Patient Leaflet Information

Canephron®N

Pharmaceutical form:

oral drops and coated tablets

Trade name:

Canephron®N

Composition:

100 g of drops contain: 29 g of aqueous-alcohol extracts from the following vulnerary herbs:

1. Herba Centauri	**0.6 g**
2. Radix Levistici	**0.6 g**
3. Folia Rosmarini	**0.6 g**

Ethanol content: 19 % (by the volume ratio)

Supplemental ingredients: distilled water

One coated tablet contains the powdered raw materials from the following vulnerary herbs:

1. Herba Centauri	**18 mg**
2. Radix Levistici	**18 mg**
3. Folia Rosmarini	**18 mg**

Supplemental ingredients:

Calcium carbonate, dextrin, spray-dried glucose syrup, lactose monohydrate, magnesium stearate, maize starch pre-gelatanized, montan glycol wax, povidone (25, 30), native castor oil, sucrose (saccharose), shellac, highly dispersed silicon dioxide, talc, dyes: iron-(III)-oxide (E172), riboflavin (E101), titanium dioxide (E171).

Description:

Oral drops: clear or slightly cloudy yellow-brown liquid.
Coated tablets: orange, round, biconvex, and smooth surface.

Pharmacological properties:

The ingredients of Canephron N are characterized by diuretic, spasmolytic, anti-inflammatory and antibacterial properties.

Indications for use:

The drug is used in multimodality therapy to treat chronic inflammatory diseases of the urinary bladder (cystitis) and kidney (pyelonephritis), occurrences of chronic non-infectious diseases of the kidney (glomerulonephritis, interstitial nephritis) and to resist the formation of stones in the urinary system (as well as after their removal).

Contraindications:

Hypersensitivity against the active substances or to any of the excipients of the drug.
Active peptic ulcers.

Side effects:

Hypersensitivity / allergic reactions and gastrointestinal disorders (nausea, vomiting, diarrhoea) may occur in very rare cases. In case of first signs of a hypersensitivity /allergic reaction Canephron N must not be taken again.

Use methodology and dosage:

Adults:	50 drops or 2 coated tablets thrice daily.
School age children:	25 drops or 1 coated tablet thrice daily.
Children from 1 year of age:	15 drops thrice daily

After an acute illness, the administration of Canephron N shall be extended for 2-4 weeks.
When necessary, e.g., in order to mitigate a bitter taste for children, drops may be taken in combination with other liquids.
The coated tablets are taken with a small quantity of water without chewing.

Overdose:
No case of overdose has been reported.
Treatment of overdose: In case of overdose, symptomatic treatment should be initiated.

Interaction with other treatment methods:
Combining Canephron N with antibacterial agents is allowed, as well as advisable. The interaction with other medications is unknown.

Pregnancy and lactation period:

There is no evidence for harmful effects during pregnancy and lactation when the recommended dosage is used. However, like any medicines Canephron N should only be used during pregnancy and lactation after risk-benefit evaluation by the attending physician

Specific instructions:

The use of Canephron coated tablets in children under 6 years of age and the use of Canephron N oral drops in children under 1 year of age is not recommended.

Please consult a doctor before use of Canephron N in case of

- impaired renal function.
- inflammatory diseases of the kidneys.
- edema due to impaired heart or kidney function.

In case of blood in urine, micturition disorder and acute urinary retention a physician should be consulted immediately.

Canephron N coated tablets contain glucose, sucrose and lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Canephron N oral drops contain 19 vol% alcohol. Because the drug contains alcohol, the solution cannot be administered to patients suffering from alcoholism, even after successful alcohol abuse treatment. In the case of a liver disease, the solution shall be administered only after a doctor's advice.

It is recommended that a lot of liquid be taken during the period of taking Canephron N.
When using, hold the flask vertically. The liquid of Canephron N may become a little cloudy or may form some sediment. This does not influence the effectiveness of this drug. Shake the flask before use.
The drug does not influence the ability to drive vehicles and operate machinery.

ATC Code

G04BX

For those suffering from diabetes mellitus:

The amount of digestible carbohydrates is approx. 0.02 of "bread units" in each coated tablets.

Packaging:

Coated tablets: blisters with 20 coated tablets in each;
Packaging: 60 and 120 coated tablets;
Oral drops: glass bottle of 100 ml.

Storage conditions:

Keep protected from light and store in a dry place at a temperature not higher than 25°C.

Please keep out of reach of children.

Shelf life:

Oral drops: 24 months.
Coated tablets: 3 years.

6 months after opening the flask.
Do not use the medication after the expiration date indicated on the package!

Dispensing procedure:

Rx. With medical prescription.

Produced by:
BIONORICA SE, D-92308 Neumarkt/Germany