

Patient information leaflet

Mint-o-cool Tablets

(Magnesium trisilicate 250 mg and Dried aluminium hydroxide gel 120 mg)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you. This medicine is available without prescription. However, you still need to take Mint-o-cool Tablets carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 7 days.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section d.

In this leaflet:

- a. What Mint-o-cool Tablets are and what they are used for
- b. Before you take Mint-o-cool Tablets
- c. How to take Mint-o-cool Tablets
- d. Possible side effects
- e. How to store Mint-o-cool Tablets
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a. What Mint-o-cool Tablets are and what they are used for

These tablets contain two active ingredients, magnesium trisilicate and dried aluminium hydroxide gel. Mint-O-Cool is used in the relief of hyper acidity, gastritis, acid indigestion, gastroesophageal reflux and management of peptic ulcers.

b. Before you take Mint-o-cool Tablets

Do not take these tablets if you:

- are allergic (hypersensitive) to magnesium trisilicate, dried aluminium hydroxide gel or to any of the other ingredients in the tablets (these are listed in Section f)
- have kidney failure
- have a blood condition called hypophosphataemia (low concentration of phosphate in the blood).

Check with your doctor before taking these tablets if you:

have kidney problems as this may result in hypermagnesaemia (high blood levels of magnesium). For symptoms of hypermagnesaemia see section d - Possible Side Effects.

Check with your doctor or pharmacist before taking these tablets if you are taking any other medicines, including any that you can buy without a prescription.

This is especially important if you are taking:

- the following medicines to treat infections: ciprofloxacin, pivampicillin, rifampicin, medicines called tetracyclines e.g. oxytetracycline, itraconazole or ketoconazole
- flecainide or mexiletine (to treat irregular heartbeat)

- quinine, chloroquine or hydroxychloroquine (to treat malaria)
- phenothiazines e.g. chlorpromazine, pericyazine
- (to treat schizophrenia and other mental disorders)
- phenytoin (to treat epilepsy)
- oral iron e.g. ferrous sulphate (to treat
- iron-deficiency anaemia)
- penicillamine (to treat severe rheumatoid arthritis)
- diflunisal or aspirin (painkillers)
- sucralfate (to treat stomach ulcers).

Other special warnings

Pregnancy and breast-feeding: Check with your doctor before taking this medicine if you are pregnant or breast feeding.

Important information about some of the ingredients of this medicine: Contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

c. How to take Mint-o-cool Tablets

Mint-O-Cool is administered orally. Tablets should be chewed before being swallowed.

Dose and frequency of administration depend on the acid secretory rate of the stomach, gastric emptying time and the disorder being treated. In fasting subjects antacids have duration of action of 20-60 minutes. However, if the drugs are administered 1 hour after meals, acid neutralizing effects may persist up to 3 hours. Antacids should be used for longer than 2week periods only under the management of a physician and as part of a carefully planned therapeutic regimen.

Not recommended for use in children under 10 years of age.

Do not take more than the dose stated above.

If symptoms persist for more than 7 days, or if you find that you need to take the tablets frequently, consult your doctor.

If you have taken too many tablets:

Contact your doctor straight away or go to the nearest hospital casualty department. Take with you any remaining tablets and the pack so that the medicine can be identified.

d. Possible side effects

Mint-o-cool Tablets are suitable for most people if they are taken at the recommended dose, but, like all medicines they can sometimes cause side effects, although not everybody gets them.

Feeling or being sick, constipation and diarrhoea have been reported.

Patients who have kidney problems may experience hypermagnesaemia (an abnormally high level of magnesium in the blood). Symptoms may include flushing of the skin, thirst, low blood pressure, drowsiness, confusion, loss of tendon reflexes, muscle weakness, breathing difficulties, irregular heartbeat, coma and cardiac arrest (heart stops pumping blood around the body).

Patients taking large doses of this medicine, or those with low phosphate diets taking normal doses, may experience problems with the levels of phosphate and calcium in their bodies.

This may increase the risk of softening of the bones (osteomalacia).

Kidney stones may occur if the tablets are taken for a long time by patients who have kidney problems. If you have a kidney stone the main symptom is severe pain felt in the belly area or side of the back which may move to the groin area or the testicles. Other symptoms include unusual urine colour, blood in the urine, chills, fever, feeling or being sick.

Do not be concerned by this list of side effects, you may not get any of them.

e. How to store Mint-o-cool Tablets

- Do not store above 30°C
- Protect from light
- Keep out of reach of children.
- Do not take the tablets if the expiry date on the pack has passed. If you have any medicines that are out of date, return them to your pharmacist for safe disposal

f. Further information

What Mint-o-cool Tablets contains

Each tablet contains Magnesium Trisilicate BP 250 mg, Dried Aluminium Hydroxide gel BP 120 mg. Other ingredients are Maize starch (Mixing), Maize starch (Paste), Sodium methyl paraben, Sodium propyl paraben, Sodium saccharin, Ponceau 4R supra, Sucrose, Methylene Chloride, Menthol, Peppermint oil, Colloidal Silicon Dioxide and Magnesium stearate.

What Mint-o-cool Tablets looks like and contents of the pack

A pink coloured round flat tablets with break line on one side and plain on other side

10 tablets are packed in Aluminium/ transparent PVC blister; such 10 blisters are packed in a unit carton along with literature insert.

1000 tablets packed in polythene bag and contained in HDPE Container with leaflet.

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