Patient Package Insert in Accordance with the Pharmacists' Regulations (Preparations) -1986
The medicine is sold without a doctor's prescription

Canephron® Coated tablets

Active ingredients and their quantity in a single dosage:
Each coated tablet contains:
Centaury, pulverized 36.0 mg; Lovage root, pulverized 36.0 mg; Rosemary leaf, pulverized 36.0 mg.
For the full list of inactive ingredients and allergens in this medicine - see section 6.
For important information about some of the ingredients of this medicine - see section 2.

Read this entire leaflet carefully before using this medicine.
This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist.
Canephron® coated tablets are intended for adults and children over the age of 12.
Take this medicine according to the instructions in the dosage section of this leaflet.
Refer to a doctor if the signs of the illness (symptoms) worsen or if they do not improve after 3 days of using the medicine.
Consult the pharmacist if you need additional information.

1. What is the medicine intended for?
A herbal medicinal product used for supportive or complementary treatment in cases of mild symptoms caused by a urinary tract infection (such as: frequent urination, a burning sensation while urinating, and needing to urinate frequently) in adults and children over the age of 12.
Therapeutic group: Urologic medicines.

2. Before using the medicine:
Do not use the medicine:

- if you are hypersensitive (allergic) to one or more of the active ingredients or to any of the other ingredients this medicine contains. The list of additional ingredients is detailed in section 6.
- if you are hypersensitive (allergic) to plants of the Apiaceae or Umbellifers group such as: anise seeds, fennel or the ingredient anethole that is derived from essential oils.
- in case of a gastric or duodenal ulcer.
- in case of edema due to impaired heart or kidney function and/or if a doctor has instructed you to drink less fluids.

Special warnings regarding the use of the medicine:
Consult a doctor immediately in any case of persistent fever, lower abdominal pain, cramps, blood in the urine, discomfort when urinating or acute retention of urine.

Children and adolescents: No adequate studies have been conducted to evaluate the use of the medicine in children under 12 years of age. Urinary tract disorders in children require medical supervision (they must be diagnosed, treated, and supervised by a doctor). Therefore, Canephron® is not intended for children under 12 years of age.

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. There are no known interactions between Canephron® and other medicines and no studies have been conducted to evaluate interactions with other medicines.

Use of this medicine and food: Canephron® can be taken with or without food.
For additional information, see section 3 – "How to use this medicine".

Pregnancy, breastfeeding and fertility: If you are pregnant, breastfeeding, think you may be pregnant or are planning to become pregnant, consult a doctor or pharmacist before taking this medicine. Canephron® can be used during pregnancy, subject to the doctor's decision.
Canephron® should not be used when breastfeeding since it is not known whether its active substances or metabolites pass into breast milk.
There is insufficient data regarding the effect of the medicine on human fertility.

Driving and using machines: No studies have been conducted to evaluate the effect of using Canephron® on the ability to drive or use machines.

Important information about some of the ingredients of this medicine:
Canephron® contains sugars of the glucose, sucrose and lactose types.
Consult the doctor before using the medicine Canephron® if you have been told by your doctor that you have an intolerance to certain sugars.
Information for diabetics: one coated tablet of the medicine Canephron® contains an average of approximately 0.3 g of carbohydrates.

3. How to use the medicine?
Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the product.
The usual recommended dosage in adults and children over 12 years of age:
One coated tablet 3 times a day.
There is no data regarding the exact dosage in patients with impaired kidney or liver function.
Do not exceed the recommended dose.

Duration of treatment: The duration of treatment depends on the duration of the illness. Refer to a doctor if the signs of the illness (symptoms) worsen or if they do not improve after 3 days of using the medicine. Do not use the medicine as self-treatment for more than two weeks without consulting a doctor.

Method of administration: Take one coated tablet of the medicine Canephron® 3 times a day (morning, noon and evening). Take the coated tablet with a little liquid (for example, a cup of water).
Be sure to drink plenty of fluids during treatment.

Crushing / halving / chewing: do not crush or chew or halve the coated tablet.

If you have accidentally taken a higher dosage tell your doctor. They will decide if any further action is needed. In case of an overdose, the side effects listed below may be more intense. If a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the medicine package with you.

If you forgot to take the medicine at the designated time, do not take a double dose. Take the next dose at the regular time and consult the pharmacist or doctor.

If you stop taking the medicine: Stopping the treatment is usually harmless.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them. If you have further questions on the use of this medicine, consult the doctor or pharmacist.

4. Side effects

Like any medicine, the use of Canephron® may cause side effects in some users.
Do not be alarmed when reading the list of side effects, you may not suffer from any of them.
If one of the following side effects occurs, stop taking the medicine and consult a doctor as soon as possible. The doctor will determine the severity of the side effects and decide if any further actions are necessary.

Side effects with unknown frequency:
Stop taking this medicine and refer to the doctor or a hospital emergency room immediately