

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

BIO-METOCLOPRAMIDE tablets

Metoclopramide

Contains sugar (101,24 mg lactose monohydrate per tablet).

Read all of this leaflet carefully before you start taking BIO-METOCLOPRAMIDE

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- BIO-METOCLOPRAMIDE has been prescribed for you personally and you should not share the 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-METOCLOPRAMIDE is and what it is used for.
2. What you need to know before you take BIO-METOCLOPRAMIDE.
3. How to take BIO-METOCLOPRAMIDE.
4. Possible side effects.
5. How to store BIO-METOCLOPRAMIDE.
6. Contents of the pack and other information.

1. What BIO-METOCLOPRAMIDE is and what it is used for

BIO-METOCLOPRAMIDE is an anti-emetic. It works on a part of your brain that prevents you from feeling sick (nausea) or being sick (vomiting). It is also used for digestive disorders such as:

- Gastrointestinal hypomotility (a syndrome in which the muscles of the digestive system show poor contraction, resulting in abnormally slow movement of ingested food through the digestive tract).
- Gastrointestinal stasis (a condition in which there is no movement of food through the digestive tract).

2. What you need to know before you take BIO-METOCLOPRAMIDE

Do not take BIO-METOCLOPRAMIDE:

- If you are hypersensitive (allergic) to metoclopramide monohydrochloride or any of the other ingredients of BIO-METOCLOPRAMIDE (see **What BIO-METOCLOPRAMIDE contains**).
- If you have bleeding, obstruction or a tear in your stomach or gut.
- If you have had gastrointestinal surgery in the last 3 - 4 days.
- If you have or suspect you may have a rare tumour of the adrenal gland, which sits on top of your kidney (pheochromocytoma).
- If you are pregnant or breastfeeding (see **Pregnancy, breastfeeding and fertility**).
- If you have experienced involuntary muscle spasms (tardive dyskinesia), when treated with a medicine.
- If you have epilepsy (fits).
- If you have Parkinson's disease.
- If you have porphyria.
- If you are taking levodopa (a medicine used for Parkinson's disease) or medicines known as dopaminergic agonists (see **Other medicines and BIO-METOCLOPRAMIDE**).
- If you are on antipsychotic treatment (medicines known as phenothiazines).
- If you have ever had abnormal blood pigment levels (methaemoglobinaemia) or NADH cytochrome-b5 deficiency.

BIO-METOCLOPRAMIDE is not intended for use in children below 1 year of age (see **Children and adolescents** below).

Warnings and precautions

Take special care with BIO-METOCLOPRAMIDE:

- If you have any neurological (brain/ nerve) problems.
- If you have high blood pressure.
- If you have a history of abnormal heartbeats (QT interval prolongation) or any other heart problems.
- If you are using other medicines known to affect the way your heart beats.
- If you have liver or kidney problems. Your doctor may reduce your dose.
- If you have a history of atopy (a problem with your immune system that makes you more likely to develop allergic diseases, including asthma).

Blood tests

Your doctor may perform blood tests to check your blood pigment levels. In cases of abnormal levels (methaemoglobinaemia), your treatment with BIO-METOCLOPRAMIDE should be stopped immediately.

General

In order to avoid overdose, you must wait at least 6 hours between each BIO-METOCLOPRAMIDE dose, even in case of vomiting and rejection of the dose.

Children and adolescents

Uncontrollable movements (extrapyramidal disorders) may occur in children and young adults. These reactions typically occur at the start of the treatment and can even happen after just one dose. If such symptoms are experienced, the use of BIO-METOCLOPRAMIDE should be discontinued immediately. Contact your doctor or healthcare provider if you notice these symptoms. BIO-METOCLOPRAMIDE must not be used in children below 1 year of age because of the increased risk of the uncontrollable movements (see **Do not take BIO-METOCLOPRAMIDE**).

Other medicines and BIO-METOCLOPRAMIDE

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

This is because some medicines can affect the way BIO-METOCLOPRAMIDE work or BIO-METOCLOPRAMIDE can affect how other medicines work. These medicines include the following:

Tell your doctor or pharmacist if you are currently using:

- Levodopa or other medicines used to treat Parkinson's disease (see above **Do not take BIO-METOCLOPRAMIDE**).
- Anticholinergic medicines (used to relieve stomach cramps or spasms).
- Morphine derivatives (used to treat severe pain).
- Sedative medicines.
- Any medicines used to treat mental health problems.
- Digoxin (used to treat heart failure).
- Ciclosporin (used to prevent organ rejection after a transplant).
- Mivacurium and suxamethonium (used to relax muscles).
- Fluoxetine and paroxetine (used to treat depression).
- Pain killers, such as aspirin or paracetamol.
- Atovaquone (used to treat pneumonia).
- Medicines used to treat a hormone imbalance in which there is too much prolactin in your blood. BIO-METOCLOPRAMIDE may increase the prolactin blood concentrations in your body.

