

PACKAGE LEAFLET: INFORMATION FOR THE USER

Domperidone Accord 10 mg tablets

This medicine is subject to additional monitoring. This allows new safety information to be identified quickly. You can help by reporting any side effects you may experience. At the end of section 4, you will read how to do this.

Read the entire 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.
- Do you have any questions? Then contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.
- Do you experience any of the side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist

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1. WHAT IS DOMPERIDONE ACCORD 10 MG AND WHAT IS IT USED FOR?

Domperidone is used to treat nausea and vomiting in adults and adolescents (from 12 years of age and weighing 35 kg or more).

2. WHEN SHOULD YOU NOT USE THIS MEDICINE OR BE EXTRA CAREFUL WITH IT?

Domperidone may be associated with an increased risk of heart rhythm disorders and cardiac arrest. This risk is higher in people over 60 years of age and in people who use more than 30 mg of domperidone per day. In adults and children, domperidone should be used at the lowest effective dose possible.

When should you not use this medicine?

- You are allergic to any of the ingredients in this medicine. These ingredients can be found in section 6.
- You have a pituitary gland tumor (prolactinoma)
- If you have or think you have a serious stomach problem, such as a stomach or intestinal bleeding (recognizable by persistent black stools) or in case of a blockage, obstruction, or damage to the stomach or intestine (usually accompanied by severe abdominal cramps).
- You have moderate or severe liver disease.
- Your ECG (electrocardiogram) indicates that you have a heart problem called 'corrected QT interval prolongation'.
- You have or have had a problem where your heart cannot pump blood adequately through your body (a condition called heart failure).

- You have a problem that causes you to have low potassium or magnesium levels or high potassium levels in your blood.
- If you are using certain medications (see “Are you using any other medications?”).
- If you have or might have a rare adrenal gland tumor (pheochromocytoma), as this could increase your blood pressure.

When should you be extra careful with this medicine?

These medicines are not suitable for newborns, infants, and children under 12 years or adolescents weighing less than 35 kg. If Domperidone is for a child, ask your doctor for a suitable dosage form for children.

Contact your doctor before using this medicine if you:

- have liver problems (liver dysfunction or liver failure) (see “When should you not use this medicine?”),
- have kidney problems (kidney dysfunction or kidney failure). It is recommended to ask your doctor for advice during long-term treatment as you may need to use a lower dose or use this medicine less frequently. Your doctor may also consider regular monitoring necessary.

Domperidone may be associated with a higher risk of heart rhythm disorders and cardiac arrest. This risk is more likely in people over 60 years of age or those using a dose higher than 30 mg per day. The risk is also greater if this medicine is used together with certain other medications. Tell your doctor or pharmacist if you are using medications for infections (fungal or bacterial infections) and/or if you have heart problems or AIDS/HIV (see the section “Are you using any other medications?”).

The lowest effective dose of domperidone should be used in adults and children.

Contact your doctor if you experience heart rhythm disorders such as palpitations, difficulty breathing, or loss of consciousness while using this medicine. Treatment with domperidone should be discontinued.

Contact your doctor or pharmacist before using this medicine.

Are you using any other medicines?

Domperidone Accord and apomorphine

Before using Domperidone Accord and apomorphine, your doctor will check if you can tolerate both medicines when used simultaneously. Ask your doctor or specialist for personal advice. Refer to the package leaflet for apomorphine.

Are you using any other medicines besides Domperidone Accord tablets, or have you recently done so, or is there a possibility that you will use other medicines in the near future? Then tell your doctor or pharmacist.

Do not use domperidone if you are taking medicines for the treatment of:

- fungal infections, such as pentamidine or azole antifungals, especially itraconazole, oral ketoconazole, fluconazole, posaconazole, or voriconazole

- bacterial infections, particularly erythromycin, clarithromycin, telithromycin, levofloxacin, moxifloxacin, spiramycin (these are antibiotics)
- heart problems or high blood pressure (e.g., amiodarone, dronedarone, quinidine, disopyramide, dofetilide, sotalol, diltiazem, verapamil, hydroquinidine, ibutilide)
- psychosis (e.g., haloperidol, pimozide, sertindole)
- depression (e.g., citalopram, escitalopram)
- gastrointestinal disorders (e.g., cisapride, dolasetron, prucalopride)
- allergy (e.g., mequitazine, mizolastine)
- malaria (especially halofantrine, lumefantrine)
- AIDS/HIV such as ritonavir or saquinavir (these are protease inhibitors);
- hepatitis C (e.g., telaprevir);
- cancer (e.g., toremifene, vandetanib, vincamine)
- bepridil, difemanil, methadone

Tell your doctor or pharmacist if you are taking medicines for infections, heart problems, or AIDS/HIV or Parkinson's disease.

It is important to ask your doctor or pharmacist if Domperidone Accord 10 mg is safe for you if you are taking other medicines, including those obtained without a prescription.

What should you pay attention to with food and drink?

It is recommended to take Domperidone before meals, as the absorption of the medicine is slightly slower after a meal.

Pregnancy and breastfeeding

It is not known whether the use of Domperidone is harmful during pregnancy.

Are you pregnant, do you think you might be pregnant, or are you planning to become pregnant? Then contact your doctor before using this medicine. Your doctor will determine if you can use this medicine.

Pregnancy

It is not known whether the use of Domperidone is harmful during pregnancy.

Are you pregnant, do you think you might be pregnant, or are you planning to become pregnant? Then contact your doctor before using this medicine. Your doctor will determine if you can use this medicine.

Breastfeeding

Small amounts of domperidone have been found in breast milk. Domperidone may have unwanted side effects that affect the heart of a breastfeeding baby. This medicine should only be used during breastfeeding if your doctor deems it strictly necessary. Ask your doctor for advice before taking this medicine.

