

Biotech Laboratories (Pty) Ltd	1.3.2 - Patient Information Leaflet
BIO-DOMPERIDONE 10, film-coated tablets Each tablet contains 10 mg domperidone	

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

BIO DOMPERIDONE 10, film-coated tablet.

Domperidone

Contains sugar (lactose monohydrate, 58 mg per tablet).

Read all of this leaflet carefully before you start taking BIO DOMPERIDONE 10

- Keep the leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- BIO DOMPERIDONE10 has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What BIO DOMPERIDONE10 is and what it is used for
2. What you need to know before you take BIO DOMPERIDONE10
3. How to take BIO DOMPERIDONE10
4. Possible side effects
5. How to store BIO DOMPERIDONE10
6. Contents of the pack and other information

1. What BIO DOMPERIDONE 10 is and what it is used for

Domperidone, the active ingredient in BIO DOMPERIDONE10 increases the movements or contractions of the stomach and bowel.

BIO DOMPERIDONE10 is used in adults and adolescents over 12 years of age and weighing over 35 kg for:

- Short term relief not exceeding 7 days for stomach discomfort due to food moving slowly through the stomach and intestines, where you may feel symptoms such as:

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- fullness during or shortly after a meal,
- a “heavy stomach”,
- bloated feeling,
- excessive belching,
- passing wind (flatulence),
- nausea and vomiting,
- a burning feeling and/or pain in the stomach area,
- Short term use not exceeding 7 days for discomfort due to backflow of stomach acid, where you may experience belching and/or heartburn,
- Short term use not exceeding 7 days except when used for nausea and vomiting due to various causes including chemotherapy, radiotherapy or other medicines where use should not exceed 4 weeks.

2. What you need to know before you take BIO DOMPERIDONE 10

BIO DOMPERIDONE 10 tablets are unsuitable for use in children at or less than 12 years of age.

BIO DOMPERIDONE 10 tablets are unsuitable for use in adolescents weighing less or 35 kg body weight.

Do not take BIO DOMPERIDONE 10 if:

- you are hypersensitive (allergic) to domperidone or any of the other ingredients of BIO DOMPERIDONE 10 (listed in section 6),
- you have a tumour that releases prolactin (prolactinoma),
- your intestines are bleeding, have been perforated or you have an intestinal obstruction,
- you are pregnant or breastfeeding (see section on pregnancy and breastfeeding),
- if you have a problem that gives you a low level of potassium or magnesium, or a high level of potassium in your blood,
- your heart beats excessively slow (bradycardia) or if you have a heart condition called heart-block,
- you have a pre-existing heart disease,
- you have a known heart condition of a congenital long QT interval or a family history thereof,

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- you are using one of the following medications: ketoconazole and itraconazole, fluconazole, voriconazole, posaconazole an anti-fungal treatment; antibiotics such as erythromycin, azithromycin, roxithromycin, clarithromycin, telithromycin, amiodarone, protease inhibitors used in the treatment of HIV such as amprenavir, atazanavir, fosamprenavir, indinavir, ritonavir, nelfinavir, saquinavir and quinolones,
- if you have a moderate or severe liver disease.

Warnings and precautions

Take special care with BIO DOMPERIDONE 10 if:

- your liver function is impaired (see “Do not take BIO DOMPERIDONE 10”),
- 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 regularly,
- you are at risk of fluid retention (such as heart failure),
- you are an elderly person,
- you are taking monoamine oxidase inhibitors such as selegiline used for the treatment of Parkinson’s disease or tranylcypromine and moclobemide used for the treatment of depression,
- you are taking other medicines to treat infections (fungal infections or bacterial infections) and/or for heart problems or AIDS/HIV (see “Do not take BIO DOMPERIDONE 10”),

While taking BIO DOMPERIDONE 10, contact your doctor if you experience heart rhythm disorders such as palpitations, trouble breathing, or loss of consciousness. Treatment with BIO DOMPERIDONE 10 should be stopped.

