5 How to store Metoclopramide tablets

Keep out of the sight and reach of children.
Store below 25ºC in a dry place and protected from light.
Do not use Metoclopramide tablets after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.
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 to protect the environment.

6 Contents of the pack and other information

What Metoclopramide tablets contain

- The active substance (the ingredient that makes the tablet work) is 10.54mg of metoclopramide hydrochloride monohydrate, which is equivalent to 10mg of metoclopramide hydrochloride.
- The other ingredients are colloidal silica, lactose monohydrate, magnesium stearate, maize starch, microcrystalline cellulose (E460).

What Metoclopramide tablets look like and contents of the pack

Metoclopramide tablets are white, circular, biconvex uncoated tablets, impressed 'C' on one face and the identifying letters 'M' and 'P' on either side of a central division line on the reverse.
The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Pack size is 28 tablets.

Marketing Authorisation Holder and Manufacturer

Accord, Barnstaple, EX32 8NS, UK

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If you require a leaflet with larger text, please contact 01271 385257.

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Package leaflet: Information for the patient

Metoclopramide 10mg Tablets

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1 What Metoclopramide tablets are and what they are used for

Metoclopramide tablets are an antiemetic. It works on a part of your brain that prevents you from feeling sick (nausea) or being sick (vomiting).

Adults

Metoclopramide tablets are 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 a migraine. Metoclopramide can be taken with oral painkillers in case of migraine to help painkillers work more effectively.

Children and adolescents

Metoclopramide tablets are indicated in children (aged 15-18 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)
- 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)
- have ever had **involuntary muscle spasms** (tardive dyskinesia), when you have been treated with a medicine
- have **epilepsy**
- have **Parkinson's disease**
- are taking **levodopa** (a medicine for Parkinson's disease) or dopaminergic agonists (see below "Other medicines and Metoclopramide tablets")
- have had **gastrointestinal surgery** in the last 3-4 days
- have ever had **abnormal blood pigment level** (methaemoglobinaemia) or **NADH cytochrome b5 deficiency.**

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

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Metoclopramide tablets if you:

- have a history of **abnormal heartbeats** (QT interval prolongation) or any other **heart problems**
- have problems with the levels of **salts in your blood**, such as potassium, sodium and magnesium

- are using other **medicines known to affect the way your heart beats**
- have any neurological (**brain**) problems
- have **liver** or **kidney** problems. The dose may be reduced (see section 3)
- have a history of **atopy** (including asthma) or **porphyria**.

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

Do not exceed a 3-month treatment because of the risk of involuntary muscle spasms.

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 take Metoclopramide tablets").

Other medicines and Metoclopramide tablets
Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines. This is because some medicines can affect the way Metoclopramide tablets work or Metoclopramide tablets can affect how other medicines work. These medicines include the following:
- levodopa or other medicines used to treat Parkinson's disease (see above "Do not take Metoclopramide tablets")
- anticholinergics (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)
- ciclosporin (medicine used to treat certain problems with the immune system)
- mivacurium and suxamethonium (medicines used to relax muscles)
- atovaquone
- fluoxetine and paroxetine (medicines 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
If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice 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.

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 movements and unusual muscle tone, causing distortion of the body after taking Metoclopramide tablets. This may affect your vision and also interfere with your ability to drive and use machines.

Metoclopramide tablets contain lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3 How to take Metoclopramide tablets

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

Adults
The recommended single dose is 10mg, repeated up to three times daily.

The maximum recommended dose per day is 30mg or 0.5mg/kg body weight.

The maximum recommended treatment duration is 5 days.

Children and Adolescents
To prevent delayed nausea and vomiting that may occur after chemotherapy (children aged 15-18 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.

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 weighing less than 61kg.

Other pharmaceutical forms/strengths may be more appropriate for administration.

Method of administration
The score line is only there to help you break the tablet if you have difficulty swallowing it whole.
You must wait at least 6 hours between each metoclopramide dose, even in case of vomiting and rejection of the dose, in order to avoid overdose.

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

Adults with kidney problems
Talk to your doctor if you have kidney problems. The dose should be reduced if you have moderate or severe kidney problems.

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

Children and adolescents
Metoclopramide must not be used in children below 1 year of age (see section 2 "Children and Adolescents").

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

If you forget to take Metoclopramide tablets
Do not take a double dose to make up for a forgotten dose.

If you have any 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 the treatment and talk straight away to your doctor, pharmacist or nurse if you experience one of the following signs while taking this medicine:
- 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
- high fever, high blood pressure, convulsions, sweating, overproduction 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.

Other side effects:
Very common (may affect more than 1 in 10 people)
- feeling drowsy.

Common (may affect up to 1 in 10 people)
- depression
- uncontrollable movements such as tics, shaking, twisting movements or muscle contracture (stiffness, rigidity)
- symptoms similar to Parkinson's disease (rigidity, tremor)
- feel restless
- blood pressure decrease (particularly with intravenous route)
- diarrhoea
- feeling weak.

Uncommon (may affect up to 1 in 100 people)
- 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
- hallucinations
- decreased level of consciousness
- slow heartbeat (particularly with intravenous route)
- allergy
- visual disturbances and involuntary deviation of the eyeball.

Rare (may affect up to 1 in 1,000 people)
- confusional state
- convulsion (especially in patients with epilepsy).

Not known (frequency cannot be estimated from the available data)
- 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)
- shock (severe decrease of heart pressure) (particularly with injection route)
- fainting (particularly with intravenous route)
- very high blood pressure.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: 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 the safety of this medicine.