

Package leaflet:
Information for the user



Canephron® N Coated Tablets

Active substances: common centaury powder, lovage root powder, rosemary leaf powder

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 Coated Tablets must nevertheless be taken as prescribed.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If you do not feel better after about 7 days, or if you feel worse, you must talk to a doctor in any case.
- 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.

In this leaflet:

1. What Canephron N Coated Tablets are and what they are used for
2. What you need to know before you take Canephron N Coated Tablets
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1. What Canephron N Coated Tablets are and what they are used for

Canephron N Coated Tablets are a traditional herbal medicinal product.

Traditionally used for the supportive treatment and for the supplementation of specific measures in case of mild complaints within the framework of inflammatory diseases of the efferent urinary tract; for irrigation of the urinary tract in order to prevent the deposition of renal sand. Note: Canephron N Coated Tablets are a traditional herbal medicinal product that has been registered for the field of application due to long standing application solely.

2. What you need to know before you take Canephron N Coated Tablets

Do not take Canephron N Coated Tablets:

- 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 Coated Tablets listed in section 6.
- if you have stomach ulcers.
- if you have inflammatory kidney diseases and/or impaired kidney function.

Irrigation therapy must not be carried out in case of oedemas due to impaired heart or kidney function.

Warnings and precautions:

Talk to your doctor or pharmacist before taking Canephron N Coated Tablets. 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 Coated Tablets should not be used to treat children under 12 years of age.

Taking other medicines and Canephron N Coated Tablets:

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 have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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 using machines

No special precautions are required.

Canephron N Coated Tablets contain the sugars glucose, sucrose and lactose.

You should therefore take Canephron N Coated Tablets only after consulting your doctor if you know that you have an intolerance to certain sugars.

3. How to take Canephron N Coated Tablets

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

Unless otherwise prescribed by your doctor, the recommended dose is:

Single dose: 2 coated tablets.

Total daily dose: Adolescents aged 12 years and over and adults take 2 coated tablets 3 times daily.

Method of administration:

Canephron N Coated Tablets are best taken whole (unchewed) with some liquid.

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 Coated Tablets“.

Please talk to your doctor or your pharmacist if you have the impression that the effect of Canephron N Coated Tablets is too strong or too weak.

If you take more Canephron N Coated Tablets than you should:

If you take more Canephron N Coated Tablets 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. Until now no cases of overdose have been reported.

If you forget to take Canephron N Coated Tablets

If you have taken too few Canephron N Coated Tablets or have forgotten a dose, do not take a double dose the next time to make up for the forgotten dose, but keep taking the medicine as prescribed by your doctor or as described in this dosage information.

If you stop taking Canephron N Coated Tablets

If you stop taking Canephron N Coated Tablets, this is usually harmless.

If you have any further questions about taking this medication, talk to your doctor or pharmacist.

4. Possible side effects

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

In the evaluation of undesirable effects, the following categories are used:

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:

fewer than 1 patient in 10,000

Unknown:

frequency cannot be estimated on the basis of the data available

Significant side effects or signs you should look out for, as well as measures 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 decide on their severity and any necessary further measures.

Reporting Side Effects

If you notice 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, D-53175 Bonn, 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 Coated Tablets

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

Do not use this medicine after the expiry date which is stated on the container (blister pack) and the folding carton with month/year. The expiry date refers to the last day of that month.

Storage conditions:

Do not store above 30°C.

6. Further information

What Canephron N Coated Tablets contain

The active substances are:

1 coated tablet contains:

Common centaury powder 18 mg

Lovage root powder 18 mg

Rosemary leaf powder 18 mg

The other ingredients are:

calcium carbonate, dextrin, spray-dried glucose syrup, lactose monohydrate, magnesium stearate, corn starch, montan glycol wax, povidone (25, 30), virgin castor oil, sucrose (saccharose), shellac, colloidal anhydrous silica, talc, dyes: iron (III) oxide (E172), riboflavin (E101), titanium dioxide (E171).

Diabetic note:

One Canephron N Coated Tablet contains approximately 0.020 allowable bread units (BU).

What Canephron N Coated Tablets look like and contents of the pack:

orange-coloured coated tablets in packs of 60 (N1), 120 (N2) and 200 (N3) coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

BIONORICA SE

Kerschensteinerstrasse 11-15

92318 Neumarkt, Germany

Telephone +49 (0) 9181 / 231-90

Fax +49 (0) 9181 / 231-265

Internet: www.bionorica.de

Email: info@bionorica.de

Co-distribution:

PLANTAMED Arzneimittel GmbH

Kerschensteinerstraße 11-15

92318 Neumarkt, Germany

Telephone: +49 (0) 9181 / 231-0

Fax: +49 (0) 9181 / 21850

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