1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

CLOPAMON INJECTION 10 mg/2 ml

Metoclopramide

Sugar free

Read all of this leaflet carefully before CLOPAMON INJECTION 10 mg/ 2 ml is administered to you

- 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.
- CLOPAMON INJECTION 10 mg/2 ml 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 CLOPAMON INJECTION 10 mg/2 ml is and what it is used for
2. What you need to know before CLOPAMON INJECTION 10 mg/2 ml is administered to you
3. How CLOPAMON INJECTION 10 mg/2 ml will be administered to you
4. Possible side effects
5. How to store CLOPAMON INJECTION 10 mg/2 ml
6. Contents of the pack and other information

1. What CLOPAMON INJECTION 10 mg/2 ml is and what it is used for

CLOPAMON INJECTION 10 mg/2 ml belongs to a group of medicines called propulsives.

CLOPAMON INJECTION 10 mg/2 ml acts on the muscles in the digestive system, helping to stop problems such as feeling sick (nausea) and being sick (vomiting).

CLOPAMON INJECTION 10 mg/2 ml is used for:

- Digestive disorders.
- Feeling sick (nausea) and being sick (vomiting).
- Delayed nausea and vomiting after radiology treatment (Diagnostic radiology).
- Emptying of duodenal content for treatment procedures (Duodenal intubation).
- In young adults and children CLOPAMON INJECTION 20mg/2ml 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).

2. What you need to know before CLOPAMON INJECTION 10 mg/2 ml is administered to you.

CLOPAMON INJECTION 10mg/2 ml should not be administered to you:

- if you are hypersensitive (allergic) to metoclopramide or any other ingredients of CLOPAMON INJECTION 10 mg/2 ml (listed in section 6).
- if you are on antipsychotic treatment (Phenothiazines).
- if you have or have had bleeding, perforation or blockage of the stomach or intestines, or if you have had an operation on your stomach or intestines recently.
- if you have or may have a rare tumour of the adrenal gland, which sits near the kidney (phaeochromocytoma).
- if you have epilepsy (CLOPAMON INJECTION 10 mg/2 ml may increase the risk of having a seizure).
- if you suffer from a rare inherited blood disease (porphyria).
- if you are pregnant

Warnings and precautions

Tell your doctor or healthcare provider before being given the injection:

- if you are elderly as there is an increased risk of extrapyramidal reactions (extreme restlessness, involuntary movements, and uncontrollable speech). These reactions usually at the beginning of the treatment and can occur after a single administration. CLOPAMON INJECTION 10 mg/2 ml should be discontinued immediately in the event of the above-mentioned symptoms.

- if you are using CLOPAMON INJECTION 10 mg/2 ml for longer than 12 weeks. As tardive dyskinesia, a potentially irreversible and disfiguring disorder which causes involuntary movements of the face, tongue or extremities may develop with prolonged treatment especially in the elderly.

  Do not exceed 3 months treatment because of the risk of involuntary muscle spasms.
- if vomiting persists you should be reassessed to exclude any underlying disorder.
- if you are receiving CLOPAMON INJECTION 10 mg/2 ml for delayed gastric emptying, then your treatment should be reviewed at an early stage for responsiveness.
- if you have kidney or liver problems. Patients with kidney or liver impairment should receive a reduced dosage.
- if you are breastfeeding.
- if you have a history of abnormal heart beats (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 any neurological (brain) problems
- if you have Parkinson's disease as symptoms of Parkinson's disease may worsen with CLOPAMON INJECTION 10 mg/2 ml.
- if you are taking any medicines known as serotonergic medicines, as taking these medications with CLOPAMON INJECTION 10 mg/2 ml can cause side effects (such as restlessness, loss of co-ordination, fast heartbeat and increased body temperature).
- if you have abnormal blood pigment level (methaemoglobinaemia) which could be related to NADH cytochrome b_5 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.
- if you have high blood pressure (hypertension),
- if you have a history of allergies, including asthma (atopy) or have a rare inherited blood disease (porphyria).
- if you are taking any other medicine by mouth. It is possible that CLOPAMON INJECTION 10 mg/2 ml may change the amount of the other medicine that gets into your body.

Children and adolescents

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

Other medicines and CLOPAMON INJECTION 10 mg/2 ml

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

Tell your doctor if you are taking any of the following:

- levodopa or other medicines used to treat Parkinson's disease (see section 2).
- alcohol as CLOPAMON INJECTION 10 mg/2 ml may increase the effect of alcohol.
- phenothiazines (medicines used to treat serious mental and emotional disorders).
- anticholinergics (medicines used to relieve stomach cramps or spasms)
- morphine derivatives (medicines used to treat severe pain)
- sedative medicines
- any medicines used to treat mental health problems
- digoxin (medicine used to treat heart failure)
- cyclosporine (medicine used to prevent organ rejection after transplantation such as a liver transplant
- mivacurium and suxamethonium (medicines used to relax muscles).
- fluoxetine and paroxetine (medicine used to treat depression that boost brain serotonin levels).
- atovaquone (antibiotic used to treat pneumonia)
- neuroleptic medicines (medicines for mental illness)
- pain killers such as aspirin or paracetamol or stronger pain killers called opioids.

CLOPAMON INJECTION 10 mg/2 ml with food, drink and alcohol

Taking alcohol during treatment with CLOPAMON INJECTION 10 mg/2 ml may increase the sedative effect of CLOPAMON INJECTION 10 mg/2 ml.

