PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

METOCLOPRAMIDE 10 OETHMAAN tablets

Metoclopramide hydrochloride

Contains sugar (lactose 62.0 mg per tablet)

Read all of this leaflet carefully before you are given METOCLOPRAMIDE 10 OETHMAAN.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- METOCLOPRAMIDE 10 OETHMAAN 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 METOCLOPRAMIDE 10 OETHMAAN is and what it is used for
2. What you need to know before you take METOCLOPRAMIDE 10 OETHMAAN
3. How to take METOCLOPRAMIDE 10 OETHMAAN
4. Possible side effects
5. How to store METOCLOPRAMIDE 10 OETHMAAN
6. Contents of the pack and other information

1. What METOCLOPRAMIDE 10 OETHMAAN is and what it is used for

METOCLOPRAMIDE 10 OETHMAAN contains the active substance metoclopramide hydrochloride, belonging to a group of medicines called anti-emetics. It works on a part of your brain that prevents you from feeling sick (nausea) and being sick (vomiting).

METOCLOPRAMIDE 10 OETHMAAN is used:

- In conditions associated with slow stomach emptying or slow bowel movement. It is also useful in management of delayed stomach emptying occurring after surgery of the vagus nerve.
- For control of nausea and vomiting associated with intake of other medicines, with conditions in which urinary constituents are in the blood, after stomach operations and other digestive disorders including stomach upset, indigestion with wind.
- METOCLOPRAMIDE 10 OETHMAAN is also used during diagnostic procedures to increase passage of barium meal in radiology treatment, facilitate examination of stomach with delayed emptying and to prevent and control nausea and vomiting of barium in patient undergoing barium meal examination.
- It also makes it easier for the introduction of a tube in the stomach and intestines in medical procedures.
- Young adults and children

  The use of METOCLOPRAMIDE 10 OETHMAAN in patients under 20 years should be restricted to the following:

  vomiting that is difficult to control and to aid gastrointestinal intubation (passing a tube through the nose or mouth into the stomach or small intestine) and diagnostic radiology (special medical procedure).

2. What you need to know before you are given METOCLOPRAMIDE 10 OETHMAAN

Do not take METOCLOPRAMIDE 10 OETHMAAN:

- If you are allergic to metoclopramide or any other ingredients of METOCLOPRAMIDE 10 OETHMAAN (listed in section 6)
- If you suffer from high blood pressure due to a tumour near the kidney (a condition known as phaeochromocytoma)
- If you have or have had bleeding, perforation or blockage of the stomach or small intestines
- If you have had an operation on your stomach or intestine within the last 3 – 4 days
- If you have a **history of muscle disorders** when using medicines with a similar action to METOCLOPRAMIDE 10 OETHMAAN tablets
- If you are taking medicines called “phenothiazines” (antipsychotic medicine).
- If you have ever had involuntary muscle spasms (tardive dyskinesia), when you have been treated with METOCLOPRAMIDE 10 OEHMAAN.
- If you suffer from epilepsy.
- If you suffer from a condition called “Parkinson’s disease”.
- If you are taking a medicine called levodopa (a medicine used to treat Parkinson’s disease).
- If you have ever had an abnormal blood pigment level (methaemoglobinaemia) or NADH cytochrome-b5 deficiency.
- Do not give METOCLOPRAMIDE 10 OETHMAAN to a child less than 1 (one) of age (see below “Children and adolescents”).
- If you are pregnant or breastfeeding.
- If you suffer from convulsive disorders.

- If you suffer from a condition called “porphyria”.

Warnings and precautions

Take special care with METOCLOPRAMIDE 10 OETHMAAN:

Check with your doctor or pharmacist before taking METOCLOPRAMIDE 10 OETHMAAN if you:

- have epilepsy (**METOCLOPRAMIDE 10 OETHMAAN may increase the risk of having a seizure)**
- have liver impairment or severe kidney disease
- suffer from allergies, or asthma
- have Parkinson’s disease (METOCLOPRAMIDE 10 OETHMAAN may make your symptoms worse)
- suffer from metabolic condition called porphyria
- have a history of abnormal heart beats (QT interval prolongation) or any other heart problems.
- have problems with the levels of salts in your blood, such as potassium, sodium and magnesium.
- are taking any medicines known as serotonergic medicines, as taking these medicines with METOCLOPRAMIDE 10 OETHMAAN can cause side effects (such as restlessness, loss of coordination, fast heartbeat and increased body temperature).
- are taking medicines known as phenothiazines for mental disorders
- are taking any other medicine by mouth. It is possible that METOCLOPRAMIDE 10 OETHMAAN may change the amount of the other medicine that gets into your body.
- have high blood pressure (hypertension).
- have any neurological (brain) problems

Take Special Care with METOCLOPRAMIDE 10 OETHMAAN tablets:

