
PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

BIO DOMPERIDONE 10, domperidone 10 mg per film-coated tablet.

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- BIO DOMEPERIDONE 10 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.

1. WHAT **BIO DOMPERIDONE 10** CONTAINS

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

The other ingredients are crospovidone, hydrogen vegetable oil, hypromellose, lactose monohydrate, macrogol 6000, magnesium stearate, maize starch, microcrystalline cellulose, polyethylene glycol, povidone (K 30) and sodium lauryl sulphate.

Contains sugar (lactose monohydrate), 58,0 mg per tablet.

2. WHAT **BIO DOMPERIDONE 10** IS USED FOR

Domperidone, the active ingredient in **BIO DOMPERIDONE 10** increases the movements or contractions of the stomach and bowel.

BIO DOMPERIDONE 10 is usually used:

- to treat stomach discomfort and acid reflux which is the result of decrease stomach movement

Each film-coated tablet contains 10 mg
domperidone

- to treat nausea and vomiting
- to treat nausea during cancer radio- or chemotherapy
- to make radio examination of the stomach easier.

3. BEFORE YOU TAKE BIO DOMPERIDONE 10

Do not take BIO DOMPERIDONE 10 if:

- you are hypersensitive (allergic) to domperidone or any of the other ingredients of BIO DOMPERIDONE 10
- you have a tumour that releases prolactin (prolactinoma)
- your intestines are bleeding, have been perforated or you have an intestinal obstruction
- you have moderate to severe liver impairment
- you are pregnant or breastfeeding your baby (see section on pregnancy and lactation)
- your heart beats excessively slow (bradycardia) or if you have a heart condition called heart-block
- you have significant electrolyte disturbances or underlying heart diseases such as congestive heart failure (a condition in which the heart's function as a pump is inadequate to meet the body's needs).
- you have a known heart condition of a congenital long QT interval or a family history thereof
- you are using potent CYP3A4 inhibitor medicine (see Taking other medicines with BIO DOMPERIDONE 10)
- you are taking QT-prolonging medicines (see Taking other medicines with BIO DOMPERIDONE 10).
- you have very poor kidney functioning
- you have magnesium or potassium deficiency in your blood.

Take special care with BIO DOMPERIDONE 10 if:

- your kidney or liver function is impaired (see Do not take BIO DOMPERIDONE 10)

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- you are at risk of fluid retention (such as heart failure)
- you are an elderly person (more than 60 years of age)
- 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.

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 30 mg per day. The risk also increases when domperidone is given together with some medicines. Tell your doctor or pharmacist if you notice any changes to your heart condition.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby do not take BIO DOMPERIDONE 10. If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking BIO DOMPERIDONE 10.

Driving and using machinery:

After taking BIO DOMPERIDONE 10, make sure that you are well enough to drive or operate machinery, as your ability to react may be impaired.

Important information about some of the ingredients of BIO-DOMPERIDONE 10:

BIO DOMPERIDONE 10 contains lactose. Patients with the rare hereditary conditions (e.g. galactosaemia) of lactose or galactose intolerance should not take BIO DOMPERIDONE 10.

Taking other medicines with BIO DOMPERIDONE 10

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

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Do not take BIO DOMPERIDONE 10 if you are taking medicine to treat:

- heart problems or high blood pressure (e.g., amiodarone, dronedarone, quinidine, disopyramide, hydroquinidine, quinidine, dofetilide, sotalol, ibutilide, diltiazem, verapamil)
- psychoses (e.g., haloperidol, pimozide, sertindole)
- depression (e.g., citalopram, escitalopram)
- bacterial infections, specifically erythromycin, clarithromycin, telithromycin, moxifloxacin (these are antibiotics)
- fungal infections such as pentamidine and azole anti-fungals, specifically oral ketoconazole, fluconazole or voriconazole
- malaria (in particular halofantrine, lumefantrine)
- gastro-intestinal disorders (e.g., cisapride, dolasetron, prucalopride) and anti-cholinergic medicines (e.g. hyoscine bromide)
- allergy (e.g., mequitazine, mizolastine)
- AIDS/HIV (protease inhibitors, e.g. ritonavir)
- cancer (e.g., toremifene, vandetanib, vincamine)
- opioids, used to treat pain or as an analgesic (e.g., methadone)
- certain other medicines such as bepridil, diphemanil

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

BIO DOMPERIDONE 10 may interact with the following medicines:

MAO inhibitors (e.g. selegiline used for the treatment of Parkinson's disease or tranylcypromine and moclobemide used for the treatment of depression)

Anti-cholinergic medicines (such as hyoscine butylbromide, mebeverine, ipratropium bromide, orphenadrine)

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Antacids, cimetidine used for heartburn and ulcers and sodium bicarbonate

Dopaminergic agonists such as cabergoline.

4. 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 instructed you. You should check with your doctor or pharmacist if you are unsure.

The tablets should be swallowed whole with a glass of water.

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

If you have the impression that the effect of BIO DOMPERIDONE 10 is too strong or too weak, tell your doctor or pharmacist.

Acute conditions (Nausea and vomiting): The dose for adults and children (over 12 years and weighing 35 kg or more) is one BIO DOMPERIDONE 10 mg three to four times a day, 15 to 30 minutes before meals.

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

Do not exceed maximum dose of 30 mg/day.

Do not take for longer than one week.

Children that weigh less than 35 kg should not take BIO DOMPERIDONE 10.

If you take more BIO DOMPERIDONE 10 than you should:

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

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

If you forget to take a dose of 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.

5. 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 doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking 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, 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 allergic reaction to BIO DOMPERIDONE 10. You may need urgent medical attention or hospitalisation.

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

- loss of balance
- fast or irregular heartbeat

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- difficulty in speaking
- hot flushes and menstrual irregularities.

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

Tell your doctor if you notice any of the following:

The following side effects have been reported less frequently:

- loss of sex drive, anxiety
- breast milk flowing from the nipple; breast pain and tenderness
- headache, dizziness, irritability, sleepiness, thirst
- pink eye (inflammation of the outermost layer of the white part of the eye and the inner surface of the eyelid)
- itching skin
- change in need to urinate
- abdominal cramps, dry mouth, change in appetite and heartburn
- constipation or diarrhoea
- leg cramps

The following side effects have been reported, frequency unknown:

- hives
- swelling of legs
- feeling worried, nervousness
- seizures, irregular eye movements, unusual movements of the tongue, and abnormal posture such as a twisted neck, trembling and muscle stiffness.
- prolonged involuntary upward deviation of the eyes

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- swelling of the breast in male patients, absence of menstruation
- changes to heart traces (ECG) indicating a heart problem
- increased risk of heart rhythm disorder and cardiac arrest
- liver function test abnormal.
- too much prolactin in the blood

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

6. STORING AND DISPOSING OF BIO DOMPERIDONE 10

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.

Do not dispose of unused medicine in drains of sewerage systems (e.g. toilets).

STORE ALL MEDICINE OUT OF REACH OF CHILDREN.

7. PRESENTATION OF BIO DOMPERIDONE 10

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

8. IDENTIFICATION OF BIO DOMPERIDONE 10

White, round, film-coated, biconvex tablets.

9. REGISTRATION NUMBER

42/5.7.2/836

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Biotech Laboratories (Pty) Ltd.
Bio Domperidone 10, film-coated tablet
(42/5.7.2/0836)

Patient Information Leaflet

21 November 2019

Each film-coated tablet contains 10 mg
domperidone

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11. DATE OF PUBLICATION

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