Children and adolescents

BIO DOMPERIDONE 10 tablets are unsuitable for use in children at or less than 12 years of age in adolescents weighing less or 35 kg body weight.

Other medicines and BIO DOMPERIDONE 10

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Always tell your healthcare provider if you are taking any other medicines. (This includes all complementary or traditional medicines).

BIO DOMPERIDONE 10 may interact with the following medicines:

Do NOT take BIO DOMPERIDONE 10 tablets if you are taking certain medicines that slow down the breaking down (metabolism) of other medicines in the body and can also affect your heart rhythm; such as:

- Antibiotics such as erythromycin, azithromycin, clarithromycin, telithromycin or levofloxacin and moxifloxacin, spiramycin,
- Medicines used for the treatment of fungal infections e.g., ketoconazole, itraconazole,
- Medicines to treat heart problems or high blood pressure such as amiodarone, dronedarone, quinidine, disopyramide, dofetilide, sotalol, diltiazem, verapamil,
- Medicines to treat psychoses; haloperidol, pimozide, sertindole,
- Depression treatment e.g., citalopram, escitalopram, tranylcypromine and moclobemide
- Malaria treatment e.g., halofantrine,
- Medicines to treat gastrointestinal disorders e.g., cisapride, dolasetron, prucalopride,
- Allergy treatment e.g., mequitazine, mizolastine,
- Cancer treatment e.g., toremifene, vandetanib, vincamine,
- Medicine to treat angina pectoris e.g., bepridil,
- Medicine to treat excessive sweating e.g., diphemanil,
- Treatment of opioid dependence e.g., methadone.
- MAO inhibitors (e.g., selegiline used for the treatment of Parkinson's disease)
- Anti-cholinergic medicines (such as hyoscine butylbromide, mebeverine, ipratropium bromide, orphenadrine)
- Antacids, cimetidine used for heartburn and ulcers and sodium bicarbonate - These medicines can be taken if you are also taking BIO DOMPERIDONE tablets but they should not be taken at the same time. You should take oral BIO DOMPERIDONE tablets before meals and the stomach acid medicine after meals.
- Dopaminergic agonists such as cabergoline.

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BIO DOMPERIDONE 10 with food and drink

Take BIO DOMPERIDONE 10, 15 – 30 minutes before meals. If taken after meals, absorption of the medicine is somewhat delayed.

Pregnancy and breastfeeding

You should not take BIO DOMPERIDONE 10 if you are pregnant.

You should not take BIO DOMPERIDONE 10 if you are breastfeeding your baby.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Driving and using machines

Do not drive or operate machines if you feel tired, sleepy or dizzy after taking BIO DOMPERIDONE 10 tablets.

It is not always possible to predict to what extent BIO DOMPERIDONE 10 may interfere with the daily activities of a patient. You should ensure that you do not engage in the above activities until you are aware of the measure to which BIO DOMPERIDONE 10 affects you.

BIO DOMPERIDONE 10 contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this BIO DOMPERIDONE 10.

3. How to take BIO DOMPERIDONE 10

Do not share medicines prescribed for you with any other person.

Always take BIO DOMPERIDONE 10 exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

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BIO DOMPERIDONE 10 tablets are most effective if taken a quarter to a half hour before the meal and, if needed, before you go to bed. The tablets should be swallowed whole with a glass of water.

The dosage of this medicine will be different for different patients. You should always take the lowest amount of BIO DOMPERIDONE 10 that works for you and you should not take it for longer than seven days.

The quantity of BIO DOMPERIDONE 10 that you take depends on your specific medical condition and the time allowed between doses.

If BIO DOMPERIDONE 10 tablets are for nausea and vomiting, you should not usually need to take it for more than one week. Talk to your doctor if your nausea and vomiting lasts for more than one week.

If BIO DOMPERIDONE 10 tablets are for stomach discomfort, stomach acid backflow or nausea and vomiting due to chemotherapy, radiotherapy or other medicines, do not take BIO DOMPERIDONE 10 tablets for longer than 4 weeks without talking to your doctor.

