



ONLY AVAILABLE
IN PHARMACY

THE ROLE OF OTC OMEPRAZOLE TABLETS 20mg IN THE PHARMACY



Omeprazole 20mg is a key active ingredient that you will be familiar with on prescription and which is newly available for customers to purchase OTC.*

LEARNING OUTCOMES:



Know how omeprazole works



Understand who can purchase OTC omeprazole 20mg



Be able to give additional lifestyle advice to customers



Be able to talk to GPs confidently about this opportunity

AN OPPORTUNITY FOR:

CUSTOMERS

To purchase an active ingredient they are familiar with – omeprazole 20mg

To recognise the expertise of the pharmacy team to advise them on heartburn and acid reflux



YOU

To recommend an effective product for heartburn and acid reflux, the same strength as the prescription product



GPs

To refer customers to the pharmacy to purchase omeprazole 20mg to support the self-care agenda



HOW OMEPRAZOLE WORKS

Symptoms of heartburn and acid reflux can be relieved by reducing the acidity of the stomach, which can be done through reducing or neutralising the acid. Omeprazole is a proton pump inhibitor (PPI) that acts to reduce the amount of acid produced in the stomach by blocking the proton pump of the cells in the stomach.

(These produce the hydrogen used in the formation of the hydrochloric acid that causes the symptoms.)

PHARMACY EXPERTISE

By completing this training and the online module, the pharmacy team can make sure they feel confident to recommend the product and recognise when customers should be referred.

SUPPORTING SELF-CARE

Heartburn has been identified as a condition suitable for self-care. GPs have been advised not to prescribe for short-term symptoms as patients can be given lifestyle advice and purchase effective products from their pharmacy to relieve their symptoms.

*New GSL license. May 2019.

HOW AND WHEN TO USE PYROCALM CONTROL TABLETS (OMEPRAZOLE 20mg)

Pyrocalm Control Tablets (Omeprazole 20mg) can be used for the treatment of reflux symptoms.¹ These include heartburn and acid reflux (when the acid from the stomach travels up to the throat).

Customers may describe having a burning sensation in their chest or an acidic taste in the mouth.² They may notice that the symptoms are worse after eating, and when lying down or bending forward. They may also get recurrent hiccups, a hoarse voice, queasiness, halitosis or a bloated sensation.

FOR: ADULTS OVER 18 YEARS OF AGE

USE:



One tablet in the morning, swallowed whole, with a glass of water



Take until symptoms have resolved (up to 14 days use only)



Can be taken with or without food



One tablet provides relief for 24 hours

AVAILABLE AS A TWO-WEEK SUPPLY



LONG-LASTING EFFECT



STRONGEST DOSE AVAILABLE OTC



IMPORTANT: It can take two to three days to achieve symptom improvement. Customers can use antacids for their symptoms while waiting for the product to have full effect.

INTERACTIONS/CAUTIONS:

Pyrocalm Control Tablets (Omeprazole 20mg) shouldn't be taken by customers who are using other PPIs or H2-antagonists (e.g. ranitidine). It interacts with nelfinavir. Customers with any allergies to the ingredients or previous sensitivities to other PPIs shouldn't take Pyrocalm Control Tablets (Omeprazole 20mg). Remind customers to read the leaflet as there are other medicines that may interact. **Customers taking other medicines (including herbal/supplements) should discuss these with the pharmacist.**

WHEN TO REFER:

A key concern is that taking omeprazole 20mg might mask the signs of something else that needs further investigation, such as a peptic ulcer or cancer.

The following should be referred to the pharmacist/GP:³

- Customers over 55 who are experiencing: symptoms for the first time; worsening symptoms; persistent symptoms; or symptoms that don't improve with medication.

Symptoms that require referral include:

- Unexplained weight loss
- Difficulty swallowing
- Stomach pain/signs of indigestion, especially after food intake
- Blood in the vomit, or dark blood (like coffee granules) in vomit
- Black stools
- Persistent symptoms for more than four weeks.

ADDITIONAL SELF-CARE ADVICE:²

The following advice can help customers to manage their symptoms.

- Try to avoid trigger foods e.g. fatty foods, chocolate
- Avoid drinks such as coffee, alcohol and fizzy drinks
- Eat smaller portions and eat slowly, particularly avoiding large meals less than three hours before bed
- Raising the head-end of the bed at night by putting something under the mattress may help with night-time symptoms
- Wear clothes that are loose around the waist
- If overweight, losing weight may help
- Smokers can be advised to try stopping smoking.

It may also be helpful to check whether the customer has been taking non-steroidal anti-inflammatories (NSAIDs), as these can cause symptoms. You can discuss their use, and if appropriate recommend reducing the dose and trying omeprazole 20mg.

