Metoclopramide 10mg tablets

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Metoclopramide tablets if you:
• have a history of abnormal heart beats (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).

Blood tests
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.

Do not exceed 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 if").

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 if")
• antihistamines (medicines used to relieve rhinitis, allergic reactions or hives)
• antispasmodics (medicines used to relax the smooth muscles of the gut or bladder)
• anticonvulsants (medicines used to treat epilepsy or other types of seizures)
• ciclosporin (medicine used to treat certain problems with the immune system)
• minocycline and saframycin (medicines used to treat infections)
• 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, 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 being given 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.

Further information
• If you think 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 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 dopamine agonists (see below "Other medicines and Metoclopramide tablets")
• you have ever had an abnormal blood pigment levels (methaemoglobinemia) or NADH-cytochromeB5 Deficiency.

Do not give Metoclopramide tablets to a child less than 1 year of age (see below "Children and adolescents").
Sugar intolerance
If you have been told you have an intolerance to some sugars, contact your doctor before taking this medicine, as it contains a type of sugar called lactose.

3 How to take

Adults
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.

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 0.15 mg/kg body weight, repeated up to 3 times daily, taken by mouth (oral route).
The maximum dose in 24 hours is 0.5 mg/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 61 kg.
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.

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 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. 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 having this medicine:

• uncontrollable movements (often involving head or neck). These may occur after one single administration. These movements will stop when treatment is stopped. Some may be signs of a condition called neuroleptic malignant syndrome.

Very common
• feeling drowsy

Common
• feeling tired
• changes in heart beat, which may be shown on an ECG test
• confusional state
• feeling weak

Uncommon
• blood pressure decrease (particularly with intravenous route)
• hallucination
• slowed level of consciousness
• slow heartbeat (particularly with intravenous route)
• allergy

Rare
• feeling very drowsy
• convulsion (especially in patients with epilepsy)

Abnormal development of breasts (gynaecomastia)
Abnormal blood pigment levels which may change the colour of your skin
Change in body weight
Increased or decreased levels of coughing
Increased or decreased levels of salivation
Abnormal development of breasts
Abnormal development of breasts
Abnormal development of breasts

5 How to store

Keep out of the sight and reach of children.
Store below 25°C in a dry place and protected from light.

Do not store above 25°C.

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

6 Further information

What Metoclopramide tablets contain

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

What Metoclopramide tablets look like and contents of the pack

Metoclopramide tablets are white uncoated tablets.

Pack sizes are 28 tablets.

Marketing Authorisation Holder and manufacturer
Accord Barm staple, UK

Date of last revision: June 2019