscle tremor and ataxia, which may also occur in association with alcohol.

##### **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 the Yellow Card Scheme, Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

#### **4.9 Overdose**

Treatment consists of gastric lavage, together with symptomatic and supportive measures.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Drugs for function bowel disorders.  
ATC Code: A03A Drugs for functional bowel disorders; A02D (Antiflatulents).

Mintec (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.

## **5.2 Pharmacokinetic properties**

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 (Mintec), 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.

Mintec 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 Mintec 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.

## **5.3 Preclinical safety data**

No additional data available.

# **6 PHARMACEUTICAL PARTICULARS**

## **6.1 List of excipients**

Capsule shell:

Gelatin

Sorbitol (E420)

Glycerol

Titanium dioxide (E171)

Sodium copper chlorophyllin (E141)

Enteric coat:

Methacrylic acid-Ethyl acrylate-Copolymer (1:1)

Polysorbate 80  
Sodium laurilsulfate  
Propylene glycol  
Glycerol monostearate

## **6.2 Incompatibilities**

Not applicable.

## **6.3 Shelf life**

36 months.

## **6.4 Special precautions for storage**

Do not store above 25°C.  
In order to protect from light, store in the original package.

## **6.5 Nature and contents of container**

Aluminium/PVC/PVDC blister strips in packs of 2, 3 (sample), 4, 6, 12, 24, 25, 84 and 100.

Not all pack sizes may be marketed.

**6.6 Special precautions for disposal**

None.

**7 MARKETING AUTHORISATION HOLDER**

Teofarma S.r.l.  
Via Fratelli Cervi 8  
27010 Valle Salimbene (PV)  
Italy

**8 MARKETING AUTHORISATION NUMBER(S)**

PL 16250/0015

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE  
AUTHORISATION**

17/06/2008

**10 DATE OF REVISION OF THE TEXT**

06/02/2024