

## NEW ZEALAND CONSUMER MEDICINE INFORMATION

### OMEZOL IV

*Omeprazole powder for intravenous infusion 40 mg*



#### What is in this leaflet

Please read this leaflet carefully before you start to be given OMEZOL IV.

This leaflet answers some common questions about OMEZOL IV.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given OMEZOL IV against the benefits they expect it will have for you.

**If you have any concerns about being given this medicine, ask your doctor or pharmacist.**

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

#### What OMEZOL IV is used for

OMEZOL IV is primarily used for the treatment of Zollinger-Ellison syndrome, and may also be used for the treatment of gastric ulcer, duodenal ulcer and reflux oesophagitis

OMEZOL IV contains the active ingredient omeprazole, which belongs to a group of medicines called proton pump inhibitors.

It works by decreasing the amount of acid made by the stomach, to give relief of symptoms and allow healing to take place.

#### **Zollinger-Ellison syndrome**

This is a rare condition where the stomach produces large amounts of

acid, much more than in ulcers or reflux disease.

#### **Peptic ulcers**

OMEZOL IV is used to treat peptic ulcers. Depending on the position of the ulcer it is called a gastric or duodenal ulcer.

A gastric ulcer occurs in the stomach. A duodenal ulcer occurs in the duodenum which is the tube leading out from the stomach.

These ulcers can be caused by too much acid being made in the stomach. They can cause pain and discomfort (indigestion) which is felt between the naval and the breast bone.

#### **Reflux oesophagitis**

OMEZOL IV is also used to treat the symptoms of reflux oesophagitis or reflux disease. This can be caused by "washing back" (reflux) of food and acid from the stomach into the food pipe, also known as the oesophagus.

Reflux can cause a burning sensation in the chest rising up to the throat, also known as heartburn. This usually occurs after eating or at night and worsens when bending over.

Your doctor may have prescribed it for another reason.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

This medicine is available only with a doctor's prescription.

This medicine is not expected to affect your ability to drive a car or operate machinery.

There is limited experience with intravenous omeprazole in children.

#### Before you are given OMEZOL IV

#### **When you must not be given it**

**Do not use OMEZOL IV if you have an allergy to:**

- any medicine containing omeprazole
- substituted benzimidazoles
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

**If you are not sure whether you should be given this medicine, talk to your doctor.**

#### **Before it is given**

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have liver problems or liver disease.**

**Tell your doctor if you have experienced:**

- significant unintentional weight loss
- recurrent vomiting
- vomiting of blood
- difficulty or discomfort in swallowing
- blood in dark sticky stools

**Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.** Your doctor can discuss with you the risks and benefits involved.

**If you have not told your doctor about any of the above, tell them before OMEZOL IV is used.**

## ***Taking other medicines***

**Tell your doctor or pharmacist 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 given OMEZOL IV.

Some medicines may interfere with OMEZOL IV. These include:

- atazanavir, nelfinavir or saquinavir (antiretroviral medicines used to treat HIV)
- citalopram and escitalopram (medicines used to treat depression)
- digoxin (a medicine used to treat various heart conditions)
- warfarin, clopidogrel or vitamin K antagonists (medicines used to treat or prevent blood clots)
- erlotinib (medicine used to treat various types of cancer)
- ketoconazole, itraconazole, posaconazole or voriconazole (medicines used to treat fungal infections)
- diazepam (a medicine used to treat anxiety or tension)
- phenytoin (a medicine used to treat epilepsy)
- cilostazol (a medicine used to treat intermittent claudication)
- clozapine (a medicine used to treat schizophrenia)
- tacrolimus (an immunosuppressant used in organ transplants)
- methotrexate (a medicine used to treat some cancers and psoriasis)
- clarithromycin or rifampicin (antibiotics)

These medicines may be affected by OMEZOL IV or may affect how well it works. You may need different amounts of your

medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

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## **How OMEZOL IV is given**

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### ***How much is given***

Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your liver function.

### ***How it is given***

OMEZOL IV is given as an infusion into the vein. It is given by a doctor or a nurse.

### ***How long to take it***

Your doctor will decide the length of time that you will receive treatment depending on your condition. Use the medicine for as long as the doctor recommends.

