

Pyrocalm Control[®] 20mg Gastro-Resistant Tablets

Omeprazole

(Referred to as Pyrocalm Control Tablets throughout this leaflet)

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 Pyrocalm Control Tablets carefully to get the best results from them.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist or doctor if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. (See section 4).
- You must talk to a doctor if you do not feel better or if you feel worse after 14 days.
 - If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet:

1. What Pyrocalm Control Tablets are and what they are used for
 2. What you need to know before you take Pyrocalm Control Tablets
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1. WHAT PYROCALM CONTROL TABLETS ARE AND WHAT THEY ARE USED FOR

This medicine contains the active substance omeprazole. It belongs to a group of medicines called 'proton pump inhibitors'. It works by reducing the amount of acid that your stomach produces.

The tablets are used in adults for the short-term treatment of reflux symptoms (for example, heartburn, acid regurgitation).

Reflux is the backflow of acid from the stomach into the gullet "foodpipe", which may become inflamed and painful. This may cause you symptoms such as a painful burning sensation in the chest rising up to the throat (heartburn) and a sour taste in the mouth (acid regurgitation).

This medicine is not meant to bring immediate relief. It might be necessary to take the tablets for 2-3 consecutive days to achieve improvement of symptoms.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PYROCALM CONTROL TABLETS

Do not take Pyrocalm Control Tablets

- If you are allergic (hypersensitive) to omeprazole or any of the other ingredients of this medicine (listed in section 6).
- If you are allergic to medicines containing other proton pump inhibitors (e.g. pantoprazole, lansoprazole, rabeprazole, esomeprazole).
- If you are taking a medicine containing nelfinavir (used for HIV infection).

Do not take Pyrocalm Control Tablets if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Warnings and precautions

Tell your doctor before taking this medicine, if:

- You are due to have a specific blood test (Chromogranin A)
- You are due to have an endoscopy or a urea breath test
- Your body does not absorb vitamin B12 (cobalamin) very well

Do not take this medicine for more than 14 days without consulting a doctor. If you do not experience relief, or if you experience a worsening of symptoms, consult your doctor.

This medicine may hide the symptoms of other diseases. Therefore, if any of the following happen to you before you start taking these tablets or while you are taking them, talk to your doctor straight away:

- You lose a lot of weight for no reason and have problems swallowing.
- You get stomach pain or signs of indigestion (such as nausea, fullness, bloating especially after food intake).
- You begin to vomit food or blood.
- You pass black stools (blood-stained faeces).
- You experience severe or persistent diarrhoea, as omeprazole has been associated with a small increase in infectious diarrhoea.
- You have had previous gastric ulcer or gastrointestinal surgery.
- You are on continuous symptomatic treatment of indigestion or heartburn for 4 or more weeks.
- You continuously suffer from indigestion or heartburn for 4 or more weeks.

- You have jaundice or severe liver disease.
- You are aged over 55 years with new or recently changed symptoms.
- You have ever had a skin reaction after treatment with a medicine similar to Pyrocalm Control Tablets that reduces stomach acid.

If you get a rash on your skin, especially in areas exposed to the sun tell your doctor as soon as you can, as you may need to stop your treatment with this medicine. Remember to also mention any other ill-effects like pain in your joints.

Seek urgent medical attention if you experience chest pain with light-headedness, sweating, dizziness or shoulder pain with shortness of breath. This could be a sign of a serious condition with your heart.

Do not take this medicine if you do not have symptoms of reflux (e.g. heartburn or acid regurgitation).

Children and adolescents

This medicine should not be used by children and adolescents under 18 years of age.

Other medicines and Pyrocalm Control Tablets

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This is because this medicine can affect the way some medicines work and some medicines can have an effect on these tablets.

Do not take this medicine if you are taking a medicine containing **nelfinavir** (used to treat HIV infection).

You should specifically tell your doctor or pharmacist if you are taking clopidogrel (used to prevent blood clots (thrombi)).

Do not take this medicine with other medicines that limit the amount of acid produced in your stomach such as other proton pump inhibitors (e.g. pantoprazole, rabeprazole or esomeprazole) or an H₂ antagonist (e.g. ranitidine or famotidine).

