

PRACTICE GUIDANCE: OTC OMEPRAZOLE

Following reclassification from prescription-only to pharmacy medicine status, omeprazole 10mg is now available for sale over the counter (OTC). This guidance outlines the OTC indications for the drug, as well as important points to consider when counter prescribing



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WHO TO REFER TO A GP

- Those aged 45 years or over:
 - with new onset of symptoms within the last year which lasted for at least four weeks
 - whose symptoms have changed
- People of any age with heartburn associated with the following symptoms:
 - unintentional weight loss
 - anaemia
 - gastrointestinal bleeding
 - dysphagia
 - pain on swallowing
 - persistent vomiting or vomiting with blood
 - epigastric mass
 - previous gastric ulcer or surgery
 - jaundice
- Those sufferers who have had to take an antacid or acid suppressor continuously for four or more weeks in order to control their symptoms
- Those who have taken an indigestion or heartburn remedy for two weeks with no relief of symptoms
- Those sufferers who are particularly anxious regarding the significance of their symptoms
- Those sufferers with any other significant medical condition (including hepatic or renal impairment)
- Pharmacists should recommend that heartburn sufferers with long-term recurrent symptoms should see their doctor at regular intervals
- Pregnant or breastfeeding heartburn sufferers

WHAT ARE THE OTC INDICATIONS?

OTC omeprazole is indicated for the relief of heartburn symptoms associated with acid reflux in adults 18 years and over.

HOW DOES OMEPRAZOLE WORK?

Omeprazole works by suppressing gastric acid secretion in the stomach. Omeprazole suppresses the final stage of gastric hydrochloric acid production by blocking the hydrogen-potassium ATPase enzyme (also known as the proton pump) in the parietal cells of the stomach wall. Proton pump inhibitors (PPIs) have been shown to be highly effective for suppressing intragastric acidity and for providing 24-hour relief. PPIs, including omeprazole, are generally accepted as being among the most effective medicines for the relief of heartburn.

IS IT HEARTBURN?

Customers often use the terms indigestion, dyspepsia and heartburn interchangeably. It is important that the pharmacist/assistant is sure that the patient is describing heartburn symptoms associated with gastro-oesophageal reflux.

Heartburn is a chronic, intermittent, relapsing disorder of varying frequency and severity manifesting as a transient retrosternal (behind the sternum) discomfort usually described as an acidic or burning



POINTS TO CONSIDER WHEN RECOMMENDING OMEPRAZOLE

- Omeprazole 10mg should be considered alongside other heartburn remedies as first line therapy for heartburn sufferers (18 years or over) who experience intermittent and relapsing symptoms.
- Patients should be advised that they may start to experience symptomatic relief after a day or so of starting treatment and that this will increase to a maximum effect after three or four days.
- The starting dose is two 10mg (20mg) tablets once daily and may need to be taken for three to four days to obtain symptom relief. When symptoms improve the dose can then be reduced to one 10mg tablet daily, returning to two tablets if symptoms return. The lowest effective dose should always be used.
- Patients requiring immediate symptomatic relief can be advised to take a simple antacid or antacid/alginat at the same time for the first few days of treatment if necessary.
- Patients taking omeprazole should be advised not to take H₂-antagonists at the same time.
- Symptomatic relief may continue after finishing the course and omeprazole may give weeks of remission from recurrent attacks.
- Tablets should be swallowed whole with plenty of liquid (eg, water or fruit juice) before a meal and should not be crushed or chewed.
- Alcohol and food do not affect the absorption of omeprazole.
- Check for possible causal agents (eg, aspirin and other NSAIDs).
- Consider counselling where appropriate on lifestyle modifications that will reduce the problem of reflux-related heartburn: weight reduction, propping up the bedhead and avoiding provoking factors (such as bending down, coffee, smoking, heavy meals late at night, fatty or spicy foods and alcohol).
- If omeprazole is recommended, monitoring of patients receiving warfarin or phenytoin is recommended and a reduction of the warfarin or phenytoin dose may be necessary. (See British National Formulary or the summary of product characteristics for information on: cilostazol, tacrolimus, voriconazole, digoxin and ¹³C-urea breath tests).

sensation. The pain of heartburn may be sharp or gripping and can radiate to the throat and back.

In clear cases of heartburn the patient will report that the pain is associated with acid regurgitation (also known as reflux which is the movement of part of the acidic contents from the stomach up into the oesophagus) and is made worse by eating large meals, bending over or lying flat (especially in bed at night). Patients may also report that hot, alcoholic or acidic drinks (such as orange juice) cause discomfort.

