

Certified translation from the German language

### Information for the user: information for patients

**Read all of this leaflet carefully before you start taking this medicine, as it contains important information**

- Keep the package leaflet. You may need to read it again later.
- Ask your doctor or pharmacist if you have any further questions.
- This medicine has been prescribed for you personally. Do not pass it on to others. It may harm other people, even if their symptoms are the same as yours.
- 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.

#### ***What is in this patient information leaflet?***

1. What Nitroxolin forte is and what it is used for
2. Before you take Nitroxolin forte
3. How to take Nitroxolin forte
4. Possible side effects
5. How to store Nitroxolin forte
6. Contents of the package and further information

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## **Nitroxolin forte**

Nitroxolin 250 mg  
Soft capsules

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### **1. What Nitroxolin forte is and what it is used for**

Nitroxolin forte is a therapeutic for the urinary tract.

Nitroxolin forte is used in acute and chronic infections of the efferent urinary tract with bacteria and yeast-like fungi sensitive to Nitroxolin and as a precaution in the event of recurrent infections (recurrence prophylaxis).

### **2. Before you take Nitroxolin forte**

#### ***Do not take Nitroxolin forte***

- if you are hypersensitive to Nitroxolin, soy oil, Ponceau 4R (E 124) or one of the other ingredients of the medicine
- if you have severe disorders of the renal and hepatic functions.

#### ***Take special care with Nitroxolin forte***

##### Children and elderly patients

As a result of its dosage, Nitroxolin forte is not intended for children. Preparations with a lower dose are available for this age group.

##### Patients with limited renal function

In the event of a limited renal function (creatinine in serum at 2 mg/100 ml), excretion is delayed, although clinically effective urine levels are achieved. In the event of strong renal insufficiency, excretion of Nitroxolin and thus also clinical effectivity are no longer guaranteed.

### Taking other medicines

Please inform your doctor or pharmacist if you are taking/using other medicines and/or have recently taken/used any other medicines, including medicines obtained without a prescription. Up to now, no interactions of Nitroxolin with other medicines are known.

### Other information

If Nitroxolin forte is taken for a long time, the liver function readings should be checked regularly.

As the active substance is excreted via the urine, intake leads to an unobjectionable yellow coloration of the urine. If the urine leads to discolorations in clothing, these marks can be removed with ordinary washing. As a precaution, clothes made of synthetic fibres should not be worn during treatment with Nitroxolin forte.

### Pregnancy and lactation

As animal data have shown that damage to the nervous system of the unborn child cannot be ruled out with absolute certainty if Nitroxolin forte is taken during pregnancy, you may only take Nitroxolin forte if the doctor treating you considers this to be absolutely necessary weighing up all the risks (following evaluation of the antibiogram).

As no data are available on passage into the mother's milk, you should not use Nitroxolin forte during lactation. The possibility of an influence on the physiological intestinal flora with diarrhoea or settlement of yeast-like fungi in breast-fed babies must be observed.

### Driving and using machines

According to experience up to now, Nitroxolin generally has no influence on the ability to concentrate and react. However, side-effects such as vertigo and insecurity of gait may occur very rarely and may lead to risks when exercising the activities stated

### Nitroxolin forte contains soy oil and Ponceau 4R

In rare cases, soy oil and Ponceau 4R (E 124) may cause severe allergic reactions

## **3. How to take Nitroxolin forte**

Always take Nitroxolin forte exactly according to the instructions from your doctor. Please ask your doctor or pharmacist if you are not quite sure.

### ***Dosage***

If not prescribed differently by your doctor, adults take 1 capsule of Nitroxolin forte 3 x a day. For chronic infections of the urinary tract and in order to avoid relapses (recurrence prophylaxis), daily intake of 1 - 2 capsules of Nitroxolin forte is recommended.

The capsules should be taken with a glass of water about 1 hour before meals. In order to avoid relapses (recurrence prophylaxis), the dose should be taken in the evening as far as possible.

### ***Duration of administration***

The duration of administration is to be based precisely on your doctor's instructions. Do not stop the treatment prematurely if the symptoms of your disorder have improved.

### ***If you take more Nitroxolin forte than you should***

Up to now, no side-effects of excessively high doses have been seen. If you have only slightly overdosed, no specific measures are necessary as a rule. If the overdose is very high, a doctor should be consulted to be on the safe side.

***If you forget to take Nitroxolin forte***

If you have forgotten to take a dose, do not compensate this by taking 2 doses at once, but continue with the dosage scheme up to the time in question.

***If you stop treatment with Nitroxolin forte***

Stopping or interrupting treatment with Nitroxolin forte may lead to a revival of the infection. If you interrupt for longer than one day and the symptoms revive, consult your doctor.

**4. Possible side effects**

Like all medicines, Nitroxolin forte may cause side effects.

Frequencies of side effects are customarily defined in the following categories:

very common: more than 1 in 10 treated persons

common: 1 to 10 in 100 treated persons

uncommon: 1 to 10 in 1,000 treated persons

rare: 1 to 10 in 10,000 treated persons

very rare: < 1 in 10,000 treated persons

unknown: frequency cannot be estimated on the basis of available data

***Possible side effects***

Commonly, gastrointestinal complaints (e.g. nausea, vomiting, diarrhoea) may occur. These phenomena normally recede during the treatment and generally do not require a stoppage of the therapy.

Uncommonly, allergic skin reactions (reddening, itching) may occur; they are either temporary or recede spontaneously after stopping the intake.

Rarely, allergic changes to the blood count (reduction of the number of blood platelets) are observed in the therapy.

Very rarely, neurological side-effects such as fatigue, headaches, vertigo and insecurity of gait may occur.

Note: Rarely, slight excretion of the active substance via sweat may occur. This may lead to an unobjectionable and temporary yellow coloration of the skin, hair and nails. Very rarely, a temporary yellow colouring of the sclera of the eye is possible.

Soy oil and Ponceau 4R (E 124) may cause severe allergic reactions in rare cases.

**Countermeasures**

If you suffer from gastrointestinal complaints at the start of the treatment, Nitroxolin forte can also be taken directly after a meal.

Please talk to your doctor if you have allergic reactions to your skin.

**Reporting 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 to the Federal Institute for Medicines and Medicinal Products, Dept. of Pharmacovigilance, Kurt-Georg-Kiesinger-Allee, D-53175 Bonn, website: [www.bfarm.de](http://www.bfarm.de).

By reporting side effects, you can help provide more information on the safety of this medicine.

**5. How to store Nitroxolin forte**

Do not store above 25°C.

Keep medicines out of the reach and sight of children.



Do not use this medicine after the "Use by" date mentioned on the label and the outer carton. The expiry date refers to the last day on the month.

## **6. Contents of the package and further information**

### ***What Nitroxolin forte contains:***

The active substance is nitroxoline.  
1 soft capsule contains 250 mg of nitroxoline.

Other ingredients are:

Yellow wax, hydrated soy oil (Ph. Eur.), partially hydrated soy oil (DAB), de-oiled phospholipids from soy beans, medium-chain triglycerides, 3-ethoxy-4-hydroxybenzaldehyde, 1-(4-methoxyphenyl)ethanon, gelatine, glycerol, purified water, titanium dioxide (E 171), Ponceau 4R (E 124)

### ***What Nitroxolin forte looks like and contents of the pack:***

Nitroxolin forte is dark red, oblong soft capsules.  
Nitroxolin forte is available in packs of 10, 20, 50 or 100 capsules.  
Possibly, not all package sizes are available.

### ***Sales***

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### ***Market authorisation holder***

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### ***Manufacturer***

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