

Patient Information Leaflet

DOMPERIDONE PIERRE FABRE 10mg orodispersible tablets

Domperidone

Read this entire leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor, or your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What DOMPERIDONE PIERRE FABRE 10 mg, orodispersible tablets is and what it is used for

DOMPERIDONE PIERRE FABRE is an orodispersible tablet (dissolves in the mouth). Domperidone, is a substance belonging to the dopamine antagonist class of drugs which acts on intestinal motility (movements within your intestines).

This medicine is used for the relief of:

- nausea (feeling sick) and vomiting,
- feelings of distension (uncomfortable abdomen),
- discomfort or gastric regurgitation (back-flow of the stomach contents into the mouth).

This medicine can be used by adults and adolescents (aged over 12 years who are also over 35kg).

2. Before you take DOMPERIDONE PIERRE FABRE 10 mg, orodispersible tablets

Do not take DOMPERIDONE PIERRE FABRE 10 mg, orodispersible tablet

- if you are hypersensitive (allergic) to domperidone or any of the other ingredients of DOMPERIDONE PIERRE FABRE;
- if you suffer from a certain brain tumour (prolactinoma);

- if you have severe abdominal pain or persistent black stools.

If you are unsure about taking this medicine, it is essential to ask your doctor or pharmacist for advice.

Take special care with DOMPERIDONE PIERRE FABRE 10 mg, orodispersible tablets

Before taking this medicine contact your doctor if you:

- suffer from hepatic insufficiency (liver function failure)
- suffer from renal insufficiency (kidney function 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.

Domperidone 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 30mg per day. Domperidone should be used at the lowest effective dose in adults and children.

DOMPERIDONE PIERRE FABRE 10 mg, orodispersible tablets are not suited for children under 12 years of age and weighing less than 35 kg.

The risk of neurological side effects is higher in young children.

If you are unsure about taking this medicine, do not hesitate to ask your doctor or pharmacist for advice.

If you take oral ketoconazole or oral erythromycin, do not take this medicine without consulting your doctor (see Using other medicines).

Using other medicines

Do not take DOMPERIDONE PIERRE FABRE if you are taking oral ketoconazole (a medicine for fungal infections), or oral erythromycin (an antibiotic) without consulting your doctor. It is important to ask your doctor or pharmacist when you are using any other medicines, including medicines obtained without prescription.

Taking DOMPERIDONE PIERRE FABRE with food and drink

It is recommended to take this medicine 15-30 minutes before meals. If this medicine is taken after meals, its effectiveness may be delayed.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

The experience with use of Domperidone in pregnant women is limited . The possible risk for humans is unknown. If you are pregnant, you should use DOMPERIDONE PIERRE FABRE only, if your physician considers this clearly necessary.

A low amount of the active substance of Domperidone passes into mother's milk. As it is not known whether this is harmful to your baby, you should not take DOMPERIDONE PIERRE FABRE if you are breast-feeding.

Driving and using machines

This medicine has no or negligible influence on the ability to drive and use machines. If you start to feel unwell you should not perform tasks that require mental alertness such as driving a car or operating machinery.

Important information about some of the ingredients of DOMPERIDONE PIERRE FABRE 10 mg, orodispersible tablets.

The tablets contain sulphur dioxide. The sulphur dioxide may rarely cause severe hypersensitivity reactions and bronchospasm.

3. How to take DOMPERIDONE PIERRE FABRE 10mg, orodispersible tablets

Always take DOMPERIDONE PIERRE FABRE exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Dosage:

Adults and adolescents (aged over 12 years who are also over 35kg in weight)
1 to 2 tablets 3 to 4 times per day.

Do not exceed the maximum dose of 8 tablets per day.

Children below 12 years and children weighing less than 35 kg

This tablet form is not suitable. Other domperidone containing products are available for children weighing less than 35kg.

Method of administration:

Taken by oral use (by mouth).

It is recommended to take this medicine 15-30 minutes before meals.

Since the tablet dissolves rapidly in the mouth with the help of the saliva, the orodispersible tablet can be taken with or without water.

Without water, place the tablet on the tongue and let it dissolve in the mouth before swallowing. If convenient, a glass of water can be taken afterwards.

The tablet can be also dispersed into a glass of water immediately before swallowing.