Driving and using machines

If you are taking Domperidone Accord tablets, you may feel drowsy or confused or have less control over your movements. If that happens, you should not drive or use tools or machines.

Domperidone Accord 10 mg contains lactose

This medicine contains lactose (a type of sugar).

If your doctor has told you that you do not tolerate certain sugars, contact your doctor before taking this medicine.

3. HOW TO USE THIS MEDICINE?

Always use this medicine exactly as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

Follow these instructions carefully, unless your doctor prescribes otherwise.

It is recommended to take Domperidone before meals, as the absorption of the medicine is slightly slower after a meal.

Treatment duration:

Symptoms usually disappear within 3-4 days after you start using this medicine. Do not use this medicine for more than 7 days without consulting your doctor.

Adults and adolescents aged 12 years and older with a body weight of 35 kg or more
The recommended dosage is one tablet, up to three times a day, preferably before meals. Do not take more than three tablets per day. Swallow the tablets with some water or other liquid. Do not chew the tablets.

Newborns, infants, and children under 12 years and adolescents weighing less than 35 kg
Domperidone Accord tablets are not suitable for newborns, infants, and children under 12 years and adolescents weighing less than 35 kg.

If Domperidone Accord is intended for a child, consult your doctor for a suitable dosage form for children.

Method of use

For oral use. It is recommended to take the tablets before meals. Swallow the tablets whole with a sufficient amount of water.

Have you used too much of this medicine?

If you have taken or used too much of this medicine, contact your doctor, pharmacist, or nearest emergency room immediately, especially if a child has taken too much. In the event of an overdose, treatment of the symptoms may be initiated. Due to the risk of a heart problem called QT interval prolongation, ECG monitoring may be performed. It is advised to take activated charcoal (Norit) immediately in case of overdose (this can prevent the absorption of domperidone in the body if used quickly after taking the tablets). Keep the packaging so the doctor can see which medicine it is.

The symptoms that occur when someone has taken too many tablets include drowsiness, confusion, uncontrolled movements (especially in children), including unusual eye movements, unusual tongue movements, or an abnormal posture (such as a twisted neck).

Have you forgotten to use this medicine?

Take the medicine as soon as you remember. However, if it is almost time for the next dose, skip the missed dose and continue with the regular schedule. Do not take a double dose to make up for a forgotten dose.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like any medicine, this medicine can cause side effects, although not everyone gets them.

Sometimes (reported by less than 1 in 100 patients):

Involuntary movements of the face or arms and legs, excessive trembling, excessive muscle stiffness or muscle spasms.

Unknown (cannot be determined from the available data)

Seizures;

A type of reaction that can occur quickly after administration and is recognized by rash, itching, shortness of breath, and/or a swollen face;

A severe hypersensitivity reaction that can occur quickly after administration and is recognized by hives, itching, hot flushes, fainting, and difficulty breathing, among other possible symptoms;

Disorders of the heart and blood vessels (the cardiovascular system):

Arrhythmias (rapid or irregular heartbeat) have been reported. If this occurs, you must stop the treatment immediately. Domperidone may be associated with an increased risk of arrhythmias and cardiac arrest. The risk may be higher in people over 60 years of age or those taking a dose higher than 30 mg per day. The lowest effective dose of domperidone should be used in adults and children.

Stop the treatment with Domperidone Accord and contact your doctor immediately if you notice the side effects described above.

Other side effects observed with Domperidone Accord are listed below:

Common (reported by at least 1 in 100 patients but by less than 1 in 10 patients):

Dry mouth.

Sometimes (reported by at least 1 in 1000 patients but by less than 1 in 100 patients):

Anxiety;

Restlessness;

Nervousness;

Loss of interest in sex or reduced interest in it;

Headache;

Drowsiness;

Diarrhea;

Skin rash;

Itching;

Hives;

Painful or tender breasts;

Milk discharge from the breasts; • General feeling of weakness;

Feeling dizzy.

Unknown (cannot be determined from the available data):

Upward rolling eyes;

Absence of menstruation in women;

Enlarged breasts in men;

Inability to urinate;
Changes in certain laboratory test results;
“Restless leg” syndrome (unpleasant feeling, with an irresistible urge to move the legs, and sometimes the arms and other body parts).

Some patients who have used Domperidone Accord for conditions and dosages requiring medical supervision have experienced the following side effects: restlessness, swollen or enlarged breasts, unusual discharge from the breasts, irregular menstruation in women, difficulties with breastfeeding, depression, hypersensitivity.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, Website: www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. HOW TO STORE THIS MEDICINE?

Keep out of the sight and reach of children.

Do not store above 30°C. Store in the original packaging.

Do not use this medicine after the expiry date. It can be found on the label after EXP. It includes a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer need. They will be destroyed in a responsible manner and will not enter the environment.

6. CONTENTS OF THE PACKAGING AND OTHER INFORMATION

What substances are in this medicine?

The active substance in this medicine is domperidone maleate, 10 mg per tablet.

The other substances in this medicine are: microcrystalline cellulose, lactose monohydrate, povidone, maize starch, magnesium stearate, colloidal silicon dioxide (anhydrous), and sodium lauryl sulfate (see section 2: When should you not use this medicine or be extra careful?).

What do Domperidone Accord tablets look like and what is in a package?

White, round, biconvex tablets with the imprint 'I36A' on one side, and no imprint on the other side.

Domperidone Accord 10 mg is supplied in blister packs of 10 tablets (2 or 3 strips per package).

Not all mentioned packages are marketed.

Marketing authorization holder

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