Package leaflet: Information for the user

Metoclopramide hydrochloride 5 mg/ml solution for injection
metoclopramide hydrochloride

Read all of this leaflet carefully before you are given 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Metoclopramide hydrochloride is and what it is used for

Metoclopramide hydrochloride is an antiemetic. It contains the active substance metoclopramide. It works on a part of your brain that prevents you from feeling sick (nausea) or being sick (vomiting).

Metoclopramide hydrochloride is used **in adults**:
- to prevent nausea and vomiting that may occur after surgery
- to treat nausea and vomiting including nausea and vomiting which may occur with a migraine
- to prevent nausea and vomiting caused by radiotherapy

Metoclopramide hydrochloride is used **in children and adolescents** (aged 1 – 18 years) only if other treatment does not work or cannot be used:
- to prevent delayed nausea and vomiting that may occur after chemotherapy
- to treat nausea and vomiting that has occurred after surgery

2. What you need to know before you are given Metoclopramide hydrochloride

Metoclopramide hydrochloride must not be given 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 hydrochloride ")
- you have ever had an abnormal blood pigment levels (methaemoglobinemia) or NADH cytochrome- b5 deficiency.
- you suffer from a prolactin-dependent tumor.

Do not give Metoclopramide hydrochloride 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 you are given Metoclopramide hydrochloride 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).
- you take atovaquone (an antimicrobial medicine).

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.

Children and adolescents
Uncontrollable movements (extrapyramidal disorders) may occur in children and adolescents. This medicine must not be used in children below 1 year of age because of the increased risk of the uncontrollable movements (see above "Metoclopramide hydrochloride must not be given if").

Other medicines and Metoclopramide hydrochloride
Tell your doctor, pharmacist or nurse if you are using, have recently used or might use any other medicines. This is because some medicines can affect the way Metoclopramide hydrochloride works or Metoclopramide hydrochloride can affect how other medicines work. These medicines include the following:
- levodopa or other medicines used to treat Parkinson's disease (see above " Metoclopramide hydrochloride must not be given 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 in anaesthesia to relax muscles)
- fluoxetine and paroxetine (medicine used to treat depression)
- atovaquone (an antimicrobial medicine).

Metoclopramide hydrochloride with alcohol
You must not consume alcohol during treatment with metoclopramide because it increases the sedative effect of Metoclopramide hydrochloride.

Pregnancy, breast-feeding
If you are pregnant or breast-feeding, 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 may be used during pregnancy. Your doctor will decide whether or not you should be given this medicine.
Metoclopramide hydrochloride 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 you are given Metoclopramide hydrochloride. This may affect your vision and also interfere with your ability to drive and use machines.

Metoclopramide hydrochloride contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per ampoule, that is to say essentially 'sodium-free'.

3. How Metoclopramide hydrochloride is given

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

Use in adults

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 recommended single dose is 10 mg, repeated up to 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.

Use in children and adolescents aged 1-18 years (all indications)

The recommended dose is 0.1 to 0.15 mg / kg body weight, repeated up to 3 times daily, given by slow injection into a vein.

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
9-15 years	30-60 kg	5 mg	Up to 3 times daily
15-18 years	Over 60 kg	10 mg	Up to 3 times daily

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.

Use in elderly
The dose may need to be reduced depending on kidney problems, liver problems and overall health.

Other pharmaceutical forms may be more appropriate for administration.

Use in 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.

Other pharmaceutical forms may be more appropriate for administration.

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

Other pharmaceutical forms may be more appropriate for administration.

Use in children less than 1 year old
Metoclopramide must not be used in children aged less than 1 year (see section 2).

If you are given more Metoclopramide hydrochloride than you should be
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 miss a dose of Metoclopramide hydrochloride
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 (fits), 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
- trouble of vision and involuntary deviation of the ocular globe

Rare (may affect up to 1 in 1.000 people)
- confusional state
- convulsion (especially in patients with epilepsy)
- abnormal flow of milk from the breasts

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, excessive production of saliva. These may be signs of a condition called neuroleptic malignant syndrome
- 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)
- allergic reaction which may be severe (particularly with intravenous route)
- very high blood pressure
- suicidal ideation

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any side effects not listed in this 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 HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Metoclopramide hydrochloride

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

Keep the ampoules in the pouch or in the commercial packaging (pouch and outer carton) in order to protect from light.

This medicine does not require any special temperature storage conditions.

After first opening:
Use within 2 months if the ampoules are stored without the pouch.

After admixture/dilution: Chemical and physical in-use stability of admixtures with sodium chloride 0.9 %, dextrose 5 %, Ringer's Lactate and 4 % dextrose in 0.18 % sodium chloride are stable for 48 hours at 15-25ºC under artificial light and for 48 hours at 5 (±3)ºC, at a concentration of Metoclopramide hydrochloride 0.1 mg / ml.
From a microbiological point of view, unless the method of opening precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

Do not use this medicine after the expiry date, which is stated on the carton, pouch and ampoule 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 you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Metoclopramide hydrochloride contains

- The active substance is metoclopramide hydrochloride.

Each ml contains metoclopramide hydrochloride monohydrate equivalent to 5 mg metoclopramide hydrochloride.

- The other ingredients are sodium chloride, sodium hydroxide (for pH adjustment), hydrochloric acid (for pH adjustment) and water for injections.

