Pharma Code

320 mm

Metoclopramide 10mg Tablets

(Metoclopramide hydrochloride)

PATIENT INFORMATION LEAFLET

Read all of 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, ask your doctor or pharmacist. This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours. If any of the side effects become serious, or if you notice any side effects not listed in this leaflet (see section 4), please tell your doctor or pharmacist.

In this leaflet:

1. WHAT METOCLOPRAMIDE TABLETS ARE AND WHAT THEY ARE USED FOR

Metoclopramide Tablets works on the muscles in the upper part of your digestive system. This helps your digestive system to work properly. It can also stop you from feeling sick (nausea) or from being sick (vomiting).

Adult population
Metoclopramide Tablets used in adults
- To prevent delayed nausea and vomiting that may occur after chemotherapy
- To prevent nausea and vomiting caused by radiotherapy
- To treat nausea and vomiting including nausea and vomiting which may occur with migraine.

Metoclopramide tablets can be taken with oral pain killers work more effectively.

Pediatric population:
Metoclopramide Tablets are indicated in children (aged 1-18 years) if other treatment does not work or cannot be used to prevent delayed nausea and vomiting that may occur after chemotherapy.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE METOCLOPRAMIDE TABLETS

Do not take Metoclopramide Tablets if:
- You are allergic to Metoclopramide or any of the other ingredients of this medicine (listed in section 6)
- You have bleeding, obstruction or a tear in your stomach or gut
- You have or may have a rare tumour of the adrenal gland, which sits near the kidney (pheochromocytoma)
- You have ever had involuntary muscle spasms (tardive dyskinesia), when you have been treated with a medicine
- You have epilepsy
- You have Parkinson's disease
- You are taking levodopa (a medicine for Parkinson's disease) or dopaminergic agonists (see below "other medicines and Metoclopramide tablets")
- You have ever had an abnormal blood pigment levels (methaemoglobinaemia) or NADH cytochrome–b5 deficiency.

Do not give Metoclopramide tablets to a child less than 1 year of age (see below "Children and adolescents").

Warning and precautions
Talk to your doctor, pharmacist or nurse before taking Metoclopramide tablets if:
- You have history of abnormal heartbeats (QT interval prolongation) or any other heart problems
- You have problems with the levels of salts in your blood, such as potassium, sodium and magnesium
- You are using other medicines known to affect the way your heartbeats
- You have any neurological (brain) problems
- You have liver or kidney problems. The dose may be reduced (see section 3).

Your doctor may perform blood test to check your blood pigment levels. In cases of abnormal levels (methaemoglobinaemia), the treatment should be immediately and permanently stopped.
You must wait at least 6 hours between each Metoclopramide dose, even in case of vomiting and rejection of dose, in order to avoid overdose.
Do not exceed 3-month treatment because of the risk of involuntary muscle spasms.

Children and adolescents
Uncontrollable moments (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 uncontrolled movements (see above "do not take Metoclopramide tablets if").

Taking other medicines:
Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.
The effects of these medicines may change, especially if you are taking:
- Levodopa or other medicines used treat Parkinson's disease (see above "do not take Metoclopramide tablets if")
- Anti-cholinergic 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 (medicines used to treat heart failure)
- Cyclosporine (medicines used to treat certain problems with immune system)
- Medicines used for short-term muscle relaxation in anaesthesia (e.g. Suxamethonium, Mivacurium)
- Fluoxetine and paroxetine (medicine used to treat depression).

Metoclopramide Tablets with Alcohol
Alcohol should not be consumed during treatment with Metoclopramide because it increases the sedative effect of Metoclopramide Tablets.

Pregnancy and Breast-feeding:
Pregnancy
If you are a pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advise before taking this medicine.
If necessary Metoclopramide tablets may be taken during pregnancy. Your doctor will decide whether or not you should be given this medicine.

Breast-feeding:
Metoclopramide tablets are 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 moments and unusual muscle tone causing distortion on the body after taking Metoclopramide tablets. This may affect your vision and also interfere with your ability to drive and use machines.

Important information about some of the ingredients of Metoclopramide Tablets:
This medicine also contains lactose. If you have been told by your doctor that you are intolerant to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE METOCLOPRAMIDE TABLETS

Always take Metoclopramide Tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Adult population
The recommended single dose is 10mg, repeated up to three times a day.
The maximum recommended dose per day is 30mg or 0.5mg/kg body weight.
The maximum recommended treatment duration is 5 days.

Use in Children and adolescents
Metoclopramide must not be used in children age less than 1 year (see section 2).
To prevent delayed nausea and vomiting that may occur after chemotherapy (children aged 1-18 years).
The recommended dose is 0.1 to 0.15mg/kg body weight, repeated up to 3 times daily, taken by mouth (oral route).
The maximum dose in 24 hours is 0.5mg/kg body weight.

