Package leaflet: information for the user

Metoclopramide HCl Noridem 5 mg/ml-solution for injection
metoclopramide hydrochloride monohydrate

Read carefully the entire leaflet before you this medicine receives administered because there is important information in for you.
- Keep this leaflet. Maybe you need it later again needed.
- Do you have questions? Then contact your doctor, pharmacist or nurse.
- Do not give this medicine to others, as it is only to you prescribed. It can be harmful to others ,even if they have the same symptoms as you. Do
- you experience any side effects one of the side effects listed in section 4 are? Or do you get a side effect that is not in this leaflet ? Then contactyour your doctor, pharmacist or nurse.

Contents of this leaflet

1. Noridem and what is it used for is this medicine medicine used?

Metoclopramide HCl Noridem is a medicine against nausea (anti- emetic). Itcontains the active ingredient metoclopramide. It affects influence influence on a part of your brain. It ensures that you do not feel nauseous or do not have to vomit.
This medicine is used in adults:
- to ensure that you do not feel nauseous and do not have to vomit after vomiting n/a a surgery
- for the treatment of nausea being and vomiting. Also if this is caused by very severe headache (migraine).
- to be ensure that you do not nauseous become and do not have to vomit due to radiation

This medicine is in children and adolescents (1 to 18 years) only used if other treatments do not work or cannot be used:
- to ensure care that children and young people no trouble get from later nauseous are and vomiting after chemotherapy
- for the treatment of nauseous being en vomiting after a surgery

2. When may you this medicine not administered receive or must you be extra careful with be?

When may you this medicine not administered receive?

- You are allergic to metoclopramide or one of the other substances in this medicine. These substances can you find in section 6 of this leaflet.
- You have a bleeding, blockage or tear in your stomach of intestines.
- You have or have possibly a rare swelling of the adrenal gland (pheochromocytoma). The adrenal gland is close at your kidney.
- You have ever movements made without that you that yourself wanted during a treatment with a medicine (tardive dyskinesia)
- You have epilepsy
- You have the disease of Parkinson
- You use levodopa or dopaminergic agonists (see below "Used you still other medications?"). Levodopa is a medication that is used in the disease of Parkinson's.
- You have ever one abnormal amount dye in your blood (methemoglobinemia) or NADH-cytochrome-b5- deficiency had.

Do not give this medicine to children than 1 year (see below 'Children and adolescents up to 18 years').

When should you be extra careful with this medicine medicine?
Contact your doctor, pharmacist or nurse before you use this medicine if:

- you have had in the past an irregular heartbeat (extension of the QT interval) or other heart problems has had
- you problems have with the amount salts in your blood. Such as potassium, sodium and magnesium.
- you other medications used that affect have on your heart rate
- you a brain disease have
- you problems have with your liver or kidneys. Your dose will then possibly reduced (see section 3).

Your doctor may your blood test to the amount dye in your blood to check. Is the amount dye in your blood not normal (methemoglobinemia)? Then must the treatment immediately and permanent become discontinued.

Children and adolescents up to 18 years
Children and adolescents up to 18 years may experience suffer from problems with stand, sit and move (extrapyramidal disorders). This medicine must not be used by children younger than 1 year. They have a greater chance of making from movements without that they that themselves want (see above: 'When may you this medicine not administered receive?').
Do you any other medications?
Do you besides Metoclopramide HCl Noridem any other medications, have you that recently done or are you going to do this soon? Inform that then your doctor, pharmacist or nurse. Some medications can affect have on the way in which Metoclopramide HCl Noridem works. Metoclopramide HCl Noridem can also affect have on the way in which other medications work. These medications are:

- levodopa or other medications for the treatment of the disease of Parkinson (see above 'When are you not allowed this medicine not administered receive?')
- medications for the treatment of cramps or spasms in your stomach (anticholinergics)
- strong painkillers (morphine derivatives)

- medicines that make you calm or drowsy (sedatives))
- medications for the treatment of psychological problems
- digoxin (medication for the treatment of heart failure)
- ciclosporin (medication for the treatment of certain diseases of the immune system)
- mivacurium and suxamethonium (muscle relaxants. These medications are used in the anesthetize for a surgery.)
- fluoxetine and paroxetine (medications against depression)

What should you consider with alcohol?
You must not alcohol drink during the treatment with this medicine. Alcohol can cause this medicine to make you even calmer and sleepier makes.