Adults and adolescents over 12 years and weighing 35 kg or more:

Take 1 of the 10 mg tablets three times per day. **Do not take more than 3 tablets per day.** The maximum dose per day is 30 mg.

Using BIO DOMPERIDONE 10 in infants and children:

Do not give BIO DOMPERIDONE 10 to infants and children who are under 12 years of age and weigh less than 35 kg.

If your kidney function is impaired your doctor or healthcare professional may decide to reduce the dosage or take the medicine less often.

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Your doctor will tell you how long your treatment with BIO DOMPERIDONE 10 will last. If you have the impression that the effect of BIO DOMPERIDONE 10 is too strong or too weak, tell your doctor or pharmacist.

If you take more BIO DOMPERIDONE 10 than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison centre.

General symptoms of overdosage are dizziness, fainting, irregular heartbeat and drowsiness.

If you forget to take BIO DOMPERIDONE 10

If you forget to take a dose, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and then go on as before. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

BIO DOMPERIDONE 10 can have side effects.

Not all side effects reported for BIO DOMPERIDONE 10 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BIO DOMPERIDONE 10, please consult your healthcare provider for advice.

If any of the following happens, stop taking / using BIO DOMPERIDONE 10 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to BIO DOMPERIDONE 10. You may need urgent medical attention or hospitalisation.

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Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- seizures (fits),
- loss of balance,
- fast or irregular heartbeat,
- difficulty in speaking,
- the sudden loss of all heart activity due to an irregular heart rhythm.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- feeling depressed,
- anxiety,
- lowering or loss of sexual drive (libido) in men,
- headache,
- feeling drowsy,
- a feeling of muscle quivering, restlessness and inability to sit still
- diarrhoea,
- dry mouth,
- breast milk flowing from the nipple or swelling or the breast in male patients,
- painful or tender breasts,
- menstrual irregularities or stopped menstrual periods,
- difficulty breastfeeding,
- itching skin,
- a general feeling of weakness.

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Less frequent side effects:

- feeling irritable, thirst
- eye inflammation,
- hot flushes,
- change in appetite,
- heartburn,
- discharge from breasts or breast swelling,
- hives, swollen tissue,
- change in need to urinate, painful urination,
- abdominal cramps,
- constipation
- leg cramps,
- painful swelling and sores inside the mouth,
- lack of energy.

Unknown frequency of side effect:

- feeling agitated,
- feeling more nervous than usual,
- feeling dizzy,
- eye movement disorder,
- uncommon tumour of the adrenal glands,
- sudden swelling often caused by an allergic reaction,
- condition where your bladder doesn't completely empty each time you urinate,
- changes in certain laboratory test results.

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Inadvertent ingestion in children resulted in:

- movements that you cannot control, such as muscle tremors, spasms or stiffness, feeling restless or difficulty sitting still, slow movement,
- seizures,
- feeling agitated.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of BIO DOMPERIDONE 10.

5. How to store BIO DOMPERIDONE 10

Store all medicines out of reach of children.

Store at or below 25 °C. Keep the blister in the outer carton until required for use. Protect from light.

Do not use BIO DOMPERIDONE 10 after the expiry date printed on the blister strip, label or carton.

Return the expired medicine to your pharmacist for safe disposal.

6. Contents of the pack and other information

What BIO DOMPERIDONE 10 contains:

The active substance is domperidone 10 mg per film-coated tablet.

The other ingredients are crospovidone, lactose monohydrate, magnesium stearate, microcrystalline cellulose, pre-gelatinised starch, povidone (K 30) and sodium lauryl sulphate. Coating ingredients: hypromellose and macrogol.

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What BIO DOMPERIDONE 10 looks like and contents of the pack

White, round, film-coated, biconvex tablets.

BIO DOMPERIDONE 10 tablets are available in transparent PVC-Aluminium blister packs of 10 or 100 tablets.

Holder of Certificate of Registration

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This leaflet was last revised in

28 September 2023

Registration number

42/5.7.2/0836