

VOMETA[®] FT TABLET

Domperidone (10mg)

What is in this leaflet

1. What VOMETA[®] FT is used for
2. How it works
3. Before you use VOMETA[®] FT
4. How to use VOMETA[®] FT
5. While you are using it
6. Side effects
7. Storage and Disposal of VOMETA[®] FT
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What VOMETA[®] FT is used for
VOMETA[®] FT is indicated for the relief of symptoms of nausea and vomiting.

How VOMETA[®] FT works
VOMETA[®] FT works by blocking the action of a chemical messenger in the brain which causes the feeling of nausea and vomiting, as well as increasing the movement or contractions of the stomach and intestines, allowing food to move more easily through the stomach, helping to increase the gastric emptying.

Before you use VOMETA[®] FT

- When you must not take it

Do not take VOMETA[®] FT if:

- You are allergic (hypersensitive) to domperidone or any of the other ingredients of VOMETA[®] FT. Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- You have a tumour of the pituitary gland (prolactinoma)
- You have a blockage or tear in your intestines
- You 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.
- You have a moderate or severe liver disease.
- You have phenylketonurics (disease caused by the liver's

inability to produce a particular type of enzyme)

- Your ECG (electrocardiogram) shows a heart problem called “prolonged QT interval”.
- You have or had a problem where your heart cannot pump the blood round your body as well as it should (condition called heart failure).
- You have abnormally slow heart rate
- You have a problem that gives you a low level of potassium or magnesium, or a high level of potassium in your blood.
- You are taking certain medicines (see “Taking other medicines”)
- You are breast-feeding. It is best not to take VOMETA[®] FT if you are breast-feeding. Small amounts of VOMETA[®] FT have been detected in breast-milk. VOMETA[®] FT may cause unwanted side effects affecting the heart in a breast-fed baby. VOMETA[®] FT should be used during breast feeding only if your physician considers this clearly necessary.

Do not take VOMETA[®] FT if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking VOMETA[®] FT.

- Before you start to take it

Before taking this medicine contact your doctor if:

- You suffer from liver problems (liver function impairment or failure) (see “When you must not take it”).
- 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.

- You are pregnant, might become pregnant or think you may be pregnant

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

- Taking other medicines

Please 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 VOMETA[®] FT can affect the way some other medicines work. Also, some medicines can affect the way VOMETA[®] FT works.

Do not take VOMETA[®] FT if you are taking medicine to treat:

- Fungal infections such as azole anti-fungals
- 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 medicines to treat infection, heart problems or AIDS/HIV.

It is important to ask your doctor or pharmacist if VOMETA[®] FT is safe

VOMETA[®] FT TABLET

Domperidone (10mg)

for you when you are taking any other medicines, including medicines obtained without prescription.

How to use VOMETA[®] FT

- How much to take

For adults and adolescents (at least 12 years old and above, at least weighing 35 kg and above):

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

- When to take it

It is recommended to take VOMETA[®] FT 15-30 minutes before meals. If taken after meals, absorption of the drug is somewhat delayed.

- How long to take it

Your doctor will decide how long you will need to take this medicine. Do not take VOMETA[®] FT for longer than 7 days without consulting your doctor.

- If you forget to take it

- If you forget to take VOMETA[®] FT, take it as soon as you remember.
- However if it is almost time for the 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.

- If you take too much (overdose)

If you have taken too many VOMETA[®] FT tablets contact your doctor, pharmacist or the poisons 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. Overdosage has been reported primarily in infants and children. Symptoms of overdosage may include agitation, altered consciousness, convulsions, disorientation, sleepiness and uncontrolled movements.

While you are using it

- Things you must do

Always follow your doctor's instructions carefully.

If you are about to be started on any new medicine, you should remind your doctor and pharmacist that you are taking VOMETA[®] FT.

If you become pregnant while taking this medicine, tell your doctor immediately.

- Things you must not do

Do not change the dosage without checking with your doctor.

Do not use VOMETA[®] FT to treat any other complaint unless your doctor says so.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

- Things to be careful of

VOMETA[®] FT may cause sleepiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Side Effects

Like all medicines, VOMETA[®] FT can have side effects, although not everybody gets them.

Stop taking VOMETA[®] FT 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 VOMETA[®] FT.
- 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.
- 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

- Dry mouth

Uncommon

- Lowering of sexual drive (libido) in men
- Feeling anxious
- 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

Very Rare

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.

VOMETA[®] FT may be associated with an increased risk of heart rhythm disorder and heart malfunctions and suddenly stops beating unexpectedly. This risk may be more likely in those over 60 years old or taking doses higher than 30 mg per day.

Not known

- Feeling agitated or irritable
- Feeling more nervous than usual
- Abnormal eye movements
- 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 individuals who have used VOMETA[®] FT have experienced the following unwanted effects: Restlessness; swollen or enlarged breasts, unusual discharge from breasts, irregular menstrual periods

VOMETA[®] FT TABLET

Domperidone (10mg)

in women, difficulty breastfeeding, depression, hypersensitivity.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and disposal of VOMETA[®] FT

- Storage

Keep VOMETA[®] FT tablets in the pack until it is time to take them. Keep VOMETA[®] FT at temperature below 30°C, protect from light.

- Disposal

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 to protect the environment.

Product description

- What it looks like

VOMETA[®] FT tablets are white to off white round tablet, flat beveled edge, has a mint odor, sweet and slight hot taste. The tablets are printed “DEXA” on one side and blank on the other side. They are available in blister packs of 10 fast-melting tablets.

- Ingredients

- Active ingredient
Domperidone
- Inactive ingredients
Cross Carmellose Sodium,
Peppermint Flavor,
Polyvinylpyrrolidone,
Ethylcellulose aqueous dispersion,
Strawberry dry flavour,
Low-substituted Hydroxypropyl Cellulose,
Colloidal Anhydrous Silica,
Crospovidone,
Mannitol,
Purified Water,

Aspartame,
Magnesium Stearate,
Sodium chloride,
Sodium Benzoate,
Talc.

- MAL number

MAL10080060AZ

Manufacturer

PT Dexa Medica
Jl. Jenderal. Bambang Utoyo 138
Palembang-Indonesia

Product Registration Holder

Apex Pharmacy Marketing Sdn. Bhd.
No.2, Jalan SS 13/5,
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Date of revision

28/04/2017

Serial Number

BPFK(R4/1)250417/00088