Pregnancy, breastfeeding
Are you pregnant, do you think you are pregnant to be, do you want to become pregnant or are you breastfeeding ? Then contact your healthcare provider? Then contact your doctor or pharmacist before you this medicine use. This medicine can during the pregnancy be used if that necessary is. Your doctor will decide if you this medicine are prescribed or not ..
medicine is not recommended for the giving give of breastfeeding. This medicine passes into the breast milk. This may affect your your baby. Driving ability

and the use of machines You
U can feel drowsy or dizzy after using this medicine . You mayalso experience muscle contractions from this medication . muscles without that you that want, shocking and writhing movements and abnormal tension in your muscles. As a result you can you a abnormal posture of your body get. These complaints can influence have on how well you can see. They can also influence have on how good you vehicles can drive and machines can operate.

This medicine contains sodium
Each ml contains 3.35 mg (0.1455 mmol) sodium.
This medicine contains less than 1 mmol sodium (23 mg) per ampoule, that means that it is in essence ' sodium-free' is.How

3. is this medicine administered ?This

medicine medicine is to you administered by a doctor or nurse. It is administered as a slow injection into a vein (at least 3 minutes) of a injection in a muscle.

Use in adults
For the treatment of nausea and vomiting ,also also throughout severe headache (migraine), and to ensure that you do not feel nauseous become and do not have to vomit due to radiation : the: the recommended dose per time is 10 mg, up to 3 times per day repeated.

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

To to ensure that you do not become nauseous and do not have to vomit after an operation : therecommended dose is 1 dose of 10 mg. of 10 mg.

Use in children and adolescents up to 18 years (all indications)

The recommended dose is 0.1 to 0.15 mg/kg body weight, up to 3 times per day repeated, administered via a slow injection into a vein.
The maximum dose in 24 hours is 0.5 mg/kg body weight.

Dosage table

Age	Body weight	Dose	Number times
1-3 years	10-14 kg	1 mg	Up to 3 times per day
3-5 years	15-19 kg	2 mg	Up to 3 times per day
5-9 years	20-29 kg	2.5 mg	Up to 3 times per day
9-15 year	30-60 kg	5 mg	Up to 3 times per day
15-18 year	Above 60 kg	10 mg	Up to 3 times per day

Are you treated for nausea and vomiting after an operation ? Then thetreatment must not exceed 48 hours in duration last.

Is you treated to ensure that you do not suffer from later nausea and vomiting after chemotherapy ? Then the n/a chemotherapy? Then the treatment not longer than 5 days last.

Use in elderly
The dose must possibly be adjusted. This depends on of kidney problems, liver problems and the overall health.

Other pharmaceutical forms are possibly better for administration to this patient group.

Use in adults with kidney problems
Consult with your doctor if you have problems with your kidneys. Do you have moderate to severe problems with your kidneys? Then your dose must be reduced ..

pharmaceutical forms may be better for for administration to this patient group.

Use in adults with liver problems
Consult with your doctor if you have problems with your has. Has you severe problems with your liver? Then must your dose be reduced.

Other pharmaceutical forms are possible better for administration to this patient group.

Use in children younger than 1 year
This medicine may not be used in children younger than 1 year (see section 2).

Have you administered too much of this medicine administered received?

Contact immediately contact with your doctor or pharmacist. You may experience issues with problems with standing, sitting and moving (extrapyramidal disorders), drowsy are, problems with your consciousness, confused are, seeing ,feeling or hearing things that are not there ((hallucinations) and problems with your heart. Your doctor may prescribe treatment treatment for these symptoms if that is necessary.

Have you forgotten to use this medicine?
Do not take a double dose to make up for a missed dose . catch up.

Do you you still other questions about the use of this medicine? Then contact your doctor, nurse or pharmacist.