Dosing table

Age	Body weight	Dose	Frequency
1-3 years	10-14 kg	1mg	up to 3 times a day
3-5 years	15-19 kg	2mg	up to 3 times a day
5-9 years	20-29 kg	2.5mg	up to 3 times a day
9-18 years	30-60 kg	5mg	up to 3 times a day
15-18 years	Over 60 kg	10mg	up to 3 times a day

You should not take this medicine for more than 5 days to prevent delayed nausea and vomiting that may occur after chemotherapy.
Metoclopramide tablets are not suitable for use in children weight less than 61kg.
Other pharmaceutical forms/strengths may be more appropriate for administration.

Method of administration:
For oral use, to be swallowed with some water. You must wait at least 6 hours between each dose even in case of vomiting and rejection of the dose, in order to avoid overdose.

Elderly
The dose may be needed to be reduced depending on kidney problems, liver problems and overall health.

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

If you take more Metoclopramide Tablets than you should:
Contact your doctor or pharmacist straight away. You may experience uncontrolled moments (extrapyramidal disorders), feel drowsy, have some troubles of consciousness, be confused, have hallucination and heart problems. Your doctor may prescribe you treatment for these signs if necessary.

If you forget to take your Metoclopramide Tablets:
Do not take double dose to make up for forgotten dose. You may have further questions on the use of this medicine, ask your doctor, nurse or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines this medicine can cause side effects, although not everybody gets them.
Stop treatment and talk straight away to your doctor, pharmacist or nurse if you experience one of the following signs while having this medicine.
- Uncontrolled movements (often involving head or neck) such as tics, shaking, twisting movements or muscle contracture (stiffness, rigidity). These may occur in children or young adults and particularly when high doses are used. These signs usually occur at beginning of treatment and may even occur after one single administration. These movements will stop when treated appropriately.
- High fever, high blood pressure, convulsions, sweating, production of saliva. These may be signs of a condition called neuroleptic malignant syndrome.
- Itching or skin rashes, swelling of the face, lips or throat, difficulty in breathing. These may be signs of an allergic reaction, which may be severe.
- Signs of severe allergic reaction (particularly with intravenous route).
- Convulsions (fits).

The other side effects are

Very common (may affect more than 1 in 10 people)
- Feeling drowsy.

Common (may affect up to 1 in 10 people)
- Depression
- Symptoms similar to Parkinson disease (rigidity, tremor)
- Feel restless
- Blood pressure decrease (particularly with intravenous route)
- Diarrhoea
- Feeling weak.

Uncommon (may affect up to 1 in 100 people)
- Irregular periods
- Hallucination
- Decreased level of consciousness
- Slow heartbeat (particularly with intravenous route)
- Visual disturbances and involuntary deviation of eye ball
- Raised levels of a hormone called prolactin in the blood which may cause: milk production in men, and women who are not breast-feeding.

Rare (may affect up to 1 in 1,000 people)
- Confusional state.

Not known (frequency cannot be estimated from the available data)
- Abnormal blood pigment level: 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 heartbeat, which may be shown on an ECG test
- Cardiac arrest (particularly with injection route)
- Shock (severe decrease of heart pressure) (particularly with injection route)
- Fainting (particularly with intravenous route)
- Very high blood pressure
- Sudden increase in blood pressure in patients with tumour of adrenal gland (pheochromocytoma).

Reporting side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the leaflet. You can also report side effects directly via Yellow card scheme Website:www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App store.
By reporting side effects you can help provide more information on safety of this medicine.

5. HOW TO STORE METOCLOPRAMIDE TABLETS

Keep this medicine out of the sight and reach of children.
Do not use Metoclopramide Tablets after the expiry date which is stated on the box. If your tablets are out of date, take them to your pharmacist who will get rid of them safely.
Do not store above 25°C. Store in the original package.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

Each Metoclopramide Tablet contains 10mg of the active substance Metoclopramide hydrochloride.

Metoclopramide Tablets also contains lactose, maize starch, povidone, colloidal silicon dioxide, industrial methylated spirits and magnesium stearate.

What Metoclopramide Tablets look like and contents of the pack:
Metoclopramide Tablets are small, round, white uncoated tablets marked with side one embossed "a" and "M /10" on either side of the breakline.
They are packed in plastic securitainers with child-proof lids of 21, 28, 56, 84, 100, 112 and 500 tablets. Also available in blister packs of 28 tablets.

Not all packs size may be marketed.

Marketing Authorisation Holder and Manufacturer:
Relonchem Limited, Cheshire House,
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PL 20395/0131

Date of Issue: December 2020.

320 mm

170 mm

170 mm

ARTWORK LEGEND

Relonchem Bell's Healthcare

VERSION	0.7 XXXXXXX	DATE	04.12.2020
PRODUCT NAME	Metoclopramide 10 mg Tablets		
PRODUCT LICENCE NO.	20395-0131		
COMPONENT	Pil	COUNTRY	UK (English)
DIMENSION	170 x 320 mm	MANUFACTURER	Adobe illustrator CC
STRENGTH	10 mg	SOFTWARE	
PACK SIZE	-	ARTIST	
FONT & SIZE	Humanst 521 Bt (11 pt, 9 pt)		
REMARKS	-		
REASON FOR CHANGE			

NO. OF COLORS 01

- Black
- Dieline