You may take this medicine with antacids (e.g. alginic acid, sodium bicarbonate, aluminium hydroxide, magnesium carbonate or combinations of these) if needed.

Tell your doctor or pharmacist if you are taking any of the following medicines:

- Ketoconazole, itraconazole, posaconazole or voriconazole (used to treat infections caused by a fungus)
- Clarithromycin (used to treat infections)
- Digoxin (used to treat heart problems)
- Diazepam (used to treat anxiety, relax muscles or in epilepsy)
- Phenytoin (used in epilepsy). If you are taking phenytoin, your doctor will need to monitor you when you start or stop taking this medicine
- Medicines that are used to thin your blood, such as warfarin or other vitamin K blockers. Your doctor may need to monitor you when you start or stop taking this medicine
- Rifampicin (used to treat tuberculosis)
- Atazanavir (used to treat HIV infection)
- Tacrolimus (in cases of organ transplantation)
- St John's wort (*Hypericum perforatum*) (used to treat mild depression)
- Cilostazol (used to treat intermittent claudication)
- Saquinavir (used to treat HIV infection)
- Erlotinib (used to treat cancer)
- Methotrexate (a chemotherapy medicine used in high doses to treat cancer) - if you are taking a high dose of methotrexate, your doctor may temporarily stop your treatment with these tablets

Pyrocalm Control Tablets with food and drink

You can take your tablets with food or on an empty stomach.

Pregnancy, breast-feeding and fertility

Before taking this medicine, tell your doctor or pharmacist if you are pregnant or trying to get pregnant. Your doctor will decide whether you can take these tablets during this time. Your doctor will decide whether you can take this medicine if you are breast-feeding. There is no evidence that this medicine has any effect on fertility.

Driving and using machines

This medicine is not likely to affect your ability to drive or use any tools or machines. Side effects such as dizziness and visual disturbances may occur (see section 4). If affected, you should not drive or operate machinery.

Pyrocalm Control Tablets contain Lactose

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE PYROCALM CONTROL TABLETS

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one 20 mg tablet once a day for up to 14

days. Contact your doctor if you are not free from symptoms after this period.

It might be necessary to take the tablets for 2-3 consecutive days to achieve improvement of symptoms. Do not take more than the recommended dose (one 20mg tablet a day) even if you don't feel an improvement immediately.

When your reflux symptoms have gone completely you should stop taking this medicine.

Taking this medicine

- It is recommended that you take your tablets in the morning.
- You can take your tablets with food or on an empty stomach.
- Swallow your tablets whole with half a glass of water. Do not chew or crush the tablets. This is because the tablets are coated with enteric coating which stops the medicine from being broken down by the acid in your stomach. The tablets release the active ingredient in the intestine, where it is absorbed by your body to give an effect.

If you take more Pyrocalm Control Tablets than you should

If you take more tablets than recommended, talk to your doctor or pharmacist straight away. You may experience symptoms such as diarrhoea, stomach ache, feeling or being sick, dizziness, headache, depression, confusion and apathy (lack of motivation).

If you forget to take Pyrocalm Control Tablets

If you forget to take a dose, take it as soon as you remember it on the same day. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Pyrocalm Control Tablets can cause side effects, although not everybody gets them.

If you notice any of the following rare but serious side effects, stop taking this medicine and contact a doctor immediately:

- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties in swallowing (severe allergic reaction).
- Reddening of the skin with blisters or peeling. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. This could be 'Stevens-Johnson syndrome' or 'toxic epidermal necrolysis'.
- Yellow skin, dark urine and tiredness which can be symptoms of liver problems.
- Blood problems such as a reduced number of white cells or platelets. This can cause weakness, bruising or make infections more likely.

This medicine may in very rare cases affect the white blood cells leading to immune deficiency. If you have an infection with symptoms such as fever with a **severely** reduced general condition or fever with symptoms of a local infection such as pain in the neck, throat or mouth or difficulties in urinating, you must consult your doctor as soon as possible so that a lack of white blood cells (agranulocytosis) can be ruled out by a blood test. It is important for you to give information about your medicine at this time.

Other side effects include:

Common side effects (may affect up to 1 in 10 people)

- Headache.
- Effects on your stomach or gut: diarrhoea, stomach pain, constipation, wind (flatulence).
- Feeling sick (nausea) or being sick (vomiting).
- Benign polyps in the stomach.

