New Zealand Consumer Medicine Information

Heartburn & Acid Reflux Relief

Omeprazole 20mg modified release capsules

What is in this leaflet

Please read this leaflet carefully before you start using **Heartburn & Acid Reflux Reli**

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This leaflet answers some common questions about **Heartburn & Acid Reflux Relief**. It does not contain all the available information. It does not take the place of talking to your pharmacist or doctor.

All medicines have risks and benefits. You should weigh the risks of taking **Heartburn**

& Acid Reflux Relief against the benefits expected for you.

If you have any concerns about using this medicine, ask your pharmacist or doctor.

Keep this leaflet with the medicine. You may need to read it again.

What Heartburn & Acid Reflux Relief is used for

Heartburn & Acid Reflux Relief capsules are used for the short-term relief of reflux- like symptoms – heartburn or regurgitation.

Heartburn is an acidic or burning feeling, rising up from the stomach towards the throat. The pain of heartburn, which is usually associated with acid regurgitation (reflux), can be caused or made worse by eating large meals, bending over or lying flat, and by hot, alcoholic or acidic drinks such as orange juice.

The symptoms below are **not** usually signs of acid reflux:

- cardiac-type chest pain often felt as a pressure or squeezing in the chest with shortness of breath and pain that may extend into the shoulders, arms or up toward the back or neck
- abdominal pain or discomfort
- nausea, belching or bloating
- sore throat or cough

See your pharmacist or doctor if you experience any of these symptoms.

How Heartburn & Acid Reflux Relief works

Heartburn & Acid Reflux Relief is a type of medicine called a proton-pump inhibitor.

Heartburn & Acid Reflux Relief works by decreasing the amount of acid made by the stomach, giving relief from acid reflux symptoms. If you suffer from acid reflux more than once a week, **Heartburn & Acid Reflux Relief** may be right for you. However, if you have reflux every day you should see your pharmacist or doctor.

Heartburn & Acid Reflux Relief does not stop food being digested in the normal

way. Ask your pharmacist or doctor if you have any questions about whether this

medicine is suitable for you.

This medicine is available without a doctor's prescription, only through your pharmacy.

Before you use Heartburn & Acid Reflux Relief

When you must not use

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Do not use Heartburn & Acid Reflux Relief:

 If you have an allergy to any medicine containing omeprazole, pantoprazole or lansoprazole, or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include swelling of parts of the body, difficulty breathing, rash, itching or hives on the skin.

 After the use by (expiry) date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using Heartburn & Acid Reflux Relief, talk to your pharmacist or doctor.

Before you start to use Heartburn & Acid Reflux Relief:

See your pharmacist or doctor if you:

are under 18 years of age

- are over 55 years of age and have not experienced reflux-like symptoms before, or the symptoms have changed recently
- have liver disease or liver problems
- · are at risk of bleeding problems
- find swallowing is difficult or painful
- experience choking during the night
- have persistent regurgitation of food
- have vomited bright red blood, or vomit regularly
- have bowel movements that are black and/or tar-like, a symptom of gastrointestinal bleeding
- have unexplained or unintentional weight loss
- have, or have previously had, a stomach or duodenal ulcer
- you have, or are at risk of having, osteoporosis or osteoporotic fractures.

If you have not told your pharmacist or doctor about any of the above, tell them before you start using Heartburn & Acid Reflux Relief.

See your pharmacist or doctor if you are pregnant or breastfeeding.

If you are pregnant or breast feeding, you should be careful using any medicine. Before using **Heartburn & Acid Reflux Relief** you should get your pharmacist or doctor's advice.

Taking other medicines

Tell your pharmacist or doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Heartburn & Acid Reflux Relief.

Some medicines and **Heartburn & Acid Reflux Relief** may interfere with each other. These include:

- Clopidogrel a medicine used to prevent blood clots. Taking this medication with Heartburn & Acid Reflux Relief is not recommended.
- Citalogram / Escitalogram medicines used to treat depression
- Clozapine an antipsychotic medicine
- Phenytoin, Carbamazepine medicines used to treat epilepsy
- Warfarin a medicine to treat or prevent blood clots
- Diazepam a medicine for anxiety or tension
- Ketoconazole, itraconazole and voriconazole antifungal medicines
- Clarithromycin, rifampicin antibiotics
- Digoxin a medicine used for heart disease
- Tacrolimus
- Antiretroviral medicines (HIV/AIDS medication) such as atazanavir, nelfinavir and saguinavir

- Erlotinib and methotrexate anticancer medicines
- St. John's Wort a herb included in some Dietary Supplements

These medicines may be affected by **Heartburn & Acid Reflux Relief**, or may affect how well it works. **Your pharmacist or doctor can advise you if you are taking any of these medicines.**

Your pharmacist or doctor has more information on medicines to be careful with or avoid while taking **Heartburn & Acid Reflux Relief**.

How to use Heartburn & Acid Reflux Relief

Follow all directions given to you by your pharmacist of doctor carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions below, or on the carton, ask your pharmacist or doctor for help.

How much to take

Take one capsule once a day swallowed whole with a glass of water. Do not use

Heartburn & Acid Reflux Relief for more than 14 days except on medical

advice. Use the lowest dose that controls your symptoms.

Heartburn & Acid Reflux Relief does not work immediately. While you should get some symptom relief from the first day of taking Heartburn & Acid Reflux Relief, it can take longer for Heartburn & Acid Reflux Relief to become fully effective. If you need immediate relief an antacid may be taken in addition to Heartburn & Acid Reflux Relief.

Do not exceed the recommended dose.

How to take

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Swallow Heartburn & Acid Reflux Relief capsules whole with a glass of water.

