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 use Metoclopramide 5 mg/ml Injection if")

Other medicines and Metoclopramide 5 mg/ml injection:

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines. This is because some medicines may interact with the way Metoclopramide 5 mg/ml Injection works or Metoclopramide 5 mg/ml injection 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 use Metoclopramide 5 mg/ml Injection if")
- anticholinergics (medicines used to relax stomach and intestines)
- morphine derivatives (medicines used to treat severe pain)
- sedative medicines
- any medicines used to treat mental health problems
- dioxin (medicine used to treat heart failure)
- cyclosporine (medicine used to treat certain problems with the immune system)
- mivacurium and somatostatin (medicines used to relax muscles)
- fluoxetine and paroxetine (medicines used to treat depression)

Metoclopramide 5 mg/ml Injection with alcohol

Alcohol should not be consumed during treatment with Metoclopramide 5 mg/ml Injection. It increases the sedative effect of Metoclopramide 5 mg/ml Injection.

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 being given this medicine. If necessary, Metoclopramide 5 mg/ml injection may be given during pregnancy. Your doctor will decide whether or not you should be given this medicine.

Metoclopramide 5 mg/ml Injection 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 uncontrolled twitching, jerking or writhing movements and unusual muscle tone causing disturbance of the body after using Metoclopramide 5 mg/ml Injection. This may affect your driving and also interfere with your ability to drive and use machines.

3. How to use Metoclopramide 5 mg/ml Injection

The medicine will normally be given to you by a doctor or a nurse. It will be given as a slow injection (over at least 3 minutes) by injection into a muscle.

In adult patients:

For the treatment of nausea and vomiting including nausea and vomiting which may occur with a migraine and for the prevention of nausea and vomiting caused by radiotherapy:

- the treatment is repeated 3 times daily. The maximum recommended dose per day is 30 mg or 0.5 mg/kg body weight.
For the prevention of nausea and vomiting that may occur after surgery: a single dose of 10 mg is recommended.

Table 1: Concentration

<table>
<thead>
<tr>
<th>Age</th>
<th>Body Weight</th>
<th>Dose</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>3-5 years</td>
<td>15-19 kg</td>
<td>2 mg</td>
<td>Up to 3 times daily</td>
</tr>
<tr>
<td>5-9 years</td>
<td>20-29 kg</td>
<td>2.5 mg</td>
<td>Up to 3 times daily</td>
</tr>
<tr>
<td>9-15 years</td>
<td>30-49 kg</td>
<td>5 mg</td>
<td>Up to 3 times daily</td>
</tr>
<tr>
<td>15-18 years</td>
<td>Over 60 kg</td>
<td>10 mg</td>
<td>Up to 3 times daily</td>
</tr>
</tbody>
</table>

The treatment should not exceed 48 hours for treatment of nausea and vomiting that has occurred after surgery.

The treatment should not exceed 5 days for prevention of delayed nausea and vomiting that may occur after chemotherapy.

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 4.4).

If you receive more Metoclopramide 5 mg/ml Injection than you should

Contact your doctor or pharmacist straight away. You may experience uncontrollable movements (extrapyramidal disorders), feel dizzy, have a reduced level of awareness, be confused, have hallucinations and cardio-respiratory arrest (your heart and breathing stop).

Your doctor may prescribe you a treatment for these if necessary.

If you forget to use Metoclopramide 5 mg/ml Injection:

Do not have 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 any 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.
- very 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)

- dryness.
- depression.
- uncontrollable movements such as tics, shaking, twisting movements or muscle contraction (stiffness, rigidity)
- symptoms similar to Parkinson's disease (rigidity, tremor)
- feeling 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 in women who are not breast-feeding.
- irregular periods.
- hallucination.
- decreased level of consciousness.
- slow heartbeat (particularly with intravenous route)
- allergy.
- Rare (may affect up to 1 in 1000 people)

- diarrhoea.
- infection.
- 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 neurological malignant syndrome.
- changes in heart beat, which may be shown on an ECG test.
- cardiac arrest (particularly with the injectable route).
- shock (severe decrease of heart pressure) (particularly with the injectable route).
- fainting (particularly with the intravenous route).
- allergic reaction which may be severe (particularly with the intravenous route).
- very high blood pressure.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any side effects listed in the leaflet.

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 - website: www.mhra.gov.uk/yellowcard. Alternatively you can call Freefone 0800 100 3352 (available from 10 a.m. to 2 p.m. Monday to Friday) or fill in a paper form available from your local pharmacy. By reporting side effects you can help to provide more information on the safety of this medicine.

5. How to store Metoclopramide 5 mg/ml Injection

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label/carton after “EXP:”.

Your injection will be stored at less than 25°C and protected from light.

6. Contents of the pack and other information

What Metoclopramide 5 mg/ml Injection contains:

This injection contains the active ingredient metoclopramide hydrochloride. Each 1 ml of solution contains metoclopramide hydrochloride equivalent to 5 mg of anhydrous metoclopramide hydrochloride in a sterile solution for injection.

This injection contains the following inactive ingredients: sodium chloride, citric acid, sodium citrate, hydrochloric acid, sodium hydroxide, nitrogen and starch water for injections.

What Metoclopramide 5 mg/ml Injection looks like and contents of the pack:

The injection is supplied in 2 ml, 10 ml and 20 ml clear glass ampoules. 10 ampoules supplied in each can with each can size being sizes may be limited.

The marketing authorisation number of this medicine is: PL 01502/0044

Marketing Authorisation Holder:

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United Kingdom

Manufacturers:

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For any information about this medicine, please contact the Marketing Authorisation Holder.

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