

Package leaflet: Information for the user

Natriumklorid Evolan 500 mg capsule, hard

sodium chloride

Read all of this leaflet carefully before you start using 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 any get 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 Natriumklorid Evolan is and what it is used for
2. What you need to know before you use Natriumklorid Evolan
3. How to use Natriumklorid Evolan
4. Possible side effects
5. How to store Natriumklorid Evolan
6. Contents of the pack and other information

1. What Natriumklorid Evolan is and what it is used for

Natriumklorid Evolan contains the salt sodium chloride (common table salt), a substance which is important for the fluid balance. Natriumklorid Evolan is used to treat sodium deficiency caused by, for example, you have a shortened bowel (stoma) or you have a disease called SIADH (overproduction of ADH, Antidiuretic Hormone, which leads to too low concentration of sodium in the blood).

2. What you need to know before you use Natriumklorid Evolan

Do not use Natriumklorid Evolan

- If you are allergic to sodium chloride or to any of the other ingredients of this medicine (listed in section 6).
- if you have severely impaired kidney function
- if you have heart failure, despite treatment
- if you have fluid retention in your body (oedema)
- if you have severely impaired liver function (liver cirrhosis)
- if you have pre-eclampsia

Warning and precautions

Talk to your doctor, pharmacist, or nurse before using Natriumklorid Evolan if any of the following apply to you:

- if you have heart failure
- if you have impaired kidney or liver function
- if you have high blood pressure
- if you are using medicines containing cortisone

Other medicines and Natriumklorid Evolan

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Natriumklorid Evolan may affect or be affected if you use any other of the following:

- medicines for lowering the blood pressure

- medicines containing lithium

Pregnancy, breast-feeding and fertility

No known risks at recommended dose.

Driving and using machines

No effects on the ability to drive and use machines have been demonstrated.

3. How to use Natriumklorid Evolan

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Your dose will be determined by your doctor and will be adjusted to your individual needs.

Adults:

Individual dosing, up to 20 capsules per day divided into several dosage occasions.

The capsules should be swallowed whole with water.

If you have any further questions on the use of this medicines, ask your doctor or pharmacist.

If you use more Natriumklorid Evolan than you should

If you have taken more of this medicine than directed, or if a child accidentally has taken this medicine, contact your doctor or emergency unit for risk assessment and advice.

If you have taken too much Natriumklorid Evolan, you may experience the following: thirst, decreased saliva, swollen tongue, palpitations, drop in blood pressure, fluid retention in the brain or body, headache, restlessness, dizziness, stomach cramps, vomiting and diarrhoea. Coma and respiratory arrest may occur in severe cases.

If you forget to use Natriumklorid Evolan

Do not take a double dose to make up for a forgotten dose.

If you stop taking Natriumklorid Evolan

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects have been reported (frequency cannot be estimated from the available data):
Nausea, vomiting

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly the national reporting system listed in Appendix V. By reporting side effects, you can help to provide more information on the safety of this medicine.

5. How to store Natriumklorid Evolan

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

Do not store above 30°C. Store in the original package in order to protect from moisture.

Do not use this medicine after the expiry date which is stated on the carton and blister 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 Natriumklorid Evolan contains

- The active substance is sodium chloride 500 mg
- The other excipients are magnesium stearate, colloidal anhydrous silica, chlorophyllin copper complex sodium (E141) and gelatin.

What Natriumklorid Evolan looks like and contents of the pack

Green gelatin capsule 19.0 x 6.6 mm.

Aluminum/PVC/PE/PVDC blister: 20, 40, 60, 80, 100, 105, 200, 300, 400, 500 and 1000 capsules.

White plastic jar (HDPE) with a plastic screw cap (PP): 105 and 120 capsules.

Not all pack sizes may be marketed.

Market Authorisation Holder

[To be completed nationally]

Manufacturer

[To be completed nationally]

This leaflet was last revised in

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