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 given Metoclopramide Injection?

Metoclopramide Injection contains the active ingredient metoclopramide hydrochloride monohydrate.

Metoclopramide Injection is used to relieve nausea and vomiting in migraine, cancer treatment, childbirth and infectious diseases; control vomiting after surgery; or to help with placing tubes into the intestine in adults over 20 years of age.

Metoclopramide Injection is used as second line therapy to treat severe vomiting of known cause or following chemotherapy or radiation treatment; or to help with placing tubes into the intestine in young adults and children (over 1 year of age).

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

2. What should I know before receiving Metoclopramide Injection?

Do not use if you have ever had an allergic reaction to metoclopramide, or any other similar medicines, such as procaine, procainamide.

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 receiving Metoclopramide Injection? in the full CMI.

3. What if I am taking other medicines?

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

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

4. How is Metoclopramide Injection given?

Metoclopramide Injection will be given to you by a doctor or nurse as an injection into the muscle or by slow injection into a vein.

More information can be found in Section 4. How is Metoclopramide Injection given? in the full CMI.

5. What should I know while receiving Metoclopramide Injection?

Things you	• Remind any doctor, dentist or pharmacist you visit that you are receiving Metoclopramide Injection.	
should do	• Tell your doctor you are receiving 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 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	
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how Metoclopramide Injection affects you. Metoclopramide Injection may cause dizziness, light-headedness, tiredness or drowsiness in some people. Children should be careful when riding bicycles or climbing trees.	
Drinking alcohol	Oo not drink alcohol while you are receiving Metoclopramide Injection.	

For more information, see Section 5. What should I know while receiving Metoclopramide Injection? in the full CMI.

6. Are there any side effects?

Common and/or serious side effects are drowsiness, tiredness, restlessness, dizziness, headache, nausea, bowel irregularities, insomnia, fast heartbeat, depression, suicidal thoughts.

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 Injection

Active ingredient(s): Metoclopramide hydrochloride monohydrate

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

- 1. Why am I given Metoclopramide Injection?
- 2. <u>What should I know before receiving Metoclopramide</u> <u>Injection?</u>
- 3. What if I am taking other medicines?
- 4. How is Metoclopramide Injection given?
- 5. <u>What should I know while receiving Metoclopramide</u> <u>Injection?</u>
- 6. Are there any side effects?
- 7. Product details

1. Why am I given Metoclopramide Injection?

Metoclopramide Injection contains the active ingredient metoclopramide hydrochloride monohydrate.

Metoclopramide Injection belongs to a group of medicines known as antiemetics. Antiemetics stop or prevent nausea and vomiting. It also acts in the stomach and upper intestine to increase muscle contractions.

Metoclopramide Injection is used in adults over 20 years of age 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 young adults and children (over 1 year of age), Metoclopramide Injection is only used as second line therapy to:

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

2. What should I know before receiving Metoclopramide Injection?

Warnings

Do not use Metoclopramide Injection if:

 you are allergic to metoclopramide, or any other similar medicines, such as procaine, procainamide.
Always check the ingredients to make sure you can use this medicine.

- you have or have had any medical 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)
 - porphyria (rare disease of blood pigments)
 - epilepsy (fits or seizures).

If you are not sure whether any of these apply to you, check with your doctor.

Check with your doctor if you:

- have or have had any medical conditions, especially the following:
 - 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
 - epilepsy (fits or seizures)
 - recent stomach surgery in the past 4 days
 - depression, including suicidal thoughts
 - high blood pressure
 - kidney problems
 - liver problems
 - 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 for them. See additional information under Section <u>6. Are there any side effects?</u>

Pregnancy and breastfeeding

Tell your doctor if you are pregnant or plan 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 breastfeeding.

Children below 1 year of age

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

3. What if I am taking other medicines?

Tell your doctor 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 and Metoclopramide Injection may interfere with each other. These include:

- painkillers
- sleeping tablets
- certain drugs used to treat psychiatric disorders including depression
- suxamethonium
- 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
- cyclosporin, used to alter the immune system in patients who receive an organ transplant
- insulin, used to treat diabetes.

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

4. How is Metoclopramide Injection given?

How much is given

Your doctor will decide what dose and how long you will receive Metoclopramide Injection. The dosage you will be given will depend on your condition, what it is being used for and other factors, such as your age, and whether or not other medicines are being given at the same time.

How is it given

Metoclopramide Injection will be given to you by a doctor or nurse as an injection into the muscle or by slow injection into a vein.

If you are given too much

This rarely happens as Metoclopramide Injection will be given to you under the care of a highly trained doctor.

In the unlikely event that you are given too much (an overdose), you may experience some of the effects listed under Section <u>6. Are there any side effects?</u>

Your doctor has information on how to recognise and treat an overdose. Ask your doctor if you have any concerns.

5. What should I know while receiving Metoclopramide Injection?

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 Injection.
- Tell any other doctors, dentists, and pharmacists who treat you that you are having this medicine.
- Tell your doctor, nurse or dentist 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 if you are about to have any blood tests that you are having 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 Injection affects you.

Metoclopramide Injection 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.

Children should be careful when riding bicycles or climbing trees.

Drinking alcohol

Do not drink alcohol while you are being given Metoclopramide Injection.

Looking after your medicine

Metoclopramide Injection is usually stored in the hospital ward, clinic or at the pharmacy.

Your doctor, nurse or pharmacist is responsible for storing Metoclopramide Injection in a cool dry place, protected from light where the temperature stays below 25°C and disposing of any unused product correctly.

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.

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	Speak to your
•	restlessness	doctor if you
•	dizziness	have any of these less
•	headache	serious side
•	nausea	effects and they
•	bowel irregularities	worry you.
•	insomnia	

Serious side effects

Serious side effects What to do			
•	fast heartbeat depression, suicidal thoughts	Tell your doctor as soon as possible if you notice any of these serious side effects. You may require medical attention.	
•	allergic reaction including fainting, swelling of limbs, face, lips, mouth or throat which may cause difficulty swallowing or breathing	Call your doctor straight away, or go straight to the Emergency Department at	
•	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	your nearest hospital if you notice any of these serious side effects.	
•	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.		

Tell your doctor or nurse 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

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at <u>www.tga.gov.au/reporting-problems</u>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor, nurse 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 Injection contains

Active ingredient (main ingredient)	Metoclopramide hydrochloride monohydrate
Other ingredients	Hydrochloric acid
(inactive	Sodium chloride
ingredients)	Sodium hydroxide
	Water for Injections

Tell your doctor or nurse if you are allergic to any of these ingredients.

What Metoclopramide Injection looks like

Metoclopramide Injection is a clear, colourless solution in a plastic ampoule.

Metoclopramide Injection 10 mg in 2 mL is available in packs of 10 or 50 ampoules (AUST R 11364)

* Not all pack sizes may be marketed.

Who manufactures and distributes Metoclopramide Injection

Bridgewest Perth Pharma Pty Ltd 15 Brodie Hall Drive Bentley WA 6102 Telephone: 1800 161 156 <u>safety@lumacina.com</u>

Supplied in New Zealand by: LumaCina New Zealand C/o Quigg Partners Level 7, The Bayleys Building 36 Brandon Street, Wellington 6011, New Zealand Telephone: 0800 822 634 safety@lumacina.com

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