What Metoclopramide hydrochloride looks like and contents of the pack

Metoclopramide hydrochloride 5 mg / ml solution for injection is a clear, colourless, solution for injection.
Polypropylene ampoules containing 2 ml of solution, packed in cartons of 5, 10 (2 x 5), 20 (4 x 5), 50 (10 x 5) or 60 (12 x 5) ampoules.
Each 5 ampoules are overwrapped with a protective pouch.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorization Holder
Noridem Enterprises Ltd.
Evagorou & Makariou,
Mitsi Building 3, Office 115,
Nicosia 1065, Cyprus

Manufacturer
DEMO S.A. PHARMACEUTICAL INDUSTRY
21st Km National Road Athens–Lamia,
14568 Krioneri, Attiki, Greece
T: +30 210 8161802, **F:** +30 2108161587

This medicine is authorised in the Member States of the European Economic Area under the following names:

Cyprus	PRIBEKINET 5 mg / mL Solution for injection
Czech Republic	Metoclopramide Noridem
Germany	Metoclopramidhydrochlorid Noridem 5 mg/ml Injektionslösung
Greece	PRIBEKINET 5 mg / mL Ενέσιμο Διάλυμα
France	METOCLOPRAMIDE NORIDEM 10 mg/2 mL, solution injectable
Hungary	Metoklopramid-hidroklorid Noridem 5 mg/ml oldatos injekció
Poland	Metoclopramidi hydrochloridum Noridem
Slovakia	Metoclopramide Noridem 5 mg/ml injekčný roztok
Spain	Metoclopramida Noridem 5 mg/ml solución inyectable EFG
Romania	Metoclopramid Noridem 5 mg/ml soluție injectabilă
Italy	Metoclopramide cloridrato Noridem 5 mg / ml Soluzione per iniezione
Austria	Metoclopramidhydrochlorid Noridem 5 mg/ml Injektionslösung
Sweden	Metoclopramide Noridem
Denmark	Metoclopramide Noridem
Norway	Metoclopramide Noridem
Finland	Metoclopramide Noridem

Ireland	Metoclopramide hydrochloride 5 mg/ml solution for injection
Netherlands	Metoclopramide HCl Noridem 5 mg/ml-oplossing voor injectie/infusie
Portugal	Metoclopramida Noridem

This leaflet was last revised in 02/2026.

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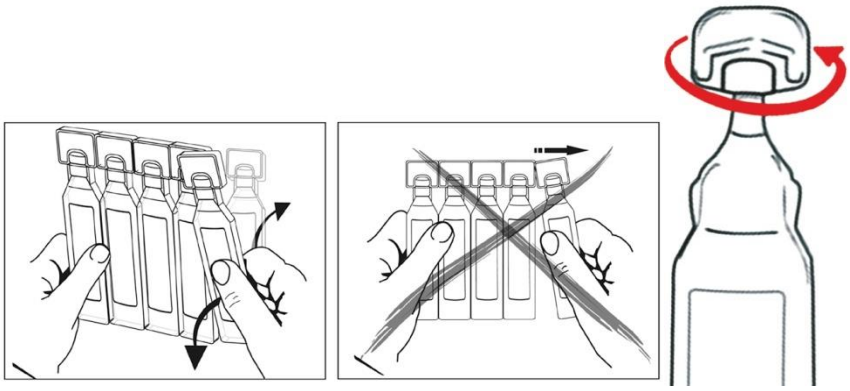
The following information is intended for healthcare professionals only:

Preparation and handling



Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products, except of the following solutions:
- Sodium chloride 0.9 % solution,
- Dextrose 5 %,
- Ringer's Lactate solution,
- 4 % dextrose in 0.18 % sodium chloride

at a final concentration of Metoclopramide hydrochloride 0.1 mg / ml.

Posology and method of administration

<u>All indications (adult patients)</u>
For posology please refer to section 3 of the Package leaflet.
The injectable treatment duration should be as short as possible and transfer to oral or rectal treatment should be made as soon as possible.

<u>Frequency of administration:</u>
A minimal interval of 6 hours between two administrations is to be respected, even in case of vomiting or rejection of the dose.

<u>Special population</u>
Elderly:
In elderly patients a dose reduction should be considered, based on renal and hepatic function and overall frailty.
Renal impairment:
In patients with end stage renal disease (Creatinine clearance < 15 ml / min), the daily dose should be reduced by 75 %.
In patients with moderate to severe renal impairment (Creatinine clearance 15 – 60 ml / min), the dose should be reduced by 50 %.
Hepatic impairment:
In patients with severe hepatic impairment, the dose should be reduced by 50 %.

Other pharmaceutical forms could be more appropriate for the treatment of those populations.
Paediatric population:
Metoclopramide is contraindicated in children aged less than 1 year.

Shelf life

3 years

After admixture/dilution: Chemical and physical in-use stability of admixtures with sodium chloride 0.9 %, dextrose 5 %, Ringer's Lactate and 4 % dextrose in 0.18 % sodium chloride are stable for 48 hours at 15-25oC under artificial light and for 48 hours at 5 (±3)ºC, at a concentration of <Invented name> 0.1 mg / ml.
From a microbiological point of view, unless the method of opening precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

After first opening:
Use within 2 months if the ampoules are stored without the pouch.

Special precautions for storage

Keep the ampoules in the pouch or in the commercial packaging (pouch and outer carton) in order to protect from light.

This medicinal product does not require any special temperature storage conditions.

Disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Overdose

Symptoms
Extrapyramidal disorders, drowsiness, decreased level of consciousness, confusion, hallucination, and cardio-respiratory arrest may occur.

Management
In case of extrapyramidal symptoms related or not to overdose, the treatment is only symptomatic (benzodiazepines in children and/or anticholinergic anti-parkinsonian medicinal products in adults).
A symptomatic treatment and a continuous monitoring of the cardiovascular and respiratory functions should be carried out according to clinical status.