

Package leaflet: Information for the user

Nieral 116.4 mg tablets

For use in children over 12 years and adults

active substance: pure goldenrod dry extract

Read all of this leaflet carefully before you start taking this medicine because it contains important information.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to your doctor if you do not feel better or if you feel worse.

What is in this leaflet

1. What Nieral 116.4 mg is and what it is used for
2. What you need to know before you take Nieral 116.4 mg
3. How to take Nieral 116.4 mg
4. Possible side effects
5. How to store Nieral 116.4 mg
6. Contents of the pack and other information

1. What Nieral 116.4 mg is and what it is used for

Nieral 116.4 mg is a herbal medicinal product for irrigation (flushing out) of the urinary tract.

Nieral 116.4 mg is used for irrigation (flushing out) in inflammatory disorders of the lower urinary tract, urinary stones and renal gravel; for preventive treatment in urinary stones and renal gravel.

A doctor must be consulted if you experience blood in urine, fever or if symptoms persist for more than 5 days.

You must talk to a doctor if you do not feel better or if you feel worse after 5 days.

2. What you need to know before you take Nieral 116,4 mg

Do not use Nieral 116.4 mg,

- if you are known to be hypersensitive (allergic) to goldenrod, other composite plants or any of the other ingredients of this medicine (listed in section 6.).
- if you have conditions where a reduced fluid intake is recommended, e.g. severe cardiac or renal diseases.

Irrigation therapy must not be performed in patients with oedema (tissue fluid accumulation) as a result of impaired heart or kidney function.

Warnings and precautions

Talk to your doctor or pharmacist before taking Nieral 116.4 mg.

A doctor must be consulted if you experience blood in urine, fever or if symptoms persist for more than 5 days.

Concomitant treatment with synthetic diuretics is not recommended.

Children and adolescents

No adequate studies are available on the use of this medicine in children. It should therefore not be used in children under 12 years.

Other medicines and Nieral 116.4 mg

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

There are no known interactions with other medicines.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Nieral 116.4 mg should not be used during pregnancy or breast-feeding, as there are no adequate studies.

Driving and using machines

No special precautions are required.

3. How to take Nieral 116.4 mg

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Unless otherwise prescribed, adults and children aged 12 years and older take 3 tablets 3 times daily with plenty of water. Care should be taken to ensure adequate hydration.

How long should you take Nieral 116.4 mg?

The duration of use is generally not restricted and depends on the type, severity and course of the disease. Please observe the information given in section 2. "What you need to know before you take Nieral 116.4 mg" and section 4. "Possible side effects".

If you take more Nieral 116.4 mg than you should

Cases of poisoning as a result of preparations made from real goldenrod have not been reported. If excessive amounts of Nieral 116.4 mg are taken, the symptoms described under "side effects" may be intensified. In that case, please contact your doctor. The doctor can decide on any necessary measures.

If you forget to take Nieral 116.4 mg

If you have not taken enough Nieral 116.4 mg or have forgotten to take them, do not take a double dose next time, but continue taking them as prescribed by your doctor or as described in the dosage instructions.

If you stop taking Nieral 116.4 mg

As a rule, Nieral 116.4 mg can be safely discontinued.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Not known: frequency cannot be estimated from the available

- gastro-intestinal complaints (nausea, vomiting, diarrhoea)
- hypersensitivity reactions (itching, rashes)

If side effects occur, the product should be stopped and a doctor consulted. He/she can assess their severity and decide on any further measures that may be required. At the first signs of a hypersensitivity reaction, you must stop taking Nieral 116.4 mg.

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 via *Bundesinstitut für Arzneimittel und Medizinprodukte* (Federal Institute for Drugs and Medical Devices), *Abt. Pharmakovigilanz* (Department of Pharmacovigilance), Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, Website: www.bfarm.de. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nieral 116.4 mg

Keep this medicine out of sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and label after "EXP". The expiry date refers to the last day of that month.

Do not store above 25 °C and store in the original package in order to protect the content from moisture.

Shelf life after opening: 8 weeks.

6. Contents of the pack and other information

What Nieral 116.4 mg contains

1 tablet contains: 116.4 mg dry extract of pure goldenrod (5-7:1), extracting agent: ethanol 60% (v/v).
Nieral 116.4 mg contains less than 0.1 BE per tablet.

The other ingredients are: colloidal anhydrous silica, crospovidone, talc, microcrystalline cellulose.

What Nieral 116.4 mg looks like and contents of the pack

Nieral 116.4 mg is a greenish brown, speckled, round tablet with a characteristic odour in polypropylene plastic containers with closure.

Original packs with 60, 2 x 60 tablets and 120 tablets.

Not all pack sizes may be marketed.

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This leaflet was last revised in Januar 2023.

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