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## **While you are given OMEZOL IV**

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### ***Things you must do***

**If you are about to be started on any new medicine, tell your doctor and pharmacist that you are given OMEZOL IV.**

**Tell any other doctors, dentists, and pharmacists who treat you that you are given this medicine.**

**If you are going to have surgery, tell the surgeon or anaesthetist that you are given this medicine.** It may affect other medicines used during surgery.

**Tell your doctor if you become pregnant or intend to breastfeed while being given this medicine.**

OMEZOL IV can be given during pregnancy as studies have shown that there is no adverse effect on the pregnancy or the health of the unborn or newborn baby.

Although OMEZOL IV appears in breast milk, it is unlikely that there will be any effect on a nursing infant when given at the recommended dose.

**If you are about to have any blood tests, tell your doctor that you are given this medicine.**

It may interfere with the results of some tests.

**Keep all of your doctor's appointments so that your progress can be checked.**

Your doctor may do some tests, such as blood test, from time to time to make sure the medicine is working and to prevent unwanted side effects.

### ***Things you must not do***

**Do not use OMEZOL IV to treat any other complaints unless your doctor tells you to.**

**Do not give your medicine to anyone else, even if they have the same condition as you.**

Do not stop using your medicine or lower the dosage without checking with your doctor.

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## **In case of overdose**

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### ***If you are given too much (overdose)***

**Immediately telephone your doctor or nurse, or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you have been given too much OMEZOL IV. Do this even if there are no signs of discomfort or poisoning.** You may need urgent medical attention.

As OMEZOL IV is usually given to you in hospital under the supervision of your doctor, it is very unlikely that you will receive an overdose.

Symptoms of an omeprazole overdose may include the side effects listed in this leaflet under 'Side effects' section, but are usually of a more severe nature.

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## Side effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are given OMEZOL IV.**

This medicine helps most people with Zollinger-Ellison syndrome, gastric ulcer, duodenal ulcer and reflux oesophagitis, 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 attention if you get some of the side effects.**

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

**Tell your doctor or pharmacist if you notice any of the following and they worry you:**

- headache
- abdominal pain
- diarrhoea, constipation, or flatulence (wind)
- nausea or vomiting
- unusual backflow of fluid

The above list includes the more common side effects of your medicine.

Tell your doctor as soon as possible if you notice any of the following:

- joint pain, muscle pain or weakness
- bleeding or bruising more easily than normal, nose bleeds
- changes in mood
- hallucinations or confusion
- signs of low levels of magnesium, such as fatigue, involuntary muscle spasm or twitching, disorientation, convulsions, dizziness, increased heart rate
- yellowing of the skin and eyes, and dark coloured urine
- blurred or impaired vision
- taste disturbances
- blistering and bleeding in the lips, eyes, mouth, nose and genitals, also known as

Stevens Johnson Syndrome

- signs of allergic reaction, such as shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

Other side effects not listed above may also occur in some people.

Some of these side effects (for example, changes in liver function or levels of sodium, potassium and calcium) can only be found when your doctor does tests from time to time to check your progress.

**Do not be alarmed by this list of side effects. You may not experience any of them.**

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## Storing OMEZOL IV

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### Storage

OMEZOL IV is stored in a pharmacy or hospital ward.

Store in a cool dry place, protected from light, where the temperature stays below 25°C.

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## Product description

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### What it looks like

OMEZOL IV is in glass vials, which contain a white powder consisting of omeprazole 40 mg. This is reconstituted with normal saline or 5% dextrose to form an infusion solution.

### Ingredients

#### Active ingredient:

One vial of OMEZOL IV contains 40 mg of omeprazole as the active ingredient.

#### Inactive ingredient(s):

OMEZOL IV also contains:

- disodium edetate
- sodium hydroxide

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

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## If you want to know more

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Should you have any questions regarding this product, please contact your pharmacist or doctor.

### Who supplies this medicine

OMEZOL IV is supplied in New Zealand by:

Mylan New Zealand Ltd,  
PO Box 11183,  
Ellerslie,  
Auckland  
NEW ZEALAND

Telephone: (09) 579 2792

### Date of Information

03 April 2019  
(Based on datasheet dated 03 April 2019)