

# BIO DOMPERIDONE 10

## 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 DOMPERIDONE 10

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

#### 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)  
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
- 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
- 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 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

42/5.7.2/0836

### 10. NAME AND ADDRESS OF REGISTRATION HOLDER

BIOTECH LABORATORIES (PTY) LTD

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### 11. DATE OF PUBLICATION

Date of registration: 26 November 2010

Date of latest revision of the text as approved by Council: 21 November 2019

# BIO DOMPERIDONE 10

## PASIENT INLICHTINGSBLAD

### SKEDULING STATUS

S4

### HANDELSNAAM, STERKTE EN FARMASEUTIESE VORM

BIO DOMPERIDONE 10, domperidone 10 mg per filmbedekte tablet.

### Lees die hele pamflet noukeurig deur voordat jy BIO DOMPERIDONE 10 begin neem

- Bewaar hierdie pamflet. Jy sal dit dalk weer moet lees.
- Indien u verdere vrae het, vra asseblief u dokter of u apteker.
- BIO DOMPERIDONE 10 is persoonlik vir jou voorgeskryf en jy moet nie jou medisyne met ander mense deel nie. Dit kan hulle benadeel, selfs al is hul simptome dieselfde as joune.

### 1. WAT BIO DOMPERIDONE 10 BEVAT

Die aktiewe bestanddeel is domperidone 10 mg per filmbedekte tablet. Die ander bestanddele is krospovidone, waterstof groente-olie, hipromellose, laktosemonohidraat, makrogol 6000, magnesiumstearaat, meliestysel, mikrokristallyne sellulose, poliëteleenglikol, povidone (K 30) en natriumlauriëlsulfaat. Bevat suiker (laktosemonohidraat), 58,0 mg per tablet.

### 2. WAARVOOR BIO DOMPERIDONE 10 GEBRUIK WORD

Domperidone, die aktiewe bestanddeel in BIO DOMPERIDONE 10 verhoog die bewegings of sametrekings van die maag en derm.

### BIO DOMPERIDONE 10 word gewoonlik gebruik:

- om maagongemak en suur refluks te behandel wat die gevolg is van verminderde maagbeweging
- om naarheid en braking te behandel
- om naarheid tydens kanker radio- of chemoterapie te behandel
- om radio-ondersoek van die maag makliker te maak.

### 3. VOORDAT U BIO DOMPERIDONE 10 GEBRUIK

#### Moet nie BIO DOMPERIDONE 10 neem as:

- jy hipersensitief (allergies) vir domperidone of enige van die ander bestanddele van BIO DOMPERIDONE 10 is
- jy 'n gewas het wat prolaktien (prolaktinoom) vrystel
- jou ingewande bloei, geperforeer is of jy 'n dermobstruksie het
- jy matige tot ernstige lewersaking het
- jy swanger is of jou baba borsvoed (sien afdeling oor swangerskap en laktasie)
- jou hart klop uitermate stadig (bradikardie) of as jy 'n harttoestand het wat hartbloe genoem word
- jy het beduidende elektrolietversteurings of onderliggende hartsiektes soos kongestiewe hartversaking ('n toestand waarin die hart se funksie as 'n pomp onvoldoende is om in die liggaam se behoeftes te voorsien).
- jy 'n bekende harttoestand van 'n aangebore lang QT-interval of 'n familiegeskiedenis daarvan het
- jy kragtige CYP3A4-remmermedisyne gebruik (sien Neem ander medisyne saam met BIO DOMPERIDONE 10)
- jy QT-verlengende medisyne gebruik (sien Neem ander medisyne saam met BIO DOMPERIDONE 10).
- jy baie swak nierfunksie het
- jy 'n magnesium- of kaliumtekort in jou bloed het.

#### Wees veral versigtig met BIO DOMPERIDONE 10 indien:

- jou nier- of leverfunksie is verswak (sien Moenie BIO DOMPERIDONE 10 neem nie)
- jy die risiko van vloeistofretensie loop (soos hartversaking)
- jy 'n bejaarde persoon is (meer as 60 jaar oud)
- jy monoamienoksidasie-inhibeerders gebruik soos selegilien wat gebruik word vir die behandeling van Parkinson se siekte of traniëlsipromien en moklobemied wat gebruik word vir die behandeling van depressie.
- Domperidone kan geassosieer word met 'n verhoogde risiko van hartritmestoornis en hartstilstand. Hierdie risiko kan meer waarskynlik wees by diegene ouer as 60 jaar of wat dosisse hoër as 30 mg per dag neem. Die risiko neem ook toe wanneer domperidone saam met sekere medisyne gegee word. Vertel jou dokter of apteker as jy enige veranderinge in jou harttoestand opmerk.

