PATIENT INFORMATION LEAFLET: EMETON TABLETS/SYRUP: {METOCLOPRAMIDE HCI}

Read this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass this medicine on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

- 1. What Emeton is and what it is used for
- 2. Before you use Emeton
- 3. How to use Emeton
- 4. Possible side effects
- 5. How to store Emeton
- 6. Further information

1. WHAT IS EMETON AND WHAT IS IT USED FOR?

The name of the medicine is Emeton Tablet/Syrup.

Indicated to prevent/ delay nausea and vomiting. This belongs to a group of medicines called antiemetics.

Adult population

Metoclopramide is used in adults: to prevent/ delay nausea & vomiting associated with chemotherapy, radiotherapy, migraines

Paediatric population

Metoclopramide is indicated in children (aged 1-18 years) if other treatment does not work or cannot be used to prevent/delay chemotherapy induce nausea &vomiting.

Each tablet contains:

Metoclopramide 10mg BP.

Each 5ml syrup contains:

Metoclopramide 5mg BP.

2. BEFORE YOU USE EMETON:

Do not use without medical advice:

- If you have had an allergy to any of the ingredients in the past.
- If you are on any other drugs.
- •You must talk to a doctor if you do not feel better or if you feel worse.
- •If in third trimester pregnancy.

Take special care with Metoclopramide and tell your doctor if you: are suffering from liver problems, kidney problems, porphyria, fits (epilepsy), allergies, asthma.

If after taking this medicine for some time you continue to be sick, please speak to your doctor/pharmacist immediately.

Taking other medicines:

Please tell your doctor/pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. The effects of these medicines may change, especially if you are taking: pain killers (opioids, paracetamol, aspirin) anticholinergic medicines, antidepressants, antipsychotics, medicines for Parkinson's disease & movement disorders, Immunosuppressant & medicines used for short-term muscle relaxation in anaesthesia (e.g. Suxamethonium, Mivacurium).

Taking Emeton with Food and Drink

Do not drink alcohol whilst taking metoclopramide as this will enhance effects of drowsiness

Emeton can be taken with or without food.

Pregnancy, Fertility & Lactation

Seek advice from your doctor if you are pregnant, think you may be pregnant or are planning to become pregnant. Do not take

Metoclopramide during the first three months of pregnancy or while breast feeding.

Driving and using machines:

Metoclopramide may make you feel drowsy, dizzy or confused and can cause movement disorders. If metoclopramide affects you in this way, do not drive or operate machinery.

3. HOW TO USE EMETON:

Always take or give this medicine exactly as your doctor has told you. Check with your doctor/ pharmacist if you are not sure. Do not take more than the recommended dose

Syrup <u>Dosing table</u>

| Age | Body Weight | Dose | Frequency |
|-------------|--------------------|--------|---------------------|
| 1-3 years | 10-14 kg | 1 mg | Up to 3 times daily |
| 3-5 years | 15-19 kg | 2 mg | Up to 3 times daily |
| 5-9 years | 20-29 kg | 2.5 mg | Up to 3 times daily |
| 9-18 years | 30-60 kg | 5 mg | Up to 3 times daily |
| 15-18 years | Over 60kg | 10 mg | Up to 3 times daily |

Do not use in children below 1 year. The maximum treatment duration is 5 days

Tablets: **Adults**: 10mg once daily for three days.

The dose may need to be adjusted in elderly patient & those with liver & kidney problems. Seek medical advice.

If you take more Metoclopramide Oral than you should

Talk to a doctor/pharmacist or go to your nearest hospital straight away. Take the medicine pack with you.

The signs of an overdose may include: confusion, drowsiness, muscle spasms, trembling, loss of consciousness, hallucinations and heart problems.

If you forget to take Emeton

Take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Metoclopramide

Do not stop taking the medicine unless your doctor tells you to. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS:

Like all medicines, Emeton can have side effects though not everyone gets them.

Diarrhoea, Asthenia, Somnolence, Depression, Hypotension. Endocrine disorders during prolonged treatment in relation with hyperprolactinemia e.g. noticeable differences in breast size, absence of menstruation (amenorrhea)

The following reactions occur more frequently when high doses are used:

- Extrapyramidal symptoms e.g. involuntary muscle contractions, tremors & stiff muscles particularly in children and young adults.
- Drowsiness, decreased level of consciousness, confusion, hallucination.

Report this or any other side effects to your doctor or pharmacist.

5. HOW TO STORE EMETON:

Do not use Emeton after the expiry date stamped on the pack. The expiry date refers to the last day of the month.

Emeton should be stored in a cool place. Do not store above 30°C, protected from direct sunlight and kept out of the sight and reach of children. Store in the original container/carton.

Medicines should not be disposed off via wastewater or household waste. Ask your pharmacist how to dispose off medicines no longer required. These measures will help protect the environment.

6. FURTHER INFORMATION:

What Emeton contains

The active substances in Emeton preparations is Metoclopramide HCl Further information on summary of product characteristics can be obtained from the regulatory affairs department of Biodeal Laboratories Ltd. regulatoryaffairs@biodealkenya.com.

This product should be used on the advice of a doctor or pharmacist. *Emeton is available as follows:*

Tablets: Blister packs of 10 x10's in unit boxes.

Syrup: 60ml in amber glass bottles,



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