PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

Pharma-Q Metoclopramide Injection 10 mg/2 ml

Solution for injection

Metoclopramide

Sugar free

Read all of this leaflet carefully before you start receiving Pharma-Q Metoclopramide Injection 10 mg/2 ml

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- Pharma-Q Metoclopramide 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 Pharma-Q Metoclopramide Injection 10 mg/2 ml is and what it is used for
2. What you need to know before you receive Pharma-Q Metoclopramide Injection 10 mg/2 ml
3. How to receive Pharma-Q Metoclopramide Injection 10 mg/2 ml
4. Possible side effects
5. How to store Pharma-Q Metoclopramide Injection 10 mg/2 ml
6. Contents of the pack and other information

1. What Pharma-Q Metoclopramide Injection 10 mg/2 ml is and what it is used for

Metoclopramide is a prokinetic medicine that stimulates the muscles of the gastro-intestinal tract including the lower oesophageal sphincter, stomach and small intestine by interacting with receptors on the gastro-intestinal muscles and nerves. It is used to correct gastro-intestinal disorders like reflux and also stimulates the muscles of the stomach to hasten gastric emptying.

Pharma-Q Metoclopramide Injection 10 mg/2 ml is used in the treatment of:

- Gastro-intestinal motility disorders (help the stomach to empty it contents normally and upper part of the digestive tract to function properly).
- Nausea and vomiting of various causes.
- Medicine-induced post-operative nausea and vomiting.

It is also used in disorders of:

- Reduced gastro-intestinal motility such as gastroparesis (stomach takes too long to empty its contents) or ileus (blockage of the intestines).
- Gastro-oesophageal reflux (acid from the stomach going back into the oesophagus) and dyspepsia (heartburn).
- Nausea and vomiting associated with various gastro-intestinal disorders.
- Gastric stasis (stopping of normal flow of gastric substances) or hypomotility (intestines unable to contract).
- Migraine or following surgery.
- Cancer chemotherapy and radiotherapy (treatments given for cancer causing nausea and vomiting).

Pharma-Q Metoclopramide Injection 10 mg/2 ml may also be used to:

- Stimulate gastric emptying during radio-graphic examinations of the stomach and/or small intestines.

- Facilitate intubation of the small bowel (passing of a tube into the small intestine for examination purposes).

2. What you need to know before you receive Pharma-Q Metoclopramide Injection 10 mg/2 ml

Do not receive Pharma-Q Metoclopramide Injection 10 mg/2 ml:

- if you are allergic (hypersensitive) to metoclopramide or any other ingredients of Pharma-Q Metoclopramide Injection 10 mg/2 ml (listed in section 6).
- if you have bleeding, obstruction or a tear in your stomach or gut.
- if you have or may have a rare tumour of the adrenal gland, which sits near the kidney (pheochromocytoma).
- if you have ever had involuntary muscle spasms (tardive dyskinesia), when you have been treated with a medicine.
- if you have epilepsy.
- if you have Parkinson's disease.
- if you are taking levodopa (a medicine for Parkinson's disease) or dopaminergic agonists (see below "Other medicines and Pharma-Q Metoclopramide Injection 10 mg/2 ml").
- if you have ever had an abnormal blood pigment levels (methaemoglobinemia) or NADH cytochrome-b5 deficiency.

Do not give Pharma-Q Metoclopramide Injection 10 mg/2 ml to a child less than 1 year of age (see below "Children and adolescents").

Warnings and precautions

Special care should be taken with Pharma-Q Metoclopramide Injection 10 mg/2 ml:

- if you are taking other medicines to treat depression (see 'Other medicines and Pharma-Q Metoclopramide Injection 10 mg/2 ml').
- if you have a history of abnormal heart beats (QT interval prolongation) or any other heart

problems.

- if you have problems with the levels of salts in your blood, such as potassium, sodium and magnesium.
- if you are using other medicines known to affect the way your heart beats.
- if you have any neurological (brain) problems.
- if you have liver or kidney problems. The dose may be reduced (see section 3).