- Production of breast milk, enlargement of breast glands (in men), absent or lighter menstrual periods may occur during treatment. The condition returns to normal after withdrawal of the METOCLOPRAMIDE 10 OETHMAAN tablets.
- Tardive dyskinesia (TD), a potentially irreversible and disfiguring disorder characterized by involuntary movements of the face, tongue, or extremities, can develop while you are treated with METOCLOPRAMIDE 10 OETHMAAN tablets. Please tell your doctor as soon as you experience any symptoms related to this syndrome. Do not exceed 3-month treatment because of the risk of involuntary muscle spasms.
- You must wait at least 6 hours between each METOCLOPRAMIDE 10 OETHMAAN dose, even in case of vomiting and rejection of dose, in order to avoid overdose.
- If vomiting persists you should be reassessed to exclude any other underlying disorder.
- If you are receiving METOCLOPRAMIDE 10 OETHMAAN for delayed gastric emptying, then your treatment should be reviewed at an early stage for responsiveness.
- Tell your doctor if you have high fever, high blood pressure, convulsions, sweating, production of saliva. These may be signs of a condition called neuroleptic malignant syndrome.
- In patients with kidney and liver disease, therapy should be at a reduced dosage (see “How METOCLOPRAMIDE 10 OETHMAAN is taken”).
- If you have abnormal blood pigment level (methaemoglobinaemia) which could be related to NADH cytochrome b5 reductase deficiency. Your doctor may perform blood tests to check your blood pigment levels. In cases of abnormal levels (methaemoglobinaemia), the treatment should be immediately and permanently stopped.
- **Children and adolescents**

  Uncontrollable movements (extrapyramidal disorders) may occur in children and young adults.

In young adults and children METOCLOPRAMIDE 10 OETHMAAN is restricted to vomiting that is difficult to control and to aid gastrointestinal intubation (passing a tube through the nose or mouth into the stomach or small intestine) and diagnostic radiology (special medical procedure).

Other medicines and METOCLOPRAMIDE 10 OETHMAAN

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

Using both METOCLOPRAMIDE 10 OETHMAAN and the phenothiazine may cause transient dystonia; care should be exercised in the event of both medicines being prescribed concurrently.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines including medicines obtained without a prescription

- Painkillers such as aspirin or paracetamol
- Cyclosporine (to prevent transplant rejection)
- Medicines to treat Parkinson's disease such as levodopa
- Antimuscarinics such as atropine
- Lithium to treat depression
- Medicines which can cause liver damage
- Digoxin to treat heart condition
- Bromocriptine (for infertility or to stop breast milk)
- Medicines that act on the brain (CNS depressants, antiepileptics, antipsychotics, medicines containing opioids)
- Mivacurium and suxamethonium (medicines used to relax muscles)
- Fluoxetine and paroxetine (medicine used to treat depression)
- Atovaquone (to treat pneumonia)

- Neuroleptic medicines (for mental illness or nausea and vomiting)

METOCLOPRAMIDE 10 OETHMAAN with food and drink and alcohol

Alcohol should not be consumed during treatment with metoclopramide because it increases the sedative effect of METOCLOPRAMIDE 10 OETHMAAN.

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 METOCLOPRAMIDE 10 OETHMAAN.

You should not take METOCLOPRAMIDE 10 OETHMAAN if you are pregnant or breastfeeding.

Driving and using machines

It is not always possible to predict to what extent METOCLOPRAMIDE 10 OETHMAAN may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which METOCLOPRAMIDE 10 OETHMAAN affects them.

METOCLOPRAMIDE 10 OETHMAAN tablets may cause dizziness and confusion or movement disorders. Make sure you are not affected before you drive or operate machinery.

3. How to take METOCLOPRAMIDE 10 OETHMAAN

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

Always take METOCLOPRAMIDE 10 OETHMAAN exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The usual dose is:

Adults and children over 14 years: 10 mg (1 x 10 mg tablet) three times daily.

Children 5 to 14 years: 5 mg (half a tablet) three times daily.

Swallow the tablets with water.

If you have the impression that the effect of METOCLOPRAMIDE 10 OETHMAAN is too strong or too weak, talk to your doctor or pharmacist.

If you take more METOCLOPRAMIDE 10 OETHMAAN than you should

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

Symptoms that you took more could include restlessness, agitation, irritability, spasm of facial and neck muscles and the muscles of the tongue.

If you forget to take METOCLOPRAMIDE 10 OETHMAAN:

Do not take a double dose to make up for forgotten doses. If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time.

If you stop taking METOCLOPRAMIDE 10 OETHMAAN

Talk to your doctor before you stop taking the tablets and follow their advice.

4. POSSIBLE SIDE EFFECTS:

METOCLOPRAMIDE 10 OETHMAAN can have side effects.

Not all side effects reported for METOCLOPRAMIDE 10 OETHMAAN are included in this leaflet. Should your general health worsen while taking METOCLOPRAMIDE 10 OETHMAAN, please consult your doctor, pharmacist or other health care professional for advice.

