

Package leaflet: Information for the patient
Epzit 10 mg Orodispersible Tablets
Domperidone

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

The name of your medicine is Epzit 10 mg orodispersible tablets. It will be called Epzit for ease from here on.

What is in this leaflet

1. What Epzit is and what it is used for
2. What you need to know before you take Epzit
3. How to take Epzit
4. Possible side effects
5. How to store Epzit
6. Contents of the pack and other information

1. What Epzit is and what it is used for

This medicine is used to treat nausea (feeling sick) and vomiting (being sick) in adults and adolescents (12 years of age and older and weighing 35 kg or more).

2. What you need to know before you take Epzit

Do not take Epzit if you:

- are allergic to domperidone or any of the other ingredients of Epzit (listed in section 6). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- have a tumour of the pituitary gland (prolactinoma)
- have or may have a rare tumour of the adrenal gland (pheochromocytoma) because it could elevate your blood pressure.
- have a blockage or tear in your intestines
- have black, tarry bowel motions (stools) or notice blood in your bowel motions. This could be a sign of bleeding in the stomach or intestines.
- have a moderate or severe liver disease.
- have an ECG (electrocardiogram) shows a heart problem called "prolonged QT corrected interval".
- have or had a problem where your heart cannot pump the blood round your body as well as it should (condition called heart failure).
- have a problem that gives you a low level of potassium or magnesium, or a high level of potassium in your blood.
- are taking certain medicines (see "Other medicines and Epzit").

Do not take Epzit if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Epzit.

Warnings and precautions

Before taking this medicine contact your doctor if you:

- suffer from liver problems (liver function impairment or failure) (see "Do not take Epzit if you")
- suffer from kidney problems (kidney function impairment or failure). It is advisable to ask your doctor for advice in case of prolonged treatment as you may need to take a lower dose or take this medicine less often, and your doctor may want to examine you regularly.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Epzit. Do this even if they have applied in the past.

Epzit may be associated with an increased risk of heart rhythm disorder and cardiac arrest. This risk may be more likely in those over 60 years old or taking doses higher than 30 mg per day. The risk also increases when Epzit is given together with some drugs. Tell your doctor or pharmacist if you are taking drugs to treat infection (fungal infections or bacterial infection) and/or if

you have heart problems or AIDS/HIV (see "Other medicines and Epzit").

Epzit should be used at the lowest effective dose.

While taking Epzit, contact your doctor if you experience heart rhythm disorders such as palpitations, trouble breathing, loss of consciousness. Treatment with Epzit should be stopped.

Adolescents weighing less than 35 kg and children

Epzit should not be given to adolescents 12 years of age and older weighing less than 35 kg, or in any children less than 12 years of age, as it is not effective in these age groups.

Other medicines and Epzit

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you can buy without a prescription, including herbal medicines. This is because Epzit can affect the way some other medicines work. Also, some medicines can affect the way Epzit works.

Do not take Epzit if you are taking medicine to treat:

- Fungal infections such as azole anti-fungals, specifically oral ketoconazole, fluconazole or voriconazole.
- Bacterial infections, specifically erythromycin, clarithromycin, telithromycin, moxifloxacin, pentamidine (these are antibiotics)
- Heart problems or high blood pressure (e.g., amiodarone, dronedarone, quinidine, disopyramide dofetilide, sotalol, diltiazem, verapamil)
- Psychoses (e.g., haloperidol, pimozide, sertindole)
- Depression (e.g., citalopram, escitalopram)
- Gastro-intestinal disorders (e.g., cisapride, dolasetron, prucalopride)
- Allergy (e.g., mequitazine, mizolastine)
- Malaria (in particular halofantrine)
- AIDS/HIV (protease inhibitors)
- Cancer (e.g., toremifene, vandetanib, vincamine)

Tell your doctor or pharmacist if you are taking drugs to treat infection, heart problems, AIDS/HIV or Parkinson's disease.

Epzit and apomorphine

Before you use Epzit and apomorphine, your doctor will ensure that you tolerate both medicines when used simultaneously. Ask your doctor or specialist for personalised advice. Please refer to the apomorphine leaflet.

It is important to ask your doctor or pharmacist if Epzit is safe for you when you are taking any other medicines, including medicines obtained without prescription.

Epzit with food and drink

Take Epzit before meals, as when taken after meals, the absorption of the medicine is slightly delayed.

Pregnancy and breast-feeding

Talk to your doctor or pharmacist before taking Epzit if:

- You are pregnant, might become pregnant or think you may be pregnant
- You are breast-feeding. It is best not to take Epzit if you are breast-feeding.

Small amounts of Epzit have been detected in breast-milk. Epzit may cause unwanted side effects affecting the heart in a breast-fed baby. Epzit should be used during breast-feeding only if your doctor considers this clearly necessary. Ask your doctor for advice before taking this medicine.