If you have trouble swallowing **Heartburn & Acid Reflux Relief**, open the capsule over an empty glass or cup and swallow the content, or suspend the content in a slightly acidic fluid e.g. fruit juice, yoghurt or soured milk and take within 30 minutes. Or, suck the capsule until it opens (1-2 minutes) and swallow the content with liquid. Do not crush or chew the capsules. If the granules in the capsules are chewed or crushed it will not work properly.

When to take

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Take **Heartburn & Acid Reflux Relief** at about the same time each day, preferably in the morning. Keeping a regular time for taking **Heartburn & Acid Reflux Relief** will help to remind you to take it.

Heartburn & Acid Reflux Relief should be taken prior to a meal.

How long to take

it

Take **Heartburn & Acid Reflux Relief** for 14 continuous days to get the best results. Two weeks of treatment may keep you free of heartburn or regurgitation for up to 3 months.

Prolonged use of **Heartburn & Acid Reflux Relief** is not recommended, except on medical advice.

If you forget to take

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If you forget to take a dose, take it as soon as you remember, and then go back to taking it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

While you are using Heartburn & Acid Reflux Relief

Things you must do

You must use **Heartburn & Acid Reflux Relief** exactly as instructed on the pack or in this leaflet, or as your pharmacist or doctor has prescribed.

See your pharmacist or doctor if:

- Your symptoms have not improved within 14 days of starting Heartburn & Acid Reflux Relief.
- Your symptoms become worse while you are taking Heartburn & Acid Reflux Relief.
- You experience fever, nausea, a generally unwell feeling, tiredness, blood in the urine or weight loss. These are symptoms of interstitial nephritis, a rare side effect of omeprazole.

 You experience abnormal eye movements, fatigue, muscle spasms, cramps or weakness, numbness or convulsions. These can be symptoms of hypomagnesaemia, a possible side effect of taking omeprazole. Stop taking Heartburn & Acid Reflux Relief and see your doctor or Accident and Emergency clinic right away.

Tell all doctors, dentists and pharmacists who are treating you that you are taking

Heartburn & Acid Reflux Relief.

If you are about to be started on any new medicine tell your pharmacist and doctor that you are taking **Heartburn & Acid Reflux Relief**.

Things you must not do

While you are taking **Heartburn & Acid Reflux Relief**, do not take other acid-suppressing medicines such as ranitidine or cimetidine (H2-antagonists). Do not give **Heartburn & Acid Reflux Relief** to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how **Heartburn & Acid**

Reflux Relief affects

you.

Heartburn & Acid Reflux Relief very occasionally causes drowsiness or affects the vision of some people. Make sure you know how you react to **Heartburn & Acid Reflux Relief** before you drive a car, operate machinery, or do anything else that could be dangerous.

Things that may help to resolve heartburn or acid reflux

Some self-help measures may help your condition. Your pharmacist or doctor can give you more information about these measures.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone

0800 POISON or 0800 764 766) or go to the nearest Accident & Emergency department immediately if you think that you or anyone else may have taken too much Heartburn & Acid Reflux Relief. Do this even if there are no signs of discomfort or poisoning.

Side Effects

Tell your pharmacist or doctor as soon as possible if you do not feel well while you are using **Heartburn & Acid Reflux Relief**.

Heartburn & Acid Reflux Relief helps most people but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Ask your pharmacist or doctor to answer any questions you may have.

Do not be alarmed by this list of possible side effects. You may not experience any of them. Tell your pharmacist or doctor if you notice any of the following and they worry you:

- constipation
- diarrhoea
- nausea and vomiting
- diarrhoea and wind (flatulence)
- headache

These are the more common side effects of **Heartburn & Acid Reflux Relief**. They are usually mild.

Tell your doctor if you notice any of the following:

- skin rash
- muscle pain, spasm, cramping or weakness
- dizziness
- "pins and needles"
- changes in sleep patterns, restlessness
- mood changes or confusion
- increase in breast size (males)
- fever
- increased bruising
- abnormal eye movements
- numbness

These side effects are less common but can be serious and may need medical attention.

This is not a complete list of all possible side effects. Others may also occur in some people and there may be some side effects not yet known.

Tell your pharmacist or doctor if you notice anything that is making you feel unwell, even if it is not on this list.

Ask your pharmacist or doctor if you don't understand anything on this list.

After using Heartburn & Acid Reflux Relief

Storage

Keep your capsules in the blister pack until it is time to take them. If you take

Heartburn & Acid Reflux Relief out of the packaging it may not keep well.

Keep the capsules in a cool, dry place where the temperature stays below

25°C. Do not store them or any other medicine in the bathroom or near a

sink. Do not

leave them on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking **Heartburn & Acid Reflux Relief** or the capsules have passed their expiry date, ask your pharmacist what to do with any capsules you have left over.

Product description

What Heartburn & Acid Reflux Relief looks like

Modified release capsule 20 mg: Size 2, opaque white capsule, containing offwhite

(ivory) to cream-white spherical micro granules. Available in packs of 14 or 28

capsules.

Ingredients

Active ingredient:

Each **Heartburn & Acid Reflux Relief** modified release capsule contains 20mg omeprazole as cream-white spherical micro granules.

Inactive ingredients:

anhydrous disodium phosphate

- gelatin
- hypromellose
- macrogol 6000
- maize starch
- mannitol
- methacrylic acid-ethyl acrylate copolymer dispersion
- polysorbate 80
- sodium laurilsulfate
- sucrose
- talc
- titanium dioxide

Heartburn & Acid Reflux Relief capsules do not contain gluten or lactose.

Distributor Details

Heartburn & Acid Reflux Relief is supplied in New Zealand

by: Multichem NZ Limited Private Bag 93527 Takapuna Auckland 0740 NEW ZEALAND Telephone: (09) 488

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