

Package leaflet:
Information for the user



Canephron® N Oral Drops

Active substance:

Extract of a mixture of common centaury, lovage root, rosemary leaves

For use by adolescents from 12 years of age and up, as well as adults.

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without a prescription. In order to achieve the best treatment results, Canephron N Oral Drops must nevertheless be taken as prescribed.

- Keep this leaflet. You may need to read it again.
- Please ask your doctor or pharmacist if you need further information or advice.
- If you do not feel better after about 7 days, or if your symptoms worsen, you must consult a doctor.
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

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1. WHAT CANEPHRON N ORAL DROPS ARE AND WHAT THEY ARE USED FOR

Canephron N Oral Drops are a traditional herbal medicine.

Traditionally used for supportive treatment and to supplement specific measures in case of mild complaints relating to inflammatory diseases of the efferent urinary tract; to flush out the urinary tract in order to prevent the deposition of renal sand.

Note: Canephron N Oral drops is a traditional herbal medicine that is registered based on long-term use for the described indication.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CANEPHRON N ORAL DROPS

DO NOT take Canephron N Oral Drops:

- if you are hypersensitive (allergic) to the active substances, to other Apiaceae (Umbelliferae, e.g. anise, fennel), to anethole (constituent of essential oils of, for example, anise, fennel) or any of the other ingredients of Canephron N Oral Drops listed in section 6.
- if you have stomach ulcers.
- in case of oedemas due to impaired heart or kidney function and/or if a doctor has recommended reduced fluid intake.

Warnings and precautions:

Talk to your doctor or pharmacist before taking Canephron N Oral Drops. If you have persistent fever, cramps, blood in your urine, discomfort when urinating and acute retention of urine, a doctor should be consulted immediately

Children:

Canephron N Oral Drops should not be used to treat children under 12 years of age.

Taking other medicines and Canephron N Oral Drops:

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

There are currently no known interactions with other medicines.

Pregnancy and breast-feeding

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

There have been no or very limited studies on the use of Canephron N by pregnant women to date. Therefore, as a precaution, Canephron N should not be used during pregnancy. It is not known whether Canephron N or its active substances / metabolites are excreted into breast milk. Canephron N should not be used when breast-feeding.

Driving and the ability to operate machinery:

No special precautions are required.

Canephron N Oral Drops contain 19% alcohol by volume!

If the dosage instructions are followed, each dose for adults and adolescents aged 12 and up contains up to 0.75 grams of alcohol.

There is a health risk to the following individuals, amongst others: patients with liver disease, alcoholics, epileptics, patients with organic diseases of the brain, pregnant and breast-feeding women and children under 12 years of age. The effect of other medicines may be impaired or enhanced.

3. HOW TO TAKE CANEPHRON N ORAL DROPS

Always take Canephron N Oral Drops exactly as described in this leaflet. Check with your doctor or pharmacist if you are not sure.

Unless otherwise prescribed by your doctor, take Canephron N Oral Drops 3 times daily using the enclosed measuring cup.

Adolescents aged 12 years and over and adults take 5 ml of liquid 3 times daily. The daily dose is equivalent to 15 ml of liquid.

Method of administration:

Where necessary, Canephron N Oral Drops can be taken at the same time as other fluids.

Shake before use!

Treatment is improved if you drink considerable amounts of fluid.

Length of administration:

The length of administration is not limited in principle, but please note the information under "Special care is required when taking Canephron N Oral Drops".

Talk to your doctor or your pharmacist if you have the impression that the effect of Canephron N Oral Drops is too strong or too weak.

If you take more Canephron N Oral Drops than you should:

If you take more Canephron N Oral Drops than you should, please tell your doctor. He or she can decide on any necessary further measures. It is possible that the side effects listed below will be more intense. No cases of overdose have been reported to date.

If you forget to take Canephron N Oral Drops

If you have taken too few Canephron N Oral Drops or have forgotten a dose, do not take a double dose the next time, but keep taking the medication as prescribed by your doctor or as described in this dosage information.

If you stop taking Canephron N Oral Drops

If you stop taking Canephron N Oral Drops, this is usually harmless.

If you have any further questions about taking 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.

The following categories are used when referring to the frequency of side effects:

Very common:

more than 1 patient in 10

Common:

1 to 10 patients in 100

Uncommon:

1 to 10 patients in 1,000

Rare:

1 to 10 patients in 10,000

Very rare:

less than 1 patient in 10,000

Unknown:

frequency cannot be estimated on the basis of the data available

Significant side effects or symptoms which you should pay attention to and measures to be taken if you are affected:

Gastrointestinal problems (nausea, vomiting, diarrhoea) are **common**.

Allergic reactions can also occur. The frequency is not known.

If side effects occur, you should stop taking the medicine immediately and consult a doctor. He or she can then decide on their severity and any necessary further measures.

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 to the Federal Institute for Drugs and Medical Devices (BfArM), Pharmacovigilance Department, Kurt-Georg-Kiesinger-Allee 3, 53175 Bonn, Germany Web page: www.bfarm.de. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE CANEPHRON N ORAL DROPS

Keep this medicine out of reach of children.

Do not use this medicine after the expiry date which is stated on the label with month/year. The expiry date refers to the last day of that month.

Storage conditions:

Do not store above 25°C.

Shelf life after opening or preparation

Can be used up to 6 months after opening.

6. FURTHER INFORMATION**What Canephron N Oral Drops contain****The active substance is:**

100 ml (= 98 g) of liquid for oral use contains an extract (1: 56) of 1.8 g of a mixture of rosemary leaves, lovage root and common centaury (1:1:1); 1st active ingredient: ethanol 59% (V/V) 2nd-4th active ingredient: purified water.

The other ingredients are:

None

What Canephron N Oral Drops look like and contents of the pack

Yellow-brown liquid for oral use in packs containing 50 ml, 100 ml (N1) and 200 ml (hospital pack of 2 x 100 ml)). Liquid may become slightly cloudy or flocculated during storage.

Not all pack sizes may be available.

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