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1. WHAT URAPIDIL NORDIC PHARMA, solution for injection IS AND WHAT IT IS USED FOR?

URAPIDIL NORDIC PHARMA, solution for injection belongs to a group of medicines called alpha blockers. This medicine reduces the blood pressure by relaxing the blood vessels wall.

URAPIDIL NORDIC PHARMA, solution for injection is used to treat severe high blood pressure:
- in case of high blood pressure emergency with short term life threatening organ injury;
- during and/or after surgery.

2. BEFORE YOU USE URAPIDIL NORDIC PHARMA, solution for injection

Do not take URAPIDIL NORDIC PHARMA, solution for injection
- If you are allergic (hypersensitive) to urapidil or any of the other ingredients of URAPIDIL NORDIC PHARMA, solution for injection (refer to section 6 – Further information);
- If you have a cardiac abnormality called aortic stenosis or a blood vessels abnormality called cardiac shunt (except the cardiac shunt in people on dialysis).

Take special care with URAPIDIL NORDIC PHARMA, solution for injection
URAPIDIL NORDIC PHARMA, solution for injection should not be used as an emergency treatment of hypertension associated with cerebral stroke. Your doctor will decide to use this medicine in case of short term life-threatening organ injury.

Before using URAPIDIL NORDIC PHARMA, solution for injection, your doctor should check:
- If you have had diarrhoea or vomiting (or any other causes of reduction of the liquids in your body);
- If your amount of sodium in blood is decreased.

Particular groups of patients
- URAPIDIL NORDIC PHARMA, solution for injection can be administrated to children and adolescents under 18 years old.
• For elderly people (over 65 years old), a reduction of the intake might be necessary.
• If you suffer from liver disease (severe liver failure), the dosage should be reduced.
• If you suffer from kidneys disease (renal failure), some tests might be necessary to check your blood circulation.

Using other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Tell your doctor before using this medicine if you are taking any of the following medicines as they may interact with URAPIDIL NORDIC PHARMA, solution for injection and this could alter their effectiveness or make side effects more likely:
• Alphablocking drugs used for urinary problems caused by prostate disease.
• Any medicines to reduce your blood pressure
• Baclofen (used to treat muscle spasms)
• Amifostine (used to treat infections)
• Imipramine (used to treat depressions)
• Neuroleptics
• Corticoids (anti-inflammatory agents, sometimes called ‘steroids’)

Using Urapidil with food and drinks
You should be cautious while drinking alcohol during treatment with URAPIDIL NORDIC PHARMA, it might increase the effect of Urapidil.

Pregnancy
The use of URAPIDIL NORDIC PHARMA, solution for injection during pregnancy is not recommended. There are no adequate data to judge the safety of the use of URAPIDIL NORDIC PHARMA, solution for injection, in pregnant women.
If a hypertension occurs during a pregnancy and needs to be treated with this medicine, the reduction of blood pressure should be gradual and always monitored by a doctor.

Ask your doctor or pharmacist for advice before taking any medicine.

Breast-feeding
There are no data on the passage of urapidil in mother’s milk. For safety reasons, breast-feeding is not advised during treatment with URAPIDIL NORDIC PHARMA, solution for injection.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
The use of URAPIDIL NORDIC PHARMA, solution for injection can affect your ability to drive a car or operate machinery, in particular:
• At the beginning of the treatment or in case of modification of the treatment;
• In association with alcoholised products.

If you feel sick, it is not advised to drive or to use any machines until symptoms disappear.

Important information about some of the ingredients of URAPIDIL NORDIC PHARMA, solution for injection
URAPIDIL NORDIC PHARMA, solution for injection contains propylene glycol. This ingredient can cause symptoms similar to alcohol.

3. HOW TO USE URAPIDIL NORDIC PHARMA, solution for injection?
URAPIDIL NORDIC PHARMA, solution for injection is to be prescribed and administrated by a healthcare professional.

URAPIDIL NORDIC PHARMA, solution injectable
Day90 MRP text, English version 3
Dosage
The doctor will decide the appropriate dosage depending on your health status.

Route of administration
URAPIDIL NORDIC PHARMA, solution for injection is administered intravenously.

Duration of treatment
The duration of treatment of URAPIDIL NORDIC PHARMA, solution for injection should not exceed 7 days.

If you take more URAPIDIL NORDIC PHARMA, solution for injection than you should
The main event in case of overdosage is a sudden fall of the blood pressure that occurs when assuming a standing position (orthostatic hypotension). In that case, lay the patient on the back with the legs raised. If the symptoms remain, contact your doctor immediately.

If you have any further questions about this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS
Like all medicines URAPIDIL NORDIC PHARMA, solution for injection can cause side effects, although not everybody gets them.

The following adverse effects may occur during the treatment. You should tell your doctor who will decide to stop or to continue your treatment.

Uncommon (more than 1 in 1,000 but less than 1 in 100 patients): Nausea; vomiting.

Very rare (less than 1 in 10,000 patients): Reduction of the number of platelets (blood cells in coagulation); skin allergic reactions (itching, unusual redness of the skin, rash).

Unknown frequency (cannot be estimated from the available data): Palpitations; increase or decrease of the cardiac rhythm; feelings of tightness in the chest and breathing difficulties; fatigue; sweating; dizziness; headaches; agitation (feeling emotionally disturbed); prolonged and painful erection; nasal congestion.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE URAPIDIL NORDIC PHARMA solution for injection?
Keep out of reach and sight of children.

No special storage conditions.

Do not use URAPIDIL NORDIC PHARMA, solution for injection after the expiry date which is stated on the carton and the ampoule. The expiry date refers to the last day of that month.

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 is URAPIDIL NORDIC PHARMA, solution for injection contains

The active substance active is:
Urapidil (as urapidil hydrochloride)........................................................................................................5 mg
For 1 ml of solution for injection

One ampoule of 5 ml contains 25 mg of urapidil.
One ampoule of 10 ml contains 50 mg of urapidil.

The other ingredients are:
Propylene glycol, sodium dihydrogen phosphate dihydrate, disodium phosphate dihydrate, diluted hydrochloric acid, sodium hydroxide, water for injection.

What URAPIDIL NORDIC PHARMA, solution for injection looks like and content of the pack
This medicine is a solution for injection in ampoule. A carton contains 5 ampoules.

Marketing Authorisation Holder and Manufacturer

- Marketing Authorisation Holder:
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  Nordic Pharma
  216, Bld. Saint Germain
  75007 Paris

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  3741 LM Baarn

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