Your doctor may perform blood tests to check your blood pigment levels. In cases of abnormal levels (methaemoglobinemia), the treatment should be immediately and permanently stopped.

Children and adolescents

Uncontrollable movements (extrapyramidal disorders) may occur in children and young adults. This medicine must not be used in children below 1 year of age because of the increased risk of the uncontrollable movements (see above "Do not receive Pharma-Q Metoclopramide Injection 10 mg/2 ml if").

Other medicines and Pharma-Q Metoclopramide Injection 10 mg/2 ml

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

You should also tell your doctor if you are taking any of the following:

- levodopa or other medicines such as bromocriptine and pergolide used to treat Parkinson's disease (see above "Do not receive Pharma-Q Metoclopramide Injection 10 mg/2 ml if")
- anticholinergics such as phenothiazines and tetrabenazine (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)
- ciclosporine (medicine used to treat certain problems with the immune system)
- mivacurium and suxamethonium (medicines used to relax muscles)
- fluoxetine and paroxetine (medicine used to treat depression)
- medicines used to treat pain such as paracetamol and aspirin
- medicines used to treat infections such as antiprotozoals (atovaquone).

Pharma-Q Metoclopramide Injection 10 mg/2 ml with, food, drink and alcohol

Alcohol should not be consumed during treatment with metoclopramide because it increases the sedative effect of Pharma-Q Metoclopramide Injection 10 mg/2 ml.

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 health care provider for advice before taking this medicine.

Pregnancy

The safety of Pharma-Q Metoclopramide Injection 10 mg/2 ml in pregnancy has not been established.

Breastfeeding

Pharma-Q Metoclopramide Injection 10 mg/2 ml is not recommended if you are breast-feeding because metoclopramide passes into breast milk and may affect your baby.

Driving and using machines

You may feel drowsy, dizzy or have uncontrollable twitching, jerking or writhing movements and unusual muscle tone causing distortion of the body after receiving Pharma-Q Metoclopramide Injection 10 mg/2 ml. This may affect your vision and also interfere with your ability to drive and

use machines.

3. How to take Pharma-Q Metoclopramide Injection 10 mg/2 ml

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

Always receive Pharma-Q Metoclopramide Injection 10 mg/2 ml exactly as your doctor has prescribed. You should check with your doctor or pharmacist if you are unsure

Pharma-Q Metoclopramide Injection 10 mg/2 ml will be given to you by a doctor or nurse in hospital. Your doctor will choose the dose that is right for you.

Pharma-Q Metoclopramide Injection 10 mg/2 ml:

- May be given by injection into a muscle or by slow injection into a vein.
- Your doctor will choose the most suitable dose to meet your requirements.
- The dosage will be different for adults and children.
- Dosages for children and young adults will be calculated according to their age and weight.
- Doses will calculated carefully in children and young adults because of the risk of dystonic reactions (muscle tension disorders involving the nerves).

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

If you receive more Pharma-Q Metoclopramide Injection 10 mg/2 ml than you should

Since this injection will be given to you by a doctor or nurse it is unlikely that you will miss a dose or that you will be given too much. However, if you are worried that you have missed a dose or that you have been given too much, talk to the doctor or nurse looking after you.

Overdosage of Pharma-Q Metoclopramide Injection 10 mg/2 ml could give rise to:

- Dyskinetic reactions (involuntary reactions) which manifest as motor restlessness.
- Agitation, irritability, spasm of facial and neck muscles and the muscles of the tongue.

- In severe cases opisthotonus (abnormal muscle spasm in spine) can result.
- Anti-Parkinson medications, e.g. biperidine will usually control these reactions.
- Further treatment is symptomatic and supportive.

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

If you missed a dose of Pharma-Q Metoclopramide Injection 10 mg/2 ml

If you think that you did not receive a dose of, contact your doctor.

4. Possible side effects

Pharma-Q Metoclopramide Injection 10 mg/2 ml can have side effects.

