

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Domperidona Baldacci 10 mg film-coated tablets
Domperidone

▼ This medicine is subject to additional monitoring. This will allow for the rapid identification of new security information. You can help by reporting any side effects you have. To learn how to report side effects, see the end of section 4.

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

- Keep this brochure. You may need to read it again.
- If you still have questions, talk to your doctor or pharmacist.
- This medicine has been prescribed for you only. You mustn't give it to others. The medicine may be harmful to them even if they show the same signs of disease.
- If you experience any side effects, including possible side effects not listed in this leaflet, talk to your doctor or pharmacist. See section 4.

What is in this leaflet:

1. What is Domperidona Baldacci and what is used for
2. What you need to know before you take Domperidona Baldacci
3. How to take Domperidona Baldacci
4. Possible side effects
5. How to save Domperidona Baldacci
6. Contents of the package and other information

1. WHAT IS DOMPERIDONA BALDACCI AND WHAT IS USED FOR

Domperidone is a drug that acts on gastric motility (stomach movement) (Pharmacotherapeutic group: Digestive tract; modifiers of gastrointestinal motility; modifiers of gastric motility or prokinetic).

This medicine is used in adults to treat nausea (feeling sick) and vomiting.

2. WHAT YOU NEED TO KNOW BEFORE TAKING DOMPERIDONA BALDACCI

Do not take Domperidona Baldacci

- If you are allergic (hypersensitive) to the active substance (domperidone) or any other component of this medicine (listed in section 6).
- If you have a prolactin-releasing pituitary disease or tumor (prolactinoma)
- In situations where stimulation of gastric motility may be harmful: gastrointestinal bleeding, mechanical obstruction or perforation.
- If you suffer from moderate or severe liver disease

- If your ECG (electrocardiogram) shows a heart problem called "corrected prolonged QT interval".
- If you have or have ever had a problem where your heart cannot pump blood into the whole body as well as it should (a condition called heart insufficiency).
- If you have a problem that causes you a low level of potassium or magnesium or a high level of potassium in your blood
- If you are taking certain medicines (see "Other medicines and Domperidona Baldacci").

Warnings and precautions

This medicine is only indicated for adults

Before taking this medicine contact your doctor if:

- You suffer from liver problems (liver failure or impairment) (see "Do not take Domperidona Baldacci").
- You suffer from kidney problems (kidney failure or renal impairment). It is advisable to talk to your doctor 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 check you regularly. Domperidone may be associated with an increased risk of heart rhythm disorders and cardiac attack. This risk may be more likely in individuals over the age of 60 years or in subjects taking doses greater than 30 mg per day. The risk also increases when domperidone is given in conjunction with certain medicines. Talk to your doctor or pharmacist if you are taking medicines for the treatment of infections (fungal infections or bacterial infection) and/or if you have heart problems or AIDS/HIV (see section for other medicines and Domperidona Baldacci).

Domperidone should be used at the minimum effective dose in adults.

When taking domperidone, contact your doctor if you suffer from heart rhythm disorders such as palpitations, breathing difficulties and loss of consciousness. In this case, treatment with domperidone should be discontinued.

Other medicines and Domperidona Baldacci

Tell your doctor or pharmacist if you are taking, or have recently taken, or if you are about to take other medicines.

Do not take Domperidona Baldacci if you are taking medicines for the treatment of:

- fungal infections such as azole antifungals, more specifically oral ketoconazole, fluconazole or voriconazole
- bacterial infections, more specifically erythromycin, clarithromycin, telitromycin, moxifloxacin, pentamidine (these are antibiotics)
- heart problems or high blood pressure (e.g., amiodarone, dronedarone, quinidine, disopyramide, dofetide, sotalol, diltiazem and verapamil)
- psychoses (e.g., haloperidol, pimozide and sertindol)

- depression (e.g., citalopram and escitalopram)
- gastrointestinal disorders (e.g., cisapride, dolasetron and prucalopride)
- allergy (e.g., mequitazine and myzolastin)
- malaria (especially halofantrine)
- AIDS/HIV (protease inhibitors)
- cancer (e.g., toremifene, vandetanib and vincana)

Tell your doctor or pharmacist if you are taking medicines to treat infections, heart problems or AIDS/HIV.

It is important to ask your doctor or pharmacist if it is safe to take Domperidona Baldacci when you are taking any other medicines, including medicines obtained without a prescription.

Pregnancy and breastfeeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, consult your doctor or pharmacist before taking this medicine.

Pregnancy

Post-marketing data on the use of domperidone in pregnant women are limited. A study with rats demonstrated reproductive toxicity at a high dose for the mother. The potential risk to humans is unknown. However, Domperidona Baldacci should only be used during pregnancy if the benefits justify the potential risks.

Breastfeeding

Small amounts of domperidone were found in breast milk. Domperidone may cause undesirable side effects that affect the heart in a baby being breastfed. Domperidone should only be used during the breastfeeding period if your doctor considers this to be clearly necessary. Consult your doctor before taking this medicine.