Duration of treatment:

The initial treatment period is 4 weeks. If the symptoms persist after 4 weeks, consult your doctor who will assess the need to continue the treatment.

If you take more DOMPERIDONE PIERRE FABRE 10 mg, orodispersible tablets than you should

If you have taken too much DOMPERIDONE PIERRE FABRE you may experience sleepiness, confusion and/or movements disorders (such as abnormal muscular movements or tremors). If you have taken too many tablets, consult your doctor or pharmacist immediately for advice.

In children, the extrapyramidal symptoms may occur in case of overdosage.

If you forget to take DOMPERIDONE PIERRE FABRE 10 mg, orodispersible tablets

Take your medicine as soon as you remember. If it is almost time for your next dose, wait until that is due then continue as normal.

Do not take a double dose to make up for a forgotten dose.

If you stop taking DOMPERIDONE PIERRE FABRE 10 mg, orodispersible tablets

If you use DOMPERIDONE PIERRE FABRE on prescription from your doctor, do not stop taking this medicine without consulting your doctor.

4. Possible side effects

Like all medicines, DOMPERIDONE PIERRE FABRE can cause side effects, although not everybody gets them.

Other reported side effects include:

Rare side effects (occurs in 1 to 10 users in 10,000):

- increased prolactin levels (hormone causing milk production),
- galactorrhoea (flow of milk outside milk production periods),
- gynecomastia (abnormal development of breasts in males),
- amenorrhoea (period disorders),
- gastrointestinal disorders, including very rare and transient intestinal cramps.

Very rare side effects (occurs in less than 1 user in 10,000):

- disorders of psychiatric system: agitation and nervousness
- disorders of the nervous system: abnormal muscle movements or tremor (shaking), convulsion, somnolence and headache can occur.

The risk of convulsion, agitation and somnolence is greatest in children.

- diarrhoea,
- Abnormal liver function test results

In case the following adverse effects occurred, you should stop the treatment immediately and consult your doctor or pharmacist immediately for advice:

- disorders of the immune system: allergic reactions (e.g. skin rash, itching, shortness of breath, wheezing and/or swollen face) have been reported;

Side effects (frequency unknown):

- Domperidone 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 30mg per day. Domperidone should be used at the lowest effective dose in adults and children.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store DOMPERIDONE PIERRE FABRE 10 mg, orodispersible tablets

Keep out of the reach and sight of children.

Do not use DOMPERIDONE PIERRE FABRE after the expiry date which is stated on the carton and on the blister foil.

The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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.

6. Further information

What DOMPERIDONE PIERRE FABRE 10 mg, orodispersible tablets contains

- The active substance is domperidone (10 mg per orodispersible tablet).
- The other ingredients are mannitol, microcrystalline cellulose, croscarmellose sodium, peppermint flavour (essential oil of star anise, clove oil, essential oil of corn mint, peppermint oil, L-menthol, maltodextrin, arabic gum, sulphur dioxide), maltodextrin, acesulfame potassium, magnesium stearate, ammonium glycyrrhizate.

What DOMPERIDONE PIERRE FABRE 10 mg , orodispersible tablets looks like and contents of the pack?

DOMPERIDONE PIERRE FABRE is presented in the form of an uniformly white or almost white, biconvex, round orodispersible tablet with a characteristic odor of mint.

DOMPERIDONE PIERRE FABRE is available in boxes containing 10 or 30 orodispersible tablets.

Marketing Authorisation holder

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Manufacturer

PIERRE FABRE MEDICAMENT PRODUCTION

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For any information on this product contact Pierre Fabre Ltd: Phone: + 44 (0) 1962 874400

Other formats

To listen to or request a copy of this leaflet in Braille, large print or audio call:

+ 44 (0)1773 375370. Be ready to give the following information:

Product name: DOMPERIDONE PIERRE FABRE 10mg orodispersible tablets

Reference number: PA 1287/2/1

This is a service provided by the Royal National Institute of the Blind.

This medicinal product is authorised in the members states of the EEA under the following names

France, Ireland : DOMPERIDONE PIERRE FABRE

Italy : NEOPERIDYS

Belgium, Cyprus, Czech Republic, Estonia, Greece, Latvia, Lithuania, Luxembourg, Poland, Romania, Slovakia ,

Spain: OROPERIDYS

This leaflet was last approved in 03/2013.