Consider asking the customer to describe the symptoms and point to the area of pain. If they describe an acid or burning pain associated with acid regurgitation and point to the gullet/sternum area then the diagnosis is probably heartburn.

HOW TO TAKE OTC OMEPRAZOLE

Omeprazole is available over the counter as a 10mg gastro-resistant tablet.

The tablets should be swallowed whole with plenty of liquid (eg water or fruit juice) before a meal. It is important that the tablets should not be crushed or chewed.

Omeprazole has the best benefit if taken daily as a course of treatment.

The initial starting dose is 20mg (that is, two tablets) once daily and may need to be taken for 3 to 4 days to obtain symptom relief.

When symptoms improve the dose can then be reduced to one 10mg tablet daily, returning to two tablets if symptoms return. The lowest effective dose should always be used and the maximum daily dose is two tablets. If continuous treatment for more than 4 weeks is required to prevent symptoms or no relief is obtained within two weeks then the patients should be referred to their doctor.

WHEN COULD OTC OMEPRAZOLE BE COUNTER PRESCRIBED?

Omeprazole 10mg should be considered alongside other heartburn remedies as first line therapy for heartburn sufferers who experience intermittent and relapsing symptoms.

After confirming a diagnosis of probable heartburn and ruling out those patients who may need GP referral (see overleaf), the pharmacist/assistant may recommend an OTC heartburn treatment based on the nature, severity and frequency of the symptoms presented.

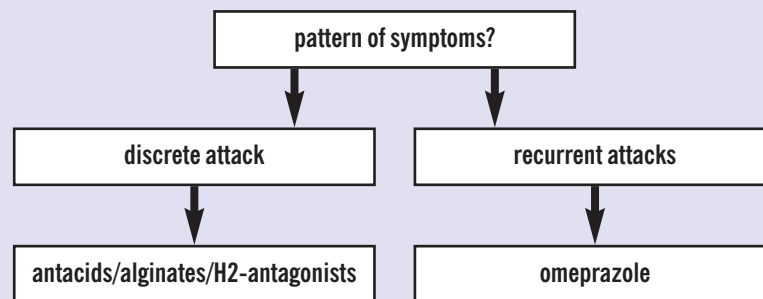
Patients experiencing a discrete one-off attack of heartburn symptoms and requiring rapid symptomatic relief can be recommended a simple antacid preparation, antacid/alginate combination or an

H₂-antagonist. Patients experiencing recurrent attacks may benefit from OTC omeprazole (see Fig 1).

Patients should be advised that they may start to experience symptomatic relief after a day or so of starting treatment with OTC omeprazole and that this will increase to a maximum effect after three or four days. Heartburn sufferers experiencing recurrent attacks but also seeking immediate symptomatic relief in a pharmacy can be advised to take a simple antacid or antacid/alginate combination for a few days while omeprazole reaches symptomatic effect.

Patients should not take another "acid suppressor" (eg, an H₂-antagonist) concomitantly with omeprazole.

Figure 1



CAUTIONS

Omeprazole, like other PPIs, should be used with caution in patients with liver disease, in pregnancy and in breast-feeding. PPIs may mask symptoms of gastric cancer; particular care is

required in those whose symptoms change and in those over 45 years of age; the presence of gastric malignancy should be excluded before treatment.

See overleaf for details of when to refer a heartburn sufferer to their GP.

ADVERSE EFFECTS OR DRUG INTERACTIONS

The reclassification of omeprazole 10mg tablets to pharmacy medicine status does not pose any additional safety concerns not already included in the SPC.

Omeprazole is well tolerated and side effects have generally been mild and reversible. Headache, diarrhoea, nausea, abdominal pain and rash are among adverse side effects reported with omeprazole (see summary of product characteristics for full details).

Omeprazole is an inhibitor of cytochrome P450 and may increase serum concentrations of other drugs metabolised by cytochrome P450 (such as warfarin, phenytoin and diazepam). It may also alter absorption of drugs dependent on gastric pH for absorption, such as itraconazole, ketoconazole and digoxin. Concomitant use of omeprazole and cilostazol results in an increase in the plasma concentration of cilostazol, therefore concomitant use should be avoided.

OVERALL ASSESSMENT

OTC omeprazole is effective for controlling intermittent and relapsing heartburn symptoms, but it can take a few days to relieve symptoms. It should be taken daily as a course of treatment. The drug will not provide the near instant relief of symptoms that some simple antacids can. It can, however, be ideal for sufferers who wish to control their symptoms rather than merely respond to them.