FAQs:



CAN PYROCALM CONTROL TABLETS (OMEPRAZOLE 20MG) BE TAKEN BY PREGNANT WOMEN?

It can, as it is not known to be harmful,⁴ but customers may want to consult with their GP first.



WILL GPs ASK THEIR PATIENTS TO BUY THIS?

Yes – in some cases customers may present with a referral form from their GP recommending that they purchase omeprazole 20mg.



ARE THERE ANY SIDE EFFECTS?

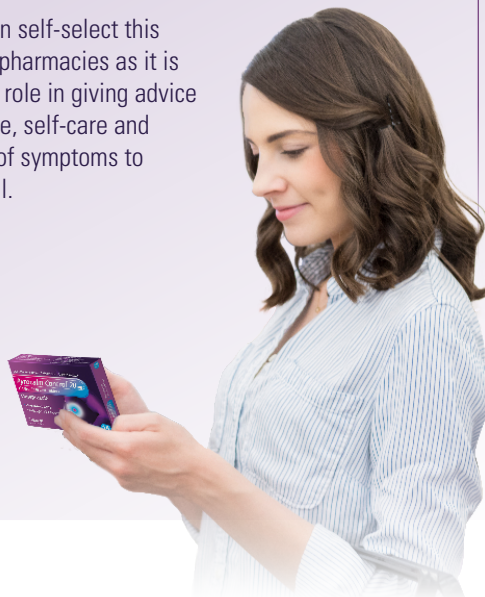
As with all medicines, there are potential side effects. Any new side effects should be recorded using the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Common side effects include headache, abdominal pain, constipation, diarrhoea, flatulence and nausea/vomiting. Rare, but serious, signs to be aware of are: allergy, reddening of the skin and peeling (potentially Stevens-Johnson syndrome), yellowing skin/dark urine indicating liver problems, bruising/severely reduced general condition and fever (indicating changes in white blood cells).



WHERE IN THE PHARMACY CAN CUSTOMERS FIND THE PRODUCT?

Customers can self-select this product from pharmacies as it is GSL, but your role in giving advice on product use, self-care and being aware of symptoms to refer is crucial.



MY LOCAL GPs OFTEN PRESCRIBE THIS. SHALL I TELL THEM ABOUT ITS OTC AVAILABILITY?

Definitely. GPs can refer customers to your pharmacy to purchase the product if appropriate. This offers an opportunity to talk to your local GPs about who they might refer to purchase, whether they would expect any follow-up, and what kinds of customers they would rather were referred to the surgery instead of trying self-treatment.



WHAT IF IT DOESN'T WORK FOR A CUSTOMER?

If they have only taken it for a short time, remind them that it can take two to three days to have full effect. If they are getting breakthrough symptoms, they can use an antacid. If they have been using it for two weeks with no effect, they should see their GP.



Self test.

1. What is the strength of omeprazole in Pyrocalm Control?

A: 10mg B: 20mg

2. How many days can it take to have full effect?

A: One to two B: Two to three

3. Who of the following should be referred?

A: Customers over 55 who are experiencing symptoms for the first time

B: Customers over 40 who are experiencing symptoms for the first time

4. True or false:

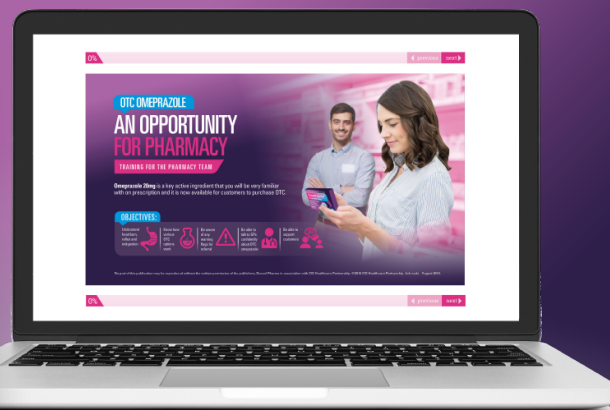
Customers can be advised to eat slowly, avoid having a main meal within three hours of bedtime and raise the head of the bed at night to help reduce symptoms.

True

False

FURTHER INFORMATION:

For further information about treating heartburn and acid reflux in the pharmacy, and customer scenarios to put your knowledge into practice, see the short e-learning module at www.pharmacy magazine.co.uk/pyrocalm



PHARMACY PROFESSIONALS:
You can use this learning as part of your revalidation.