Driving vehicles and using machinery

Domperidona Baldacci does not affect or have negligible influence on the ability to drive and use machines.

Domperidona Baldacci contains monohydrate lactose.

If you have been told by your doctor that you have an intolerance to some sugars, contact them before taking this medicine.

3. HOW TO TAKE DOMPERIDONA BALDACCI

Follow these instructions strictly unless otherwise indicated by your doctor.

Duration of treatment:

Symptoms usually disappear within 3 to 4 days of taking this medicine. Do not take Domperidona Baldacci for more than 7 days without consulting your doctor.

Adults

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

If you take more Domperidona Baldacci than you should

If you have used or taken an excessive amount of Domperidona Baldacci, contact your doctor, pharmacist or poison centre immediately, especially if a child has taken too much. In the event of overdose, symptomatic treatment can be implemented. ECG monitoring may be performed due to the possibility of a heart problem called prolonged QT interval.

If you forget to take Domperidona Baldacci

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

If you still have questions about the use of this medicine, talk to your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Domperidona Baldacci can cause side effects, although these do not manifest in everyone.

Rare (occur in 1 or more in 10,000 patients and in less than 1 in 1,000 patients):

- Endocrine disorders: increased prolactin levels.
- Diseases of the genitals and breast: galactorrhoea (appearance of milk), gynecomastia (increase in breast volume), amenorrhea (irregular or absent menstrual period).
- Gastrointestinal disorders: gastrointestinal changes, including transient (very rare) intestinal cramping pains.

In rare cases, increased prolactin levels can lead to side effects such as galactorrhea, gynecomastia, and amenorrhea.

Very rare (occur in less than 1 in 10,000 patients):

- Diseases of the nervous system: abnormal muscle movements or tremor may occur. The risk of abnormal muscle movements is higher in newborns, infants and children. These

side effects reverse spontaneously and completely as soon as treatment is discontinued. Convulsions, drowsiness, and headaches may also occur.

- Gastrointestinal diseases: diarrhea.
- Diseases of the immune system: allergic reactions have been reported (e.g., rash, itching, shortness of breath, wheezing and/or swelling of the face); if this happens, you should stop treatment immediately.
- Psychiatric disorders: agitation, nervousness.
- Skin and subcutaneous tissue infections: hives, itching, rash.
- Complementary diagnostic tests: abnormal liver function tests.

Other central nervous system-related effects such as seizure, agitation, and drowsiness are also very rare and reported primarily in infants and children.

Unknown (frequency cannot be calculated from available data)

Disorders of the cardiovascular system: heart rhythm disorders (rapid or irregular heartbeat) have been reported; in this case, you should immediately suspend treatment. Domperidone may be associated with an increased risk of heart rhythm disorder and cardiac attack. This risk may be more likely in individuals over the age of 60 years or in subjects taking doses greater than 30 mg per day. Domperidone should be used at the minimum effective dose in adults

Communication of side effects

If you experience any side effects, including possible side effects not listed in this leaflet, talk to your doctor, pharmacist, or nurse. You can also report side effects directly to INFARMED, I.P. through the contacts below. By reporting side effects, you are helping to provide more information about the safety of this medicine.

INFARMED, I.P.

Directorate of Drug Risk Management
Parque da Saúde de Lisboa, Av. Brasil 53
1749-004 Lisboa

Tel: +351 21 798 71 40

Fax: +351 21 798 73 97

Website: <http://extranet.infarmed.pt/page.seram.frontoffice.seramhomepage>

E-mail: farmacovigilancia@infarmed.pt

5. HOW TO STORE DOMPERIDONA BALDACCI

Do not store above 25°C.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date printed on the outer packaging after Val. The expiry date is the last day of the month indicated.

Do not use Domperidona Baldacci if you experience visible signs of deterioration.

Do not throw away any medicines in the plumbing or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. PACKAGING CONTENTS AND OTHER INFORMATION

Domperidona Baldacci composition

- The active substance is domperidone. Each film-coated tablet contains 10 mg of domperidone.

The other components are: monohydrated lactose, corn starch, crospovidone, povidone K30, sodium laurylsulfate, hydrogenated vegetable oil, magnesium stearate and microcrystalline cellulose.

Coating: hypromellose (type E5) and macrogol 6000.

What Domperidona Baldacci looks like and the contents of the pack

Domperidona Baldacci is a medicine that presents as white, oblong film-coated tablets, with groove on one side, for oral administration, in packs of 20 or 60 tablets.

It is possible that not all presentations are marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Baldacci - Portugal, S.A.

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1549-005 Lisboa

Tel: 217783031

Fax: 217785457

E-mail: medico@baldacci.pt

Manufacturer

Farmalabor – Produtos Farmacêuticos, SA

Zona Industrial de Condeixa-a-Nova

3150-194 Condeixa-a-Nova

Portugal

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