#### Swangerskap en borsvoeding:

As jy swanger is of jou baba borsvoed, moenie BIO DOMPERIDONE 10 neem nie. As jy swanger is of jou baba borsvoed, raadpleeg asseblief jou dokter, apteker of ander gesondheidswerker vir advies voordat jy BIO DOMPERIDONE 10 neem.

#### Bestuur en gebruik van masjinerie:

Nadat u BIO DOMPERIDONE 10 geneem het, maak seker dat u goed genoeg is om te bestuur of masjinerie te gebruik, aangesien u vermoë om te reageer kan verswak word.

#### Belangrike inligting oor sommige van die bestanddele van BIO-DOMPERIDONE 10:

BIO DOMPERIDONE 10 bevat laktose. Pasiënte met die seldsame oorerflike toestande (bv. galaktosemie) van laktose of galaktose-intoleransie moet nie BIO DOMPERIDONE 10 neem nie.

#### Ander medisyne saam met BIO DOMPERIDONE 10

Vertel altyd jou gesondheidswerker as jy enige ander medisyne gebruik. (Dit sluit komplementêre of tradisionele medisyne in).

#### Moenie BIO DOMPERIDONE 10 neem as jy medisyne neem om die volgende te behandel:

- hartprobleme of hoë bloeddruk (bv. amiodaron, dronedaron, kinidien, disopiramide, hidrokinidien, kinidien, dofetilied, sotalol, ibutilied, diltiazem, verapamil)
- psigoses (bv. haloperidol, pimozied, sertindol)
- depressie (bv. citalopram, escitalopram)
- bakteriële infeksies, spesifiek eritromisien, klaritromisien, telitromisien, moksifloksasien (dit is antibiotika)
- swaminfeksies soos pentamidien en asool anti-swammiddels, spesifiek orale ketokonasool, flukonasool of vorikonasool
- malaria (veral halofantrine, lumefantrine)
- gastro-intestinale afwykings (bv. sisapried, dolasetron, prukalopriede) en anti-cholinergiese medisyne (bv. hiosienbromied)
- allergie (bv. mequitasiën, mizolastien)
- VIGS/MIV (protease-inhibeerders, bv. ritonavir)
- kanker (bv. toremifene, vandetanib, vincamine)
- opioïede, gebruik om pyn te behandel of as 'n pynstiller (bv. metaadon)
- sekere ander medisyne soos bepridil, difemanil

#### Vertel jou dokter of apteker as jy medisyne gebruik om infeksie, hartprobleme of VIGS/MIV te behandel.

#### BIO DOMPERIDONE 10 kan interaksie hê met die volgende medisyne:

MAO-inhibeerders (bv. selegilien wat gebruik word vir die behandeling van Parkinson se siekte of traniëlsipromien en moklobemied wat gebruik word vir die behandeling van depressie) Anticholinergiese medisyne (soos hiosienbutielbromied, mebeverien, ipratropiumbromied, orfenadrien) Teensuurmiddels, simetidien wat gebruik word vir sooi-brand en maagsere en natriumbikarbonaat Dopaminergiese agoniste soos kabergolien.

### 4. HOE OM BIO DOMPERIDONE 10 TE NEEM

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie. Neem BIO DOMPERIDONE 10 altyd presies soos jou dokter jou voorgeskryf het. Jy moet jou dokter of apteker raadpleeg as jy onseker is.

Die tablette moet heel ingesluk word met 'n glas water. Die hoeveelheid BIO DOMPERIDONE 10 wat jy neem hang af van jou spesifieke mediese toestand en die tyd wat toegelaat word tussen dosisse. As jy die indruk kry dat die effek van BIO DOMPERIDONE 10 te sterk of te swak is, vertel jou dokter of apteker.

*Akute toestande (Naarheid en braking):* Die dosis vir volwassenes en kinders (oor 12 jaar en wat 35 kg of meer weeg) is een BIO DOMPERIDONE 10 mg drie tot vier keer per dag, 15 tot 30 minute voor etes. As jou nierfunksie benadeel is, kan jou dokter of gesondheidswerker besluit om die dosis verminder. Moenie die maksimum dosis van 30 mg/dag oorskry nie. Moenie langer as een week neem nie. Kinders wat minder as 35 kg weeg, moet nie BIO DOMPERIDONE 10 neem nie.

### As jy meer BIO DOMPERIDONE 10 neem as wat jy behoort:

In die geval van oordosis, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum. Algemene simptome van oordosis is duiseligheid, floute, onreëlmatige hartklop en lomerigheid.