Driving and using machines

Epzit can affect your ability to drive or use machinery as it may make you sleepy. Do not drive while taking this medicine until you know how it affects you.

Epzit tablets contains 7.5 mg aspartame in each tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. How to take Epzit

Follow these instructions closely unless your doctor has advised you otherwise.

You should check with your doctor or pharmacist if you are not sure.

	
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Barcode \ Artwork Number may be added

Duration of treatment

Your doctor will decide how long you will need to take this medicine.
Symptoms usually resolve with 3-4 days of taking this medicine.
Do not take Epzit for longer than 7 days without consulting your doctor.

The usual dose is:

Adults and adolescents 12 years of age and older and with a body weight of 35 kg or more

The usual dose is one tablet taken up to three times per day, if possible before meals. Do not take more than three tablets per day.

This product is not suitable for children under 12 years of age and older with a body weight of less than 35 kg.

Since the orodispersible tablets are fragile, do not press them through the foil, as this would break or damage the tablet.

- Take this medicine by mouth.
- The tablet should be placed on the tongue and allowed to disintegrate before swallowing with or without water, according to patient preference.

People with kidney problems

Your doctor may tell you to take a lower dose or to take the medicine less often.

If you take more Epzit than you should:

If you have used or taken too much Epzit, contact your doctor, pharmacist or the poison centre at your nearest hospital casualty department immediately. Take the carton and any tablets left with you. This is so the doctors know what you have taken.
In the event of overdose, symptomatic treatment could be implemented. An ECG monitoring could be undertaken, because of the possibility of a heart problem called prolonged QT interval.
The signs of taking more than you should include feeling sleepy, confused, uncontrolled movements which include unusual eye movements, unusual movements of the tongue or abnormal posture (such as a twisted neck).

If you forget to take Epzit

Take your medicine as soon as you remember. If it is almost time for your next dose, wait until that is due and then continue as normal. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines, this medicine can cause side effects although not everybody gets them.

Stop taking Epzit and see your doctor or go to a hospital straightaway if:

- You get swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria). This may mean you are having an allergic reaction to Epzit.
- You notice any uncontrolled movements. These include irregular eye movements, unusual movements of the tongue, and abnormal posture such as a twisted neck, trembling and muscle stiffness. These symptoms should stop once you stop taking Epzit.
- You have a very fast or unusual heartbeat. This could be a sign of a life-threatening heart problem.
- You have a fit (seizure).

Other side effects include:

Common (affects less than 1 in 10 people):

- Dry mouth

Uncommon (affect less than 1 in 100 people):

- Lowering of sexual drive (libido) in men
- Feeling anxious
- Feeling agitated or irritable
- Feeling more nervous than usual
- Feeling drowsy
- Headaches
- Diarrhoea
- Itchy skin. You may also have a rash
- Unusual production of breast milk in men and women

- Painful or tender breasts
- A general feeling of weakness

Not known (frequency cannot be estimated from the available data)

- Disorders of the cardiovascular system: heart rhythm disorders (rapid or irregular heart beat) have been reported; if this happens, you should stop the treatment immediately. Epzit may be associated with an increased risk of heart rhythm disorder and cardiac arrest. This risk may be more likely in those over 60 years old or taking doses higher than 30 mg per day. Epzit should be used at the lowest effective dose.
- Abnormal eye movements
- Feeling the urge to move your legs, arms or other parts of your body (restless legs syndrome). These symptoms may become worse in patients suffering from Parkinson's disease.
- Inability to urinate
- Breast enlargement in men
- In women, menstrual periods may be irregular or stop
- A blood test shows changes in the way your liver is working.

Some patients who have used Epzit for conditions and dosages requiring longer term medical supervision have experienced the following unwanted effects:

Restlessness; swollen or enlarged breasts, unusual discharge from breasts, irregular menstrual periods in women, difficulty breast-feeding, depression, hypersensitivity.

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 Epzit

- Keep this medicine out of the reach and sight of children.
- This medicinal product does not require any special temperature storage conditions. Store in the original pack in order to protect from moisture.
- Do not use after the stated expiry date on the carton and blister.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Epzit contains

- The active substance is domperidone. Each orodispersible tablet contains 10 mg domperidone.
- The other ingredients are Mannitol (E421); Silica, Colloidal Anhydrous; Cellulose, Microcrystalline; Aspartame (E951); Crospovidone; Peppermint flavour; Magnesium stearate.

What Epzit looks like and contents of the pack

Epzit 10 mg Orodispersible Tablets are white to off-white, round, flat, bevelled edged tablets, plain on both sides, having peppermint odour.

Epzit 10 mg Orodispersible Tablets are available in blister packs of 10, 20, 30, 50 or 100 Orodispersible tablets.

Not all pack size may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation

Novumgen Limited
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N1 7GU, United Kingdom

The Manufacturer

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