METOCLOPRAMIDE HCI MEDSURGE

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being given Metoclopramide HCl Medsurge?

Metoclopramide HCl Medsurge contains the active ingredient Metoclopramide hydrochloride (as monohydrate). Metoclopramide HCl Medsurge is used to relieve nausea and vomiting in migraine, cancer treatment, childbirth, infectious diseases and control vomiting after surgery help with placing tubes into the intestine.

For more information, see Section 1. Why am I being given Metoclopramide HCl Medsurge? in the full CMI.

2. What should I know before I am given Metoclopramide HCl Medsurge?

Do not use if you have ever had an allergic reaction to metoclopramide or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I am given Metoclopramide HCl Medsurge? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Metoclopramide HCl Medsurge and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How is Metoclopramide HCl Medsurge given?

- Follow all directions given to you by your doctor or nurse carefully. They may differ from the information contained in this leaflet. Metoclopramide HCl Medsurge is given by injection into the muscle or by slow injection into a vein.
- More instructions can be found in Section 4. How is Metoclopramide HCl Medsurge given? in the full CMI.

5. What should I know while I am given Metoclopramide HCl Medsurge?

Things you should do	Remind any doctor, dentist, nurse or pharmacist you visit that you are receiving Metoclopramide HCl Medsurge.
Driving or using machines	 Metoclopramide HCl Medsurge may cause dizziness, light-headedness, tiredness or drowsiness in some people. If affected do not drive, operate machinery or anything else that could be dangerous.
Drinking alcohol	Be careful when drinking alcohol while you are having this medicine. If you drink alcohol, it may make you sleepy
Looking after your medicine	The ampoules should be stored where the temperature stays below 25°C.

For more information, see Section 5. What should I know while i am given Metoclopramide HCl Medsurge? in the full CMI.

6. Are there any side effects?

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are being given Metoclopramide HCl Medsurge.

Side effects of Metoclopramide HCl Medsurge include drowsiness, tiredness, restlessness, dizziness, headache, nausea, bowel irregularities, insomnia.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

METOCLOPRAMIDE HCI MEDSURGE

Metoclopramide hydrochloride monohydrate

Consumer Medicine Information (CMI)

This leaflet provides important information about using Metoclopramide HCl Medsurge. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Metoclopramide HCl Medsurge.

Where to find information in this leaflet:

- 1. Why am I being given Metoclopramide HCl Medsurge?
- 2. What should I know before I am given Metoclopramide HCl Medsurge?
- 3. What if I am taking other medicines?
- 4. How is Metoclopramide HCl Medsurge given?
- 5. What should I know while I am given Metoclopramide HCl Medsurge?
- 6. Are there any side effects?
- 7. Product details

1. Why am I being given Metoclopramide HCl Medsurge?

Metoclopramide HCl Medsurge contains the active ingredient Metoclopramide hydrochloride monohydrate. Metoclopramide HCl Medsurge belongs to a group of medicines known as antiemetics. This medicine works by blocking the action of a chemical in the brain which causes nausea and vomiting. It also acts in the stomach and upper intestine to increase muscle contractions.

Metoclopramide HCl Medsurge is used to:

- relieve nausea and vomiting in migraine, cancer treatment, childbirth and infectious diseases
- · control vomiting after surgery
- help with placing tubes into the intestine

When used to treat children and young adults under 20 years of age, Metoclopramide should be restricted to the following conditions and only used as second line therapy:

- treat severe vomiting of known cause, or following chemotherapy or radiation treatment
- help with placing tubes into the intestine.

Ask your doctor if you have any questions about why this medicine has been prescribed for you or your child.

2. What should I know before I am given Metoclopramide HCl Medsurge?

Warnings

Do not use Metoclopramide HCl Medsurge if:

- you are allergic to Metoclopramide hydrochloride monohydrate or any of the ingredients listed at the end of this leaflet, any other similar medicines, such as procaine, procainamide.
 - Some of the symptoms of an allergic reaction may include:
 - o shortness of breath
 - o wheezing or difficulty breathing
 - swelling of the face, lips, tongue or other parts of the body
 - o rash, itching or hives on the skin.
- You have or have had any medicial conditions, especially the following:
 - phaeochromocytoma (a rare tumour of the adrenal gland that may cause high blood pressure)
 - bleeding of the stomach and/or digestive tract
 - blockage of the stomach and/or digestive tract
 - take other medication such as antipsychotic/neuroleptic medication and certain antidepressants that can cause movement disorders (extrapyramidal reactions)
 - o porphyria (rare disease of blood pigments)
 - o epilepsy (fits or seizures).

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes.
- have or have had any of the following medical conditions:
 - tardive dyskinesia, a disorder of constant, uncontrollable movements of the tongue, mouth, jaw and cheeks
 - neuroleptic malignant syndrome. Symptoms may include fever, severe muscle cramps/stiffness, sweating, tremors, incontinence, palpitations, unstable blood pressure
 - breast cancer
 - o recent stomach surgery in the past 4 days
 - o depression, including suicidal thoughts
 - high blood pressure
 - o kidney problems
 - liver problems
 - o Parkinson's disease

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor them. See additional information under Section <u>6</u>. Are there any side effects?