Uncommon side effects (may affect up to 1 in 100 people)

- Swelling of the feet and ankles.
- Disturbed sleep (insomnia).
- Dizziness, tingling feelings such as "pins and needles", feeling sleepy.
- Spinning feeling (vertigo).
- Changes in blood tests that check how the liver is working.
- Skin rash, lumpy rash (hives) and itchy skin.
- Generally feeling unwell and lacking energy.

Rare side effects (may affect up to 1 in 1,000 people)

- Allergic reactions, sometimes very severe, including swelling of the lips, tongue and throat, fever, wheezing.
- Low levels of sodium in the blood. This may cause weakness, being sick (vomiting) and cramps.
- Feeling agitated, confused or depressed.
- Taste changes.
- Eyesight problems such as blurred vision.
- Suddenly feeling wheezy or short of breath (bronchospasm).
- Dry mouth.
- An inflammation of the inside of the mouth.
- An infection called "thrush" which can affect the gut and is caused by a fungus.
- Liver problems, including jaundice which can cause yellow skin, dark urine, and tiredness.
- Hair loss (alopecia).
- Skin rash on exposure to sunshine.
- Joint pains (arthralgia) or muscle pains (myalgia).

- Severe kidney problems (interstitial nephritis).
- Increased sweating.
- Inflammation in the gut (leading to diarrhoea).

Very rare side effects (may affect up to 1 in 10,000 people)

- Changes in blood count including agranulocytosis (lack of white blood cells).
- Aggression.
- Seeing, feeling or hearing things that are not there (hallucinations).
- Severe liver problems leading to liver failure and inflammation of the brain.
- Sudden onset of a severe rash or blistering or peeling skin. This may be associated with a high fever and joint pains (Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis).
- Muscle weakness.
- Enlarged breasts in men.
- Hypomagnesaemia (low level of magnesium in the blood).

Not Known (Frequency cannot be estimated from the available data)

- Rash, possibly with pain in the joints.

Do not be concerned by this list of possible side effects. You may not get any of them. **If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.**

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE PYROCALM CONTROL TABLETS

- Keep out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the pack after EXP. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Store this blister in the original package in order to protect from moisture.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Pyrocalm Control Tablets contain

The active substance is omeprazole. Pyrocalm Control Tablets contain 20 mg of omeprazole. The other ingredients are lactose monohydrate, sodium starch glycolate, sodium stearyl fumarate, sodium stearate, hypromellose acetate succinate, brownish pink colour (which contains propylene glycol, titanium dioxide (E171), red iron oxide (E172), hypromellose and yellow iron oxide (E172)), talc, triethyl citrate, monoethanolamine, sodium lauryl sulfate and traces of carnauba wax.

What Pyrocalm Control Tablets look like and contents of the pack

Pyrocalm Control 20 mg Gastro-Resistant Tablets are brownish-pink film coated capsule shaped tablets.

Blisters of 7, 14 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Dexcel® - Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire, NN11 8PB, UK.

This leaflet was last revised in July 2019.

Further Helpful Information

What are the symptoms of heartburn?

The normal symptoms of reflux are a painful sensation in the chest rising up to your throat (heartburn) and a sour taste in the mouth (acid regurgitation)

Why do you get these symptoms?

Heartburn can be a result of eating too much, eating high fat food, eating too quickly and drinking lots of alcohol. You may notice that when you lie down your heartburn gets worse. If you are overweight or smoke you increase the chance of suffering from heartburn.

What can I do to help relieve my symptoms?

- Try to avoid spicy and fatty foods and large meals late before bedtime.
- Avoid fizzy drinks, coffee, chocolate and alcohol.
- Eat slowly and eat smaller portions.
- Try to lose weight.
- Stop smoking.

When should I seek advice or help?

- You should seek urgent medical advice if you experience chest pain with light-headedness, sweating, dizziness or shoulder pain with shortness of breath.
- If you experience any of the symptoms detailed in Section 2 of this leaflet and it advises you to talk to your doctor or pharmacist.
- If you are suffering from any of the side effects detailed in Section 4 which require medical attention.