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

- **Severe allergic reactions** such as swelling of the face, lips, throat or tongue, difficulty breathing, very fast heart beat or even loss of unconsciousness
- **Central Nervous System (CNS):**
    - Extrapyramidal or Parkinsonian effects (difficulty in speaking or swallowing, loss of balance control, mask-like face, shuffling walk, stiffness of arms or legs, trembling and shaking of hands and fingers)
    - Dystonic effects (spasms of facial muscles and jaw muscles which prevent the jaw from opening, rhythmic protrusion of the tongue, difficulty speaking, spasms of muscles around the eye, involuntary arching of the head and neck)

These are very serious side effects. If you have them, you may have had a serious reaction to METOCLOPRAMIDE 10 OETHMAAN. 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:

- Neuroleptic Malignant Syndrome: excessive temperature, drowsiness, rigid muscles, rapid breathing, restlessness and uncontrolled movements. This is more likely to occur if you are taking neuroleptic, medicines such as chlorpromazine
- Blood: Your medicines may alter the numbers and types of your blood cells; you may notice increased bruising or nose bleeds. Your doctor may want to give you a blood test
- Uncontrollable movements (often involving head or neck). 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. These movements will stop when treated appropriately
- Chest pain, angina, changes in the way your heart beats, for example, if you notice it beating faster, cardiac arrest (particularly with the injectable route)

- Shock (severe decrease of heart pressure)
- Sudden increase in blood pressure in patients with tumour of the adrenal gland (pheochromocytoma)
- Very high blood pressure

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 may be experienced while using METOCLOPRAMIDE 10 OETHMAAN:

Frequent

- Depression
- Sleepiness, restlessness, drowsiness, dizziness, headache, uncontrollable movements (often involving head or neck) such as tics, shaking, twisting movements or muscle contracture (stiffness, rigidity), an inability to remain still
- Symptoms similar to Parkinson's disease (rigidity, tremors)
- Low blood pressure
- Constipation, diarrhoea
- Feeling weak

Less frequent:

- Allergic reactions
- Raised levels of a hormone called prolactin in the blood which may cause: milk production in men, and women who are not breast-feeding
- Irregular periods
- Hallucination, feeling confused

- Anxiety and agitation, Parkinsonism, involuntary muscle spasms after prolonged use, particularly in elderly patients, uncontrollable muscle contractions including visual disturbances and involuntary deviation of the eye ball, decreased level of consciousness, convulsions especially if you are epileptic
- Slow heart beat

The following side effects have been reported but their frequencies are unknown:

- Reduction in white blood cells
- Abnormal blood pigment levels: which may change the colour of your skin
- Abnormal development of breasts (gynaecomastia)
- Repetitive, involuntary movements, such as grimacing and eye blinking, Neuroleptic Malignant Syndrome: excessive temperature, drowsiness, rigid muscles, rapid breathing, restlessness and uncontrolled movements.
- Cardiac arrest, heart rhythm disorder that causes the heart to beat more slowly than it should, heartbeat pauses or stops, abnormal rhythm of the heart
- Shock (critical condition brought on by the sudden drop in blood flow through the body), fainting, sudden increase in blood pressure
- Itchy skin rash, hives
- Loss of bladder control (urinary incontinence)

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 or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of METOCLOPRAMIDE 10 OETHMAAN.

5. How to store METOCLOPRAMIDE 10 OETHMAAN

Keep well-closed and store below 25 °C in a dry place and protect from light.

Do not remove the blister from the carton until required for use.

KEEP OUT OF REACH OF CHILDREN.

Do not store in bathrooms.

Do not use after the expiry date stated on the label or carton.

Return all unused medicine to your pharmacy. Do not dispose of unused medicine in drains or sewerage systems e.g. toilets.

6. Contents of the pack and other information

What METOCLOPRAMIDE 10 OETHMAAN contains

The active substance is 10 mg metoclopramide hydrochloride.

The other ingredients are:

Maize starch, lactose, povidone K30 and magnesium stearate.

What METOCLOPRAMIDE 10 OETHMAAN looks like and contents of the pack

White, round, flat, bevel-edged tablets with a score line on one side.

METOCLOPRAMIDE 10 OETHMAAN are packed in:

Amber plastic containers, amber glass containers, securitainers, sealed aluminium bags or blister packs of 20 or 100 tablets.

Amber plastic containers, amber glass containers, securitainers or blister packs of 500 or 1 000.

Holder of Certificate of Registration

Oethmaan Biosims (Pty) Ltd

207A Sherwood House

Greenacres Office Park

c/o Victory and Rustenburg Roads

Victory Park

Johannesburg

2195

Telephone number: 011 433 0602

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Access to the corresponding Professional Information

www.oethmaan.co.za

Telephone number: 011 433 0602

Email: info@oethmaan.co.za