BIO-METOCLOPRAMIDE with food, drink and alcohol

Alcohol should not be consumed during treatment with BIO-METOCLOPRAMIDE because it increases the sedative effect of BIO-METOCLOPRAMIDE.

Pregnancy, breastfeeding and fertility

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 BIO-METOCLOPRAMIDE.

Do not take BIO-METOCLOPRAMIDE during pregnancy or breastfeeding.

Driving and using machines

BIO-METOCLOPRAMIDE can cause side effects, such as drowsiness, dizziness, uncontrollable movement disorders and vision problems which may interfere with your ability to drive and operate machines. Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how BIO-METOCLOPRAMIDE affects you.

BIO-METOCLOPRAMIDE contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, consult your doctor before taking BIO-METOCLOPRAMIDE.

3. How to take BIO-METOCLOPRAMIDE

Do not share medicines prescribed for you with any other person. Always take BIO-METOCLOPRAMIDE exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Adults:

Take one tablet three times daily.

Children (5 to 14 years):

Take half a tablet three times daily.

The total daily dose in children and young adults should not exceed 0,5 mg/kg body mass.

Do not exceed the recommended dosage.

Do not take BIO-METOCLOPRAMIDE for more than 3 months because of the risk of involuntary muscle spasms.

BIO-METOCLOPRAMIDE can be taken with or without food.

Your doctor will tell you how long your treatment with BIO-METOCLOPRAMIDE will last. Do not stop treatment early because you feel better. If you have the impression that the effect of BIO-METOCLOPRAMIDE is too strong or too weak, tell your doctor or pharmacist.

If you take more BIO-METOCLOPRAMIDE than you should

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

Take this leaflet and the rest of the remaining BIO-METOCLOPRAMIDE with you so the doctor will know what you have taken. See **General** under **Warnings and precautions**.

4. Possible side effects

BIO-METOCLOPRAMIDE can have side effects.

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

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

- Swelling of your 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-METOCLOPRAMIDE. 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:

- Uncontrollable movements (often involving your head or neck). This could also include your neck twisting in odd ways, your tongue sticking out rhythmically, a change in your speech, or your jaw clenching tightly. You might also find your head and shoulders positioned awkwardly. Your muscles may also become generally stiffer particularly if you are a young female. These may occur in children or young adults and particularly when high doses are used. These signs usually occur at the beginning of treatment and may even occur after one single administration.
- Neuroleptic malignant syndrome (a reaction to medicines characterised by symptoms like very high fever, rigid muscles, and rapid heartbeat).
- Changes in the way your heart beats (beating faster or slower than normal).
- Fits (seizures) especially in epileptic patients.
- Uncontrolled movements of your face (lips, jaw, or tongue) (tardive dyskinesia).
- Shock (sudden drop in blood flow through your body).
- Severe high blood pressure.

Tell your doctor if you notice any of the following:

Side effects occurring frequently:

- Feeling depressed.
- Drowsiness, dizziness, headache, sleepiness.
- Symptoms similar to Parkinson's disease (rigidity, tremor).
- Feeling of inner restlessness and a compelling need to be in constant motion.
- Low blood pressure.
- Diarrhoea, constipation.
- Feeling weak.

Side effects occurring less frequently:

- Raised levels of a hormone called prolactin in your blood which may cause milk production in men, and women who are not breastfeeding.
- Breast enlargement in men.
- Absence of menstrual bleeding (period) in women.
- Hallucination (seeing or hearing things that does not exist), being confused.
- Visual disturbances and involuntary deviation (typically upward movement) of your eyes.
- Twisting movements or muscle contractions (stiffness, rigidity).
- Decreased level of consciousness.
- Hard, swollen, and painful breasts in women.
- Impotence (inability to get or maintain an erection).

Side effects which may occur, but the frequency is unknown:

- Abnormal blood pigment levels which may change the colour of your skin.
- Abnormal breast enlargement in men (gynaecomastia).
- Increased aldosterone levels when blood tests are done.
- Feeling anxious, difficulty falling or staying asleep (insomnia).
- Sudden increase in blood pressure in patients with tumour of the adrenal gland (phaeochromocytoma).
- Nausea (feeling sick), upset bowel.
- Hives (red, itchy, swollen areas on your skin).
- Loss of bladder control.
- Feeling physically or mentally tired.

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 or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reactions Reporting Form**”, found online under SAHPRA’s publications: <http://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of BIO-METOCLOPRAMIDE.

5. How to store BIO-METOCLOPRAMIDE

- Store at or below 25 °C and protect from light.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the packaging.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What BIO-METOCLOPRAMIDE contains

The active substance is metoclopramide.

Each tablet contains 10 mg metoclopramide monohydrochloride.

The other ingredients are colloidal silicone dioxide, lactose monohydrate, magnesium stearate and maize starch.

What BIO-METOCLOPRAMIDE looks like and contents of the pack

White biconvex tablets, with breakline on one side, plain on other side.

Securitainers containing 10, 100 and 500 tablets.

Holder of certificate of registration

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