PACKAGE LEAFLET: INFORMATION FOR THE USER
Metoclopramide Hydrochloride 10 mg tablets
(Metoclopramide Hydrochloride)

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 Hydrochloride tablets is and what it is used for

Metoclopramide Hydrochlride is an antiemetic. It contains a medicine called "metoclopramide". It works on a part of your brain that prevents you from feeling sick (nausea) or being sick (vomiting).

Adult population:

Metoclopramide Hydrochloride is 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.

Paediatric population

Metoclopramide Hydrochloride is 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 Hydrochloride tablets

Do not take Metoclopramide Hydrochloride tablets:

- if you are allergic (hypersensitive) to metoclopramide or any of the other ingredients of this medicine (listed in section 6)
- if you have bleeding, obstruction or a tear in your stomach or gut.
- if you have or may have a rare tumour of the adrenal gland, which sits near the kidney (pheochromocytoma).
- if you have ever had involuntary muscle spasms (tardive dyskinesia), when you have been treated with a medicine.
- if you have epilepsy

- if you have Parkinson's disease
- if you are taking levodopa (a medicine for Parkinson's disease) or dopaminergic agonists (see below "Other medicines and **Metoclopramide Hydrochloride tablets**")
- if you have ever had an abnormal blood pigment levels (methaemoglobinemia) or NADH cytochrome-b5 deficiency

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

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking **Metoclopramide Hydrochloride tablets** if:

- you have a history of abnormal heart beats (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 heart beats
- 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 tests to check your blood pigment levels. In cases of abnormal levels (methaemoglobinemia), 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 the dose, in order to avoid overdose.

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 Hydrochloride tablets if").

Other medicines and Metoclopramide Hydrochloride 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 Hydrochloride tablets works or Metoclopramide Hydrochloride 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 Hydrochloride tablets if")
- 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)
- cyclosporine (medicine used to treat certain problems with the immune system)
- mivacurium and suxamethonium (medicines used to relax muscles)
- fluoxetine and paroxetine (medicine used to treat depression)

Metoclopramide Hydrochloride tablets with alcohol
Alcohol should not be consumed during treatment with metoclopramide because it increases the sedative effect of Metoclopramide Hydrochloride tablets.

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

Trade Metoclopramide Hydrochloride tablets name is 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 Hydrochloride tablets. This may affect your vision and also interfere with your ability to drive and use machines.

Metoclopramide Hydrochloride tablets contains 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 Hydrochloride 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.

Adult population:
The recommended single dose is 10 mg, repeated up to three times daily.

The maximum recommended dose per day is 30 mg or 0.5 mg/kg body weight.
The maximum recommended treatment duration is 5 days.
To prevent delayed nausea and vomiting that may occur after chemotherapy (children aged 1-18 years)
The recommended dose is 0.1 to 0.15 mg/kg body weight, repeated up to 3 times daily, taken by Mouth.
The maximum dose in 24 hours is 0.5 mg/kg body weight.

Dosing table

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

Device / instruction for use
You should not take this medicine for more than 5 days to prevent delayed nausea and vomiting that may occur after chemotherapy.

Metoclopramide Hydrochloride tablets is not suitable for use in children weighing less than 30 kg. Other pharmaceutical forms/strengths may be more appropriate for administration

Method of administration
Swallow the tablet with glass of water.

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.

Older people
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 aged less than 1 year (see section 2).

If you take more Metoclopramide Hydrochloride 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 hallucination and heart problems. You doctor may prescribe you a treatment for these signs if necessary.

If you forget to take Metoclopramide Hydrochloride 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, Metoclopramide Hydrochloride tablets 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 having 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, 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.

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 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
• hallucination
• decreased level of consciousness
• slow heartbeat (particularly with intravenous route)
• allergy
• Visual disturbances and involuntary deviation of the eye ball

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
• high fever, high blood pressure, convulsions, sweating, production of saliva. These may be signs of a condition called neuroleptic malignant syndrome
• 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)
• allergic reaction which may be severe (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.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Metoclopramide Hydrochloride tablets

Keep this medicine out of the sight and reach of children.
- Store below 30 °C.
- Do not use this medicine after the expiry date which is stated on the strips and carton after 'EXP'. 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 no longeruse. These measures will help to protect the environment.

6. Contents of the pack and other information

What Metoclopramide Hydrochloride tablets contains
The name of your medicine is Metoclopramide Hydrochloride tablets, and the active substance is metoclopramide hydrochloride.
Metoclopramide Hydrochloride tablets contain 10 mg metoclopramide hydrochloride.
The tablets contain the following non-active ingredients:
Lactose monohydrate, pre-gelatinised starch, maize starch, anhydrous colloidal silica, magnesium stearate.

What Metoclopramide Hydrochloride tablets looks like and contents of the pack
White to off-white, round, biconvex tablets with the inscription 'BD' on one side and a score line on the other side.
The tablet can be divided into equal halves.

The tablets are packaged in PVC/PVdC/aluminium blister strips.
The carton contains 20, 24, 28, 30, 40, 50, 60, 84, 100, 500 tablets.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
Accord Healthcare Limited,
Sage House, 319 Pinner Road, North Harrow,
Middlesex HA1 4HF, United Kingdom

Manufacturer
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This medicinal product is authorised in the Member States of the EEA under the following names:

Name of the Member State	Name of the medicinal product
Cyprus	Metoclopramide Accord 10 mg tablety
Spain	Metoclopramide Accord 10 mg comprimidos
Italy	Metoclopramide Accord
The Netherlands	Metoclopramidemonohydrochloride Accord 10 mg Tabletten
Malta	Metoclopramide10 mg tablets
United Kingdom	Metoclopramide Hydrochloride 10 mg tablets
Austria	Metoclopramid hydrochloride Accord 10 mg Tabletten
Denmark	Metoclopramide hydrochloride Accord
Estonia	Metoclopramide Accord
Finland	Metoclopramide Accord 10 mg tabletti
Ireland	Metoclopramide Hydrochloride 10 mg tablets
Norway	Metoclopramide Accord
Poland	Olamide
Sweden	Metoclopramide Accord 10 mg tabletter

This leaflet was last approved in 10/2019.