4. Possible side effects

Like any medicine can also this medicine side effects have. Not everyone experiences them . If.

experience any of the following complaints during the use of this medicine? Then stop the treatment. Contact immediately your doctor, pharmacist or nurse nurse:

- make without without that you that want (often of the head or the neck). This can in children or young adults occur. Especially in use of high dosages. You usually experience at the start of the treatment symptoms from these complaints. You may also after 1 1 already experience symptoms .. These movements will stop with a good treatment.
- high fever, high blood pressure, seizures of epilepsy (convulsions), sweating or excessive production of saliva. These can be symptoms of the neuroleptic malignant syndrome ..
- or skin rash skin rash, swelling of your face, lips or throat or problems with breathing. These can symptoms be of an allergic reaction. This can very are.

Very often (occur in more than 1 in 10 users)drowsy

- are Often (

occurin less than 1 in 10 less than 1 in 10 users)

- depression
- movements make without that you that yourself want. Such as tics, tremors, rotating movements or contractions of muscles (stiff are, rigid are)
- complaints that resemble those of disease of Parkinson (rigid are, trembling)
- restless are
- drop in the blood pressure (especially with administration via a vein)
- diarrhea
- feel weak Sometimes (

occurin less than 1 in 100 users less than 1 in 100 more)

- more prolactin in your blood. Prolactin is a hormone. This can cause production of milk in men and in women women who do not breastfeed ..
- regularly menstruate are see
- things ,feel or hear that are not there ((hallucinations)

- less consciousness
- slow heartbeat (especially with administration via a vein)
- allergy
- problems with vision and rolling eyes of your eyeball without that you that want

Rarely (occur in less than 1 in 1,000 users)confused

- are seizures
- of of epilepsy (convulsions). Especially in patients with epilepsy.

Not known (cannot with the available data not be determined)

- abnormal amount colorant in your blood. This can cause for the discoloration of your skin.
- swelling of the breasts in men (gynecomastia)
- involuntary muscle spasms after long use. Especially in elderly patients.
- high fever, high blood pressure, seizures of epilepsy (convulsions), sweating or excessive production of saliva. These can be symptoms of a disease that neuroleptic malignant syndrome is called.
- changes in your heartbeat. These can you see on your ECG.
- cardiac arrest (especially in administration via injection)
- shock (severe drop in your blood pressure. Especially in administration via injection)
- fainting (especially with administration via a vein)
- allergic reaction that can be severe (especiallywith administration via via a vein)
- whole high blood pressure
- thoughts about suicide

Do you experience side effects ? Then contactyour doctor, pharmacist or nurse . Thisapplies applies also for possible side effects that are not in this leaflet ..

side effects If you experience side effects
, contact your doctor, please contact pharmacist doctor, pharmacist or nurse. This applies also to side effects that are not in this leaflet . Youcan side effects also report report via the Dutch Side effects Center Lareb, website: www.lareb.nl. By reporting side effects to report, you help us gain more information about the safety of this medicine.

5. How to store you this medicine?

Keep out of sight and reach of children ..

ampoules in the pouch and and the box store for protection against light.

For this medicine there are no special storage instructions regarding concerning the temperature.

After first opening:
Within 2 months use if the ampoules without the pouch are stored.

After mixing/dilution: The chemical and physical stability during use of mixtures with sodium chloride 0.9%, dextrose 5%, Ringer's lactate and 4% dextrose in 0.18% sodium chloride are stable for 48 hour at 15-25oC under artificial light and for 48 hours at 5(±3)oC at a concentration of Metoclopramide HCl Noridem 0.1 mg/ml.
Out microbiological point of view must the medicine immediately after opening be used. Except if there no chance is of microbial contamination by the method the hereby is used. If it not immediately is used, are the storage times and conditions during the use the responsibility of the user.

Do not use this medicine after the expiry date . You findit on the sachet and the box the box after EXP. There is a month and a year. The last day of that month is the expiry date.

Do not flush medications through the sink or the toilet and throw them not in the trash. Ask your pharmacist what you should do with medications that you do not more used. If you medications at the correct way dispose are they in the correct way destroyed and do they not into the environment end up.

6. Contents of the package and other information Which substances are in this medicine?

- The active ingredient in this medicine is metoclopramide hydrochloride monohydrate. Each ml of the solution contains 5.27 metoclopramide hydrochloride monohydrate. This is equivalent to 5 mg anhydrous metoclopramide hydrochloride.
- The other ingredients in this medicine are sodium chloride, sodium hydroxide and/or hydrochloric acid and water for injections.