Not all side effects reported for Pharma-Q Metoclopramide Injection 10 mg/2 ml are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving Pharma-Q Metoclopramide Injection 10 mg/2 ml, please consult your health care provider for advice.

If any of the following happens, stop receiving Pharma-Q Metoclopramide 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, tongue and mouth or throat, which may cause difficulty in swallowing or breathing.

These are all very serious side effects. If you have them, you may have had a serious reaction to Pharma-Q Metoclopramide 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:

Frequent:

- 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.

Frequency unknown:

- high fever, high blood pressure, convulsions, sweating, production of saliva. These may be signs of a condition called neuroleptic malignant syndrome.
- convulsions (especially in patients with epilepsy);
- allergic reaction which may be severe (particularly with intravenous route);
- shock (severe decrease of heart pressure) (particular with injection route);
- 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:

Frequent side effects

- feeling drowsy,
- depression,
- symptoms similar to Parkinson disease (rigidity, tremor),
- feel restless,
- blood pressure decrease (particularly with intravenous route),
- diarrhoea,
- feeling weak.

Less frequent side effects

- 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,

- involuntary upward deviation of eye ball,
- hallucination,
- decreased level of consciousness,
- slow heartbeat (particularly with intravenous route),
- confusional state.

Frequency unknown:

- 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,
- changes in heart beat, which may be shown on an ECG test,
- cardiac arrest (particularly with injection route),
- fainting (particularly with intravenous route),
- dyspnoea (difficulty breathing),
- sudden increase in blood pressure in patients with tumour of the adrenal gland (pheochromocytoma),
- very high blood pressure.

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 Reaction Reporting Form", found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of Pharma-Q Metoclopramide Injection 10 mg/2 ml.

5. How to store Pharma-Q Metoclopramide Injection 10 mg/2 ml

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Protect from light.
- Reject ampoules showing a yellow discolouration.
- Do not store in a bathroom
- Do not use after the expiry date stated on the label / carton / bottle

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 Pharma-Q Metoclopramide Injection 10 mg/2 ml contains

Each 2 ml contains: 10 mg Metoclopramide base as hydrochloride monohydrate.

The other ingredients are: hydrochloric acid, nitrogen, sodium chloride, water for injection.

What Pharma-Q Metoclopramide Injection 10 mg/2 ml looks like and contents of the pack

Clear, colourless solution in clear, colourless, type 1, glass ampoules.

Contents of the pack:

2 ml, type 1, clear, colourless, glass ampoules packed in cartons of 10 or 100.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

To follow

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS S4

Pharma-Q Metoclopramide Injection 10 mg/2 ml

Oplossing vir inspuiting

Metoklopramied

Suikervry

Lees hierdie hele inligtingstuk sorgvuldig voordat jy Pharma-Q Metoclopramide Injection 10 mg/2 ml ontvang

- Hou hierdie inligtingsblad. Dit mag wees dat jy dit weer wil lees.
- Indien jy verdere vrae het, raadpleeg jou dokter, apteker, verpleegster of ander gesondheidswerker.
- Pharma-Q Metoclopramide Injection 10 mg/2 ml is vir jou persoonlik voorgeskryf en jy behoort nie jou medisyne met ander te deel nie. Selfs al het hulle dieselfde simptome as jy, kan dit vir hulle skadelik wees.

Wat hierdie inligtingsblad bevat

1. Wat Pharma-Q Metoclopramide Injection 10 mg/2 ml is en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy Pharma-Q Metoclopramide Injection 10 mg/2 ml ontvang
3. Hoe om Pharma-Q Metoclopramide Injection 10 mg/2 ml te ontvang
4. Moontlike newe-effekte
5. Hoe om Pharma-Q Metoclopramide Injection 10 mg/2 ml te bewaar
6. Inhoud van die pak en ander inligting

1. Wat Pharma-Q Metoclopramide Injection 10 mg/2 ml is en waarvoor dit gebruik word

Metoklopramied is 'n prokinetiese medisyne wat die spiere van die spysverteringskanaal stimuleer insluitend die onderste esofageale sfinkter, maag en dunderm deur interaksie met reseptore op die gastroïntestinale spiere en senuwees. Dit word gebruik om gastroïntestinale afwykings soos refluks reg te maak en stimuleer ook die maagspiere om maaglediging te bespoedig.

Pharma-Q Metoclopramide Injection 10 mg/2 ml word gebruik vir die behandeling van:

- Gastroïntestinale beweeglikheidsversteurings (help die maag om die inhoud normaal te ledig en die boonste deel van die spysverteringskanaal om behoorlik te funksioneer).
- Naarheid en braking van verskeie oorsake.
- Medisyne-geïnduseerde na-operasie naarheid en braking.

Dit word ook gebruik by versteurings van:

- Verminderde gastroïntestinale beweeglikheid soos gastroparese (maag neem te lank om die inhoud leeg te maak) of ileus (verstopping van die ingewande).
- Gastroësofageale refluks (suur van die maag gaan terug na die slukderm) en dispepsie (sooibrand).
- Naarheid en braking geassosieer met verskeie gastroïntestinale versteurings.
- Maagstase (stop van normale vloei van maagstowwe) of hipomotiliteit (ingewande kan nie saamtrek nie).
- Migraine of na 'n operasie.
- Kanker chemoterapie en bestraling (behandelings wat toegedien word vir kanker wat naarheid en braking veroorsaak).

Pharma-Q Metoclopramide Injection 10 mg/2 ml kan ook gebruik word vir:

- Stimuleer maaglediging tydens radiografiese ondersoeke van die maag en/of dunderm.

- Fasiliteer intubasie van die dunderm (installering van 'n buis in die dunderm vir ondersoekdoeleindes).

2. Wat jy moet weet voordat jy Pharma-Q Metoclopramide Injection 10 mg/2 ml ontvang

Moenie Pharma-Q Metoclopramide Injection 10 mg/2 ml ontvang:

- indien jy allergies (hipersensitief) is vir metoklopramied of enige van die ander bestanddele van Pharma-Q Metoclopramide Injection 10 mg/2 ml (gelys in afdeling 6).
- indien jy bloeding, obstruksie of 'n skeur in jou maag of derms het.
- indien jy n skaars tumor van die adrenale klier het, of moontlik het, wat naby die nier sit (feochromositoom)
- indien jy al ooit voorheen onwillekeurige spierspasma (laatdiskinesie) gehad het, tydens behandeling met 'n medisyne
- indien jy epilepsie het.
- indien jy Parkinson-siekte het.
- indien jy levodopa ('n medisyne vir Parkinson-siekte) of dopaminergiese agoniste (sien onder "Ander medisyne en Pharma-Q Metoclopramide Injection 10 mg/2 ml") neem.
- indien jy al ooit abnormale bloedpigment vlakke (methemoglobinemie) of NADH sitochroom-b5 tekort gehad het.

Moet nie Pharma-Q Metoclopramide Injection 10 mg/2 ml vir 'n kind onder 1 jaar van ouderdom toedien nie (sien onder "Kinders en adolessente").

Waarskuwings en voorsorgmaatreëls

Spesiale sorg moet geneem word met Pharma-Q Metoclopramide Injection 10 mg/2 ml:

- indien jy ander medisyne vir die behandeling van depressie neem (sien 'Ander medisyne en Pharma-Q Metoclopramide Injection 10 mg/2 ml').
- indien jy 'n geskiedenis van abnormale hartkloppings (QT interval verlenging) of enige ander hart probleme het.

- indien jy probleem met soutvlakke in jou bloed het, soos kalium, natrium en magnesium.
- indien jy ander medisyne neem wat bekend is om die manier wat jou hart klop aan te tas
- indien jy enige neurologiese (brein) probleme het.
- indien jy lewer of nier probleme het. Die dosis kan verlaag word (sien afdeling 3).

Jou dokter kan bloed toetse doen om jou bloedpigment vlakke te kontrolleer. Die behandeling moet onmiddelik en permanent gestaak word in gevalle van abnormale vlakke (methemoglobinemie).

Kinders en adolessente

Onbeheerbare bewegings (ekstrapiramidale afwyking) kan in kinders en jong volwassenes voorkom. Aangesien daar daar 'n groter risiko van onbeheerbare bewegings is, moet hierdie medisyne nie in kinders onder 1 jaar gebruik word nie (sien bo "Moenie Pharma-Q Metoclopramide Injection 10 mg/2 ml ontvang").

Ander medisyne en Pharma-Q Metoclopramide Injection 10 mg/2 ml

Vertel altyd jou gesondheidsorgwerker indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

Vertel ook jou dokter indien jy enige van die volgende neem:

- levodopa en ander medisyne soos bromokriptien en pergolied, gebruik vir die behandeling van Parkinson-siekte (sien bo "Moenie Pharma-Q Metoclopramide Injection 10 mg/2 ml ontvang")
- anticholinergiese middels soos fenotiasiene en tetrabenasien (medisyne wat gebruik word om maagkrampe of spasmas te verlig)
- morfienderivate (medisyne wat gebruik word om erge pyn te behandel)
- kalmeermiddels
- enige medisyne wat gebruik word vir die behandeling van verstandelike gesondheids

probleme

- digoksien (medisyne wat gebruik word om hartversaking te behandel)
- siklosporien (medisyne wat gebruik word om sekere probleme van die immuunstelsel te behandel)
- mivakurium en suksametonium (medisyne wat gebruik word om spiere te verslap)
- fluoksetien en paroksetien (medisyne wat gebruik word om depressie te behandel)
- medisyne wat gebruik word om pyn te behandel soos parasetamol en aspirien
- medisyne wat gebruik word om infeksies te behandel soos antiprotosoale middels (atovakoon).

Pharma-Q Metoclopramide Injection 10 mg/2 ml met kos, drank en alkohol

Alkohol moet vermy word gedurende metoklopramied behandeling omdat dit die kalmerende effek van Pharma-Q Metoclopramide Injection 10 mg/2 ml verhoog.

Swangerskap, borsvoeding en fertiliteit

Indien jy swanger is of jou baba borsvoed, dink jy kan dalk swanger wees of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgwerker vir advies voordat jy hierdie medisyne ontvang.

Swangerskap

Die veiligheid van Pharma-Q Metoclopramide Injection 10 mg/2 ml in swangerskap is nie vasgestel nie.

Borsvoeding

Pharma-Q Metoclopramide Injection 10 mg/2 ml word nie aanbeveel as jy borsvoed nie, aangesien metoklopramied oorgedra word in borsmelk en jou baba kan affekteer,

Bestuur en gebruik van masjinerie

Jy kan lomerig, duiselig voel of onbeheerbare rukkens, trekkings of krimpende bewegings kry

en ongewone spiertonus wat verdraaiing van die liggaam veroorsaak nadat jy Pharma-Q Metoclopramide Injection 10 mg/2 ml ontvang het. Dit kan jou visie affekteer en ook inmeng met jou vermoë om te bestuur en masjinerie te gebruik.

3. Hoe om Pharma-Q Metoclopramide Injection 10 mg/2 ml te ontvang

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.

Ontvang altyd Pharma-Q Metoclopramide Injection 10 mg/2 ml presies soos jou dokter dit voorgeskryf het. Vra jou dokter of apteker indien jy onseker is.

Pharma-Q Metoclopramide Injection 10 mg/2 ml sal toegedien word deur 'n dokter of verpleegster in die hospitaal. Jou dokter sal die dosis wat reg is vir jou kies.

Pharma-Q Metoclopramide Injection 10 mg/2 ml:

- Kan toegedien word deur inspuiting in 'n spier of deur stadige inspuiting in 'n aar.
- Jou dokter sal die mees geskikste dosis kies wat aan jou vereistes sal voldoen.
- Die dosis sal verskillend wees vir volwassenes en kinders.
- Dossisse vir kinders en jong volwassenes sal bereken word volgens hul ouderdom en gewig.
- Dossisse sal sorgvuldig bereken word vir kinders en jong volwassenes as gevolg van die risiko van distoniese reaksies (spier spanningsteurings wat die senuwees betrek).

Jou dokter sal jou inlig oor hoe lank jou behandeling met Pharma-Q Metoclopramide Injection 10 mg/2 ml sal duur. Indien jy onder die indruk is dat die effek van Pharma-Q Metoclopramide Injection 10 mg/2 ml te sterk of te swak is, moet jy jou dokter of apteker vertel.

Indien jy meer Pharma-Q Metoclopramide Injection 10 mg/2 ml ontvang as wat jy moet

Aangesien hierdie inspuiting deur jou dokter of verpleegster toegedien gaan word is dit onwaarskynlik dat jy 'n dosis sal mis of dat jy te veel gegee sal word. Indien jy egter bekommerd is dat jy 'n dosering oorgeslaan het of te veel ontvang het, praat met die dokter of verpleegster wat na jou kyk.

Oordosering van Pharma-Q Metoclopramide Injection 10 mg/2 ml kan tot die volgende lei:

- Diskinetiese reaksies (onwillekeurige reaksies) wat kan manifisteer as motoriese rusteloosheid.
- Agitasie, prikkelbaarheid, spasma van die gesig en nek spiere en die spiere van die tong.
- In erge gevalle kan dit lei tot opistotonus (abnormals spierspasma in die ruggraat).
- Anti-Parkinson medikasie, bv. biperidien sal gewoonlik hierdie reaksies beheer.
- Verdere behandeling is simptomaties en ondersteunend.

In die geval van oordosering, raadpleeg jou dokter of apteker. Indien beide nie beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

Indien jy 'n dosis van Pharma-Q Metoclopramide Injection 10 mg/2 ml gemis het

Kontak jou dokter indien jy vermoed dat jy nie 'n dosis ontvang het nie.

4. Moontlike newe-effekte

Pharma-Q Metoclopramide Injection 10 mg/2 ml kan newe-effekte hê.

Nie al die newe-effekte wat aangemeld is vir Pharma-Q Metoclopramide Injection 10 mg/2 ml, in hierdie inligtingstuk ingesluit nie. Indien jou algemene gesondheid agteruitgaan of as jy enige onnodige effekte ondervind terwyl jy Pharma-Q Metoclopramide Injection 10 mg/2 ml ontvang, kontak jou gesondheidsorgwerker vir advies.

Indien jy enige van die volgende ervaar, hou op om Pharma-Q Metoclopramide Injection 10 mg/2 ml te ontvang en kontak jou dokter onmiddelik of gaan na die ongevalle afdeling van die naaste hospitaal:

- swelling van die hande, voete, enkels, gesig, lippe, tong en mond of keel, wat moeilike sluk of asemhaling kan veroorsaak.

Hierdie is almal baie ernstige newe-effkte. Indien jy dit het, het jy moontlik 'n baie ernstige

reaksie van Pharma-Q Metoclopramide Injection 10 mg/2 ml gehad. Jy mag dringende mediese aandag en hospitalisering nodig hê.

Vertel jou dokter dadelik of gaan na die ongevalle afdeling van jou naaste hospitaal indien jy enige van die volgende oplet:

Gereeld:

- onbeheerbare bewegings (sluit dikwels kop en nek in). Hierdie kan in kinders of jong volwassenes voorkom en veral wanneer hoë dosisse gebruik word. Hierdie tekens gebeur gewoonlik met aanvang van behandeling en kan selfs na een enkele toediening voorkom. Hierdie bewegings sal stop as dit op die regte manier behandel word.

Frekwensie onbekend:

- hoë koors, hoë bloeddruk, konvulsies, sweet, speeksel produksie. Hierdie kan tekens wees van 'n toestand wat neuroleptiese kwaadaardige sindroom genoem word.
- konvulsies (veral by pasiënte met epilepsie);
- allergiese reaksie wat baie erg kan wees (veral met binneaarse roete);
- skok (erge afname in hartdruk) (veral met inspuitings roete);
- baie hoë bloeddruk.

Hierdie is almal erge new-effekte. Jy mag dringende mediese aandag nodig hê.

Vertel jou dokter indien jy enige van die volgende oplet:

Gereelde newe-effekte

- voel lomerig,
- depressie,
- simptome soortgelyk aan Parkinson-siekte (rigiditeit, bewing),
- voel rusteloos,
- bloeddruk verlaag (veral met binneaarse roete),
- diarree,

- voel swak.

Minder gereelde newe-effekte:

- verhoogde vlakke van 'n hormoon genaamd prolaktien in die bloed wat: melkproduksie by mans, en vrouens wat nie borsvoed nie, kan veroorsaak,
- onreëlmatige periodes,
- onwillekeurige opwaartse afwyking van oogbal,
- hallusinasie,
- verlaagde vlak van bewussyn,
- stadige hartklop (veral met binneaarse roete),
- verwarringstaat.

Frekwensie onbekend:

- abnormale bloedpigment vlakke: wat die kleur van jou vel kan verander,
- abnormale ontwikkeling van borste (ginekomastie),
- onwillekeurige spierspasmas na verlengde gebruik, veral by bejaarde pasiënte,
- veranderinge in hartklop, wat op 'n EKG toets kan wys,
- hartaanval (veral met inspuitings roete),
- floute (veral met binneaarse roete),
- dispnee (moeilike asemhaling),
- skielike toename in bloeddruk by pasiënte met tumor van die adrenale klier (feochromositoom),
- baie hoë bloeddruk.

Lig asseblief jou dokter of apteker in indien jy 'n newe-effek ervaar wat nie in hierdie inligtingsblad genoem word nie.

Aanmelding van newe-effekte

As jy newe-effekte kry, vertel jou dokter of apteker. Jy kan ook newe-effekte aanmeld by

SAHPRA via die "6.04 Adverse Drug Reaction Reporting Form", aanlyn gevind onder SAHPRA se publikasies:

https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte te rapporteer, kan jy help om meer inligting te gee oor die veiligheid van Pharma-Q Metoclopramide Injection 10 mg/2 ml.

5. Hoe Pharma-Q Metoclopramide Injection 10 mg/2 ml bewaar moet word

Bewaar alle medisyne buite die bereik van kinders.

- Bewaar by of benede 25 °C.
- Beskerm teen lig.
- Verwerp ampules wat 'n geel verkleuring wys.
- Moet nie in 'n badkamer stoor nie.
- Moet nie na die vervaldatum op die etiket en karton gebruik nie

Neem al die ongebruikte medisyne terug na jou apteker.

Moenie ongebruikte medisyne in die rioolstelsel (bv. toilet) gooi nie.

6. Inhoud van die pak en ander inligting

Wat Pharma-Q Metoclopramide Injection 10 mg/2 ml bevat

Elke 2 ml bevat: 10 mg Metoklopramied basis as hidrochloriedmonohidraat.

Die ander bestanddele is: asynsuur, stikstof, natriumchloried, water vir inspuiting.

Hoe Pharma-Q Metoclopramide Injection 10 mg/2 ml lyk en inhoud van die pak

Helder, kleurlose oplossing in deursigtige, kleurlose, tipe 1, glas ampules.

Inhoud van die pak:

2 ml, tipe 1, deursigtige, kleurlose, glas ampules verpak in kartonne van 10 of 100.

Houer van die sertifikaat van registrasie

Pharma-Q Holdings (Pty) Ltd

Commandoweg 50

Industria Wes 2003

Johannesburg

Suid-Afrika

Hierdie inligtingsblad is laas hersien in

29 Augustus 2011

Registrasienommer

34/5.7.2/0051

Toegang tot die ooreenstemmende Professionele Inligting

Sal volg