### As jy vergeet om 'n dosis BIO DOMPERIDONE 10 te neem:

As jy vergeet om 'n dosis te neem, neem dit so gou as wat jy onthou. As dit egter amper tyd is vir jou volgende dosis, slaan die oorgeslane dosis oor en gaan dan voort soos voorheen. Moenie 'n dubbeldosis neem om vergete individuele dosisse in te haal nie.

### 5. MOONTLIKE NEWE-EFFEKTE

BIO DOMPERIDONE 10 kan nuwe-effekte hê. Nie alle nuwe-effekte wat vir BIO DOMPERIDONE 10 aangemeld is, is in hierdie pamflet ingesluit nie. Indien u algemene gesondheid versleg of as u enige nadelige effekte ervaar terwyl u BIO DOMPERIDONE 10 neem, raadpleeg asseblief u dokter, apteker of ander gesondheidswerker vir advies.

### As enige van die volgende gebeur, hou op om BIO DOMPERIDONE 10 te neem en vertel jou dokter dadelik of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat probleme kan veroorsaak om te sluk of asem te haal
- uitslag of jeuk
- flou word

Dit is alles baie ernstige nuwe-effekte. As jy dit het, het jy dalk 'n ernstige allergiese reaksie op BIO DOMPERIDONE 10 gehad. Jy mag dalk dringende mediese aandag of hospitalisasie benodig.

### Vertel jou dokter dadelik of gaan na die nood geval afdeling van jou naaste hospitaal as jy enige van die volgende opmerk:

- Balans verlies
  - Vinnige of onreëlmatige hartklop
  - Belemmering van spraak
  - Warm Gloede en menstruele onreëlmatigheid
- Hierdie is almal ernstige nuwe-effekte. Jy mag dringende mediese aandag benodig.

### Vertel jou dokter as jy enige van die volgende opmerk:

*Die volgende nuwe-effekte is minder gereeld aangemeld:*

- verlies aan seksdrang, angs
- borsmelk wat uit die tepel vloei; borspyn en sagtheid
- hoofpyn, duiseligheid, prikkelbaarheid, slaperigheid, dors
- pienk oog (ontsteking van die buitenste laag van die wit deel van die oog en die binneste oppervlak van die ooglid)
- jeukerige vel
- verandering in behoefte om te urineer
- abdominale krampe, droë mond, verandering in eetlus en sooi-brand
- hardlywigheid of diarree
- beenkrampe

*Die volgende nuwe-effekte is aangemeld, frekwensie onbekend:*

- korwe
  - swelling van bene
  - voel bekommerd, senuweeagtigheid
  - aanvalle, onreëlmatige oogbewegings, ongewone bewegings van die tong, en abnormale postuur soos 'n gedraaide nek, bewing en spierstyfheid.
  - langdurige onwillekeurige opwaartse afwyking van die oë
  - swelling van die bors by manlike pasiënte, afwesigheid van menstruasie
  - veranderinge aan hartspore (EKG) wat 'n hartprobleem aandui
  - verhoogde risiko van hartritmestoornis en hartstilstand
  - leverfunksietoets abnormaal.
  - te veel prolaktien in die bloed
- Indien u enige nuwe-effekte opmerk wat nie in hierdie pamflet genoem word nie, stel asseblief u dokter of apteker in kennis.

### 6. BERGING EN WEGDOEN VAN BIO DOMPERIDONE 10

Berg by of onder 25 °C. Hou die stulpstroom in die karton totdat dit benodig word vir gebruik.

Beskerm teen lig. Moenie BIO DOMPERIDONE 10 gebruik na die vervaldatum wat op die stulpstroom, etiket of karton gedruk is nie. Moenie BIO DOMPERIDONE 10 gebruik na die vervaldatum wat op die stulpstroom, etiket of karton gedruk is nie. Stuur die vervalde medisyne terug na u apteker vir veilige wegdoening. Moenie ongebruikte medisyne in rioolpype (bv. toilette) weggooi nie. BERG ALLE MEDISYNE BUITE BEREIK VAN KINDERS.

### 7. AANBIEDING VAN BIO DOMPERIDONE 10

BIO DOMPERIDONE 10 tablette is beskikbaar in deursigtige PVC-Aluminium stulpverpakings van 10 of 100 tablette.

### 8. IDENTIFIKASIE VAN BIO DOMPERIDONE 10

Wit, ronde, filmbedekte, bikonvekse tablette.

### 9. REGISTRASIE NOMMER

42/5.7.20/0836

### 10. NAAM EN ADRES VAN DIE HOUER VAN DIE REGISTRASIE

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### 11. DATUM VAN HIERDIE PUBLIKASIE

Datum van registrasie: 26 November 2010

Datum van laaste hersiening van hierdie teks soos goedgekeur deur SAHPRA: 21 November 2019

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