What does Metoclopramide HCl Noridem look like and what is in a package? Metoclopramide hydrochloride 5 mg / ml solution for injection is a clear, colorless solution for injection.
Polypropylene ampoules with therein 2 ml solution. These are packaged in cardboard boxes of 5, 10 (2 x 5), 20 (4 x 5), 50 (10 x 5) or 60 (12 x 5) ampoules.
Every 5 ampoules are packaged in a protective sachet.

It is possible that not all pack sizes in the market are placed.

Holder of the authorization for placing on the market bring en manufacturer
Marketing Authorization Holder:
Noridem Enterprises Limited. Evagorou & Makariou,
Mitsi Building 3, Office 115,
Nicosia 1065, Cyprus

Manufacturer:
DEMO S.A. PHARMACEUTICAL INDUSTRY,
21st km National Road Athens – Lamia,
145 68 Krioneri, Attiki, Greece
T: +30 210 8161802, F: +30 210816158

In the register registered under: RVG 133746

This medicine is registered in member states of the European Economic Area under the following names:

Cyprus	PRIBEKINET 5 mg / mL Solution for injection
Czech Republic	Metoclopramide Noridem
Germany	Metoclopramide hydrochloride Noridem 5 mg/ml Injection solution
Greece	PRIBEKINET 5 mg / mL Injectable Solution
France	METOCLOPRAMIDE NORIDEM 10 mg/2 mL, solution injectable
Hungary	Metoclopramide hydrochloride Noridem 5 mg/ml solution injection
Poland	Metoclopramide hydrochloride Noridem
Slovakia	Metoclopramide Noridem 5 mg/ml injection solution
Spain	Metoclopramide Noridem 5 mg/ml solution injectable EFG
Romania	Metoclopramide Noridem 5 mg/ml solution injectable
Italy	Metoclopramide hydrochloride Noridem 5 mg/ml Solution for injection
Austria	Metoclopramide hydrochloride Noridem 5 mg/ml Injection solution
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 solution for injection
Portugal	Metoclopramide Noridem

This leaflet is for the last approved in December 2024.

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The following information is only intended for professionals in the healthcare:

Preparation and use

Cases of incompatibility

In absence of research on incompatibilities, may this medication not with other medications mixed be, except for the following solutions:

- Sodium chloride 0.9% solution,
- Dextrose 5 %,
- Ringer's lactate solution,
- 4% dextrose in 0.18% sodium chloride
  in a final concentration of Metoclopramide HCl Noridem 0.1 mg/ml.

Dosage and method of administration

All indications (adult patients) Dosage: see section 3 of this leaflet.
The duration of the injectable treatment must as short as possible be held and there must as quickly as possible be switched to an oral or rectal treatment.

Frequency of administration:
Between two administrations a minimum interval of 6 hours must be respected respectedeven in case of outbreaks or rejection rejection of the dose.

Special patient groups
Elderly
In elderly patients a dose reduction should be considered , basedon liver and kidney function kidney function en general weakness.
Renal impairment

In patients with a kidney disease in the end stage (creatinine clearance < 15 ml/min) the daily dose should be be reduced by 75%. with 75%.
In patients with a moderate to severe renal impairment (creatinine clearance 15-60 ml/min) the dose should be reduced reduced with 50%.
Hepatic impairment
In patients with a severe hepatic impairment should the dose be reduced by 50%. Other pharmaceutical forms are possibly more suitable for for the treatment of these patient groups.
Pediatric patients
Metoclopramide is contraindicated in children younger than 1 year.

Removal
All the unused medication or waste material must be destroyed in accordance with local regulations.
Overdose

Symptoms
Extrapyramidal disorders, drowsiness, reduced consciousness, confusion, hallucinations and cardiorespiratory arrest may occur.

Treatment
In case of extrapyramidal symptoms, whether or not related to overdose, is the treatment only symptomatic (benzodiazepines in children and/or anticholinergic antiparkinsonian drugs in adults).
A symptomatic treatment a a continue monitoring of the cardiovascular and respiratory functions should be performed based on the clinical condition ..