ESSENTIAL PRODUCT INFORMATION

Pyrocalm Control® 20mg Gastro-Resistant Tablets **Pharmaceutical form:** Gastro-resistant tablets. **Indications:** For the short-term treatment of reflux symptoms in adults. **Active ingredient:** Omeprazole. **Posology:** Once daily for up to 14 days. Discontinue treatment once complete relief of symptoms has occurred. The majority of patients achieve complete relief of heartburn within 7 days. **Method of administration:** Take one tablet in the morning, swallowed whole with half a glass of water. Do not chew or crush the tablets. **Contraindications:** Children under 18 years; Hypersensitivity to the active substance, substituted benzimidazoles or to any of the excipients; nelfinavir. **Special warnings and precautions for use:** In the presence of any alarm symptom (e.g. significant unintentional weight loss, recurrent vomiting, dysphagia, haematemesis or melena) and when gastric ulcer is suspected or present, malignancy should be excluded. It is not recommended to co-administrate with atazanavir. Do not use concomitantly with clopidogrel. The tablets contain lactose therefore patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. Treatment may lead to slightly increased risk of gastrointestinal infections such as Salmonella and Campylobacter and, in hospitalised patients, possibly also Clostridium difficile. Consult the doctor in the following conditions: previous gastric ulcer or gastrointestinal surgery; continuous symptomatic treatment of indigestion or heartburn for 4 or more weeks; jaundice or severe liver disease; aged over 55 years with new or recently changed symptoms of indigestion or heartburn. Do not take as a preventative medication. Do not take another PPI or H2 antagonist concomitantly. Seek medical help promptly if lesions occur, especially in sun-exposed areas of the skin, and if accompanied by arthralgia. This might associate with very infrequent cases of SCLE (Subacute cutaneous lupus erythematosus). Stop using for at least 5 days before CgA measurements in laboratory test. Increased CgA level may interfere with investigations for neuroendocrine tumours. Consult your doctor before taking this medicinal product if you are due to have an endoscopy or urea breath test. Omeprazole may reduce the absorption of vitamin B12 (cyanocobalamin) in patients with risk factors. **Interaction with other medicinal products and other forms of interaction:** atazanavir, digoxin, clopidogrel, posaconazole, erlotinib, ketoconazole, itraconazole, saquinavir, ritonavir, tacrolimus, methotrexate. Active substances metabolised by CYP2C19 such as: vitamin K antagonists (R-warfarin, ciltastazol, phenytoin and diazepam). Active substances known to inhibit CYP2C19 or CYP3A4 (such as clarithromycin and voriconazole). Active substances known to induce CYP2C19 or CYP3A4 or both (such as rifampicin and St John's wort). Concomitant administration of omeprazole with nelfinavir is contraindicated. **Use during pregnancy and lactation:** can be used during pregnancy and breastfeeding. **Effects on ability to drive and use machines:** None expected. Adverse drug reactions such as dizziness and visual disturbances may occur. If affected, patients should not drive or operate machinery. **Side effects:** The most common side effects (1-10% of patients) are headache, abdominal pain, constipation, diarrhoea, flatulence and nausea/vomiting. Another common side effect is fundic gland polyps (benign). Uncommon side effects: Insomnia, dizziness, paraesthesia, somnolence, vertigo, increased liver enzymes, dermatitis, pruritus, rash, urticarial, malaise and peripheral oedema. Rare side effects: Hypersensitivity reactions e.g. fever, angioedema and anaphylactic reaction/shock; leukopenia, thrombocytopenia, hyponatraemia, agitation, confusion, depression, taste disturbance, blurred vision, bronchospasm, dry mouth, stomatitis, gastrointestinal candidiasis, microscopic colitis, hepatitis with or without jaundice, alopecia, photosensitivity, arthralgia, myalgia, interstitial nephritis, increased sweating. Very rare side effects: agranulocytosis, pancytopenia, hypomagnesaemia, aggression, hallucinations, hepatic failure, encephalopathy in patients with pre-existing liver disease, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (TEN), muscular weakness, gynaecomastia. Side effect with 'Not known' frequency: Subacute cutaneous lupus erythematosus. **Legal Category:** GSL. **Price:** 7 Tablets £5.83, exc. VAT, 14 Tablets £9.16 exc. VAT **Product licence number and holder:** PL 14017/0277 Dexcel® Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, UK. **Date of preparation:** October 2019. Pyrocalm Control Tablets is a registered trademark.

REFERENCES:

1. Pyrocalm Control® 20mg Gastro-Resistant Tablets SPC 2. <https://www.nhs.uk/conditions/heartburn-and-acid-reflux/> 3. <https://www.nice.org.uk/guidance/qs96/chapter/Quality-statement-1-Advice-to-support-selfmanagement> 4. BNF 77. BMA/Royal Pharmaceutical Society. Online references last accessed October 2019.

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Answers: 1b, 2b, 3a, 4 True

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pharma