Pregnancy, breastfeeding and fertility

You should not take CLOPAMON INJECTION 10 mg/2 ml if you are pregnant or 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 CLOPAMON INJECTION 10 mg/2 ml.

CLOPAMON INJECTION 10 mg/2 ml is not recommended if you are breastfeeding because metoclopramide passes into breast milk and may affect your baby.

Driving and using machines

CLOPAMON INJECTION 10 mg/2 ml may cause drowsiness, dizziness or involuntary movement disorders which may interfere with your ability to drive and operate machines.

It is not always possible to predict to what extent CLOPAMON INJECTION 10 mg/2 ml 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 CLOPAMON INJECTION 10 mg/2 ml affects you (see section 4).

CLOPAMON INJECTION 10 mg/ml contains 17,0 mg sodium chloride.

This medicine contains less than 1 mmol sodium (23 mg) per 2 ml, that is to say essentially 'sodium-free'**.**

3. How CLOPAMON INJECTION 10 mg/ml will be administered to you

You will not be expected to give yourself CLOPAMON INJECTION 10 mg/2 ml. It will be given to you by a person who is qualified to do so.

CLOPAMON INJECTION 10 mg/2 ml may be given intravenously or intramuscularly. A doctor or healthcare professional will administer CLOPAMON INJECTION 10 mg/2 ml.

Your doctor will tell you how long your treatment with CLOPAMON INJECTION 10 mg/2 ml will last. If you have the impression that the effect of CLOPAMON INJECTION 10 mg/2 ml is too strong or too weak, tell your doctor or pharmacist.

Adults with kidney problems

Talk to your doctor if you have kidney problems. The dose should be reduced if you have moderate or severe kidney problems.

Adults with liver problems

Talk to your doctor if you have liver problems. The dose should be reduced if you have severe liver problems.

Children and adolescents

Children and young patients should be treated with care as they are at increased risk of side effects usually at the beginning of the treatment and can occur after a single administration. CLOPAMON INJECTION 10 mg/2 ml should be discontinued immediately in the event of side effects.

If you receive more CLOPAMON INJECTION 10 mg/2 ml than you should

Since a doctor or healthcare professional will administer CLOPAMON INJECTION 10 mg/2 ml, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use CLOPAMON INJECTION 10 mg/2 ml

Since a healthcare provider will administer CLOPAMON INJECTION 10 mg/2 ml, it is unlikely that the dose will be missed.

If you stop using CLOPAMON INJECTION 10 mg/2 ml

Do not stop using CLOPAMON INJECTION 10 mg/2 ml without talking to your doctor first. Even when you feel better, do not stop receiving CLOPAMON INJECTION 10 mg/2 ml. Talk to your doctor first. If you have any further questions on the use of this medicine, ask your doctor.

4. **Possible side effects**

CLOPAMON INJECTION 10 mg/2 ml can have side effects.

Not all side effects reported for CLOPAMON INJECTION 10 mg/2 ml are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using CLOPAMON INJECTION 10 mg/2 ml, please consult your healthcare provider for advice.

If any of the following happens, stop receiving CLOPAMON INJECTION 10 mg/2 ml 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 CLOPAMON INJECTION 10 mg/2 ml. 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:

- 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) (particularly with the injectable route),
- 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,
- high fever, high blood pressure, fitting, sweating, production of saliva. These may be signs of a condition called neuroleptic malignant syndrome,
- fitting (especially in patients with epilepsy).

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:

- depression,
- uncontrollable movements such as tics, shaking, twisting movements or muscle contracture (stiffness, rigidity),
- symptoms similar to Parkinson's disease (rigidity, tremor),
- feeling restless,
- decrease in blood pressure (particularly with intravenous route),
- diarrhoea, constipation,
- feeling drowsy, feeling weak (asthenia),

Less frequent side effects:

- raised levels of a hormone called prolactin in the blood which may cause milk production in men and in women who are not breastfeeding,
- irregular periods,
- visual disturbances and involuntary upward deviation of eyeball,
- hallucination (seeing or hearing things that are not there), confusional state,
- decreased level of consciousness,

Side effects with an unknown frequency:

- abnormal blood pigment levels, which may change the colour of your skin,
- abnormal development of breasts (gynaecomastia),
- involuntary muscle spasms after prolonged use, particularly in elderly patients,
- sudden increase in blood pressure in patients with tumour of the adrenal gland (phaeochromocytoma),
- very high blood pressure,
- urinary incontinence,
- retention of fluid in the body,
- pain at site of injection.

If you notice any side effects not listed in this leaflet, please consult your doctor, pharmacist or other health care professional for advice.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to:

SAHPRA: https://www.sahpra.org.za/health-products-vigilance/

5. How to store CLOPAMON INJECTION 10 mg/2 ml

Store all medicines out of reach of children.

Store at or below 25 °c, protect from light.

Should inadvertent exposure occur, reject ampoules showing a yellow discolouration.

Do not store in bathrooms.

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

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What CLOPAMON INJECTION 10 mg/2 ml contains

The active substance is 10 mg of metoclopramide (base).

The other ingredients are sodium chloride and water for injection.

What CLOPAMON INJECTION 10 mg/2 ml looks like and contents of the pack

CLOPAMON INJECTION 10 mg/2 ml is clear, colourless liquid.

Packs of 10 glass ampoules each containing 10 mg/2 ml.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/