Children below 1 year of age

Metoclopramide HCl Medsurge should not be used in children below 1 year of age.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Metoclopramide is excreted in breast milk and can be absorbed by your baby if you are breast-feeding. Your doctor can discuss with you the risks and benefits involved.

3. What if I am taking other medicines?

Tell your doctor, nurse or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Metoclopramide HCl Medsurge and affect how it works. Tell your doctor or pharmacist if you are taking any of the following:

- painkillers
- sleeping tablets
- certain drugs used to treat psychiatric disorders including depression
- suxamethonium
- medicines for hay fever, other allergies or colds
- penicillin antibiotics
- medicines used to treat Parkinson's disease, such as bromocriptine, dopamine or levodopa
- medicines used to treat stomach disorders, such as cimetidine or hyoscine
- medicines used for cancer treatments
- quinidine, used to treat malaria infections, and also heart rhythm disorders
- digoxin, used to treat heart disorders
- ciclosporin, used to alter the immune system in patients who receive an organ transplant
- insulin, used to treat diabetes.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Metoclopramide HCl Medsurge.

4. How is Metoclopramide HCl Medsurge given?

Follow all directions given to you by your doctor or nurse carefully.

They may differ from the information contained in this leaflet.

How much Metoclopramide HCl Medsurge is given?

 Your doctor will decide what dose and how long you will receive Metoclopramide HCl Medsurge.

When is Metoclopramide HCl Medsurge given?

 This may depend on your age, your condition and whether or not you are taking any other medicines.

How is Metoclopramide HCl Medsurge given?

 Metoclopramide HCl Medsurge is given by injection into the muscle or by slow injection into a vein

If you are given too much Metoclopramide HCl Medsurge

As Metoclopramide HCl Medsurge is given to you in hospital under the supervision of your doctor, it is unlikely that you will receive an overdose.

If you think that you are given too much Metoclopramide HCl Medsurge, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Symptoms of an overdose may include:

- drowsiness, confusion
- tremor, twitching or uncontrolled spasm of muscles.

5. What should I know while I am given Metoclopramide HCl Medsurge?

Things you should do

If you are about to be started on any new medicine, remind your doctor or pharmacist that you are having Metoclopramide HCl Medsurge.

Tell any other doctors, dentists, and pharmacists who treat you that you are having this medicine.

Tell your doctor you are taking this medicine if you are going to have surgery, an operation or dental treatment.

It may affect other medicines used during surgery.

Tell your doctor immediately if you become pregnant while taking this medicine.

Tell your doctor if you are about to have any blood tests that you are taking this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Metoclopramide HCl Medsurge affects you.

Metoclopramide HCl Medsurge may cause dizziness, lightheadedness, tiredness or drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues, talk to your doctor.

Drinking alcohol

Be careful drinking alcohol after you have been given this medicine. Tell your doctor if you drink alcohol.

Looking after your medicine

The pharmacy is responsible for the appropriate storage of Metoclopramide HCl Medsurge injection.

The ampoules should be stored where the temperature stays below 25°C and protected from light.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are being given Metoclopramide HCl Medsurge.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
 drowsiness, tiredness restlessness dizziness headache nausea bowel irregularities insomnia. 	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do		
 fast heartbeat depression, suicidal thoughts. allergic reactions including fainting, swelling of limbs, face, lips, mouth or throat which may cause difficulty swallowing or breathing. uncontrolled or repeated movements, e.g. sucking or smacking of the lips, darting of the tongue, chewing movements, uncontrolled movements of the arms or legs. This may be a sign of Tardive Dyskinesia, a movement disorder which can be potentially irreversible. shuffling walk, slowing of all movement, muscle tremor a sudden increase in body temperature, extremely high blood pressure and severe convulsions (neuroleptic malignant syndrome) jaundice or a yellowing of the skin or eyeballs, often with fever, fatigue, loss of appetite, dark coloured urine or light coloured bowel movements. 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.		

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions

https://nzphvc.otago.ac.nz/reporting/

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Metoclopramide HCl Medsurge contains

Active ingredient	Metoclopramide hydrochloride monohydrate	
(main ingredient)		
Other ingredients	Sodium Chloride	
(inactive ingredients)	Sodium hydroxide	
	Hydrochloric acid	

What Metoclopramide HCl Medsurge looks like

Metoclopramide HCl Medsurge is a clear, colorless solution, essentially free from visible particles in a 2 mL clear glass ampoule.

It is available in packs of 2,10 and 50 ampoules. (AUST R 414532).

Who distributes Metoclopramide HCl Medsurge

New Zealand Sponsor

Medsurge Pharma Limited P O Box 331054 Takapuna Auckland 0622

Marketed and distributed by Medsurge Healthcare Pty Ltd.

Telephone: 0800 788 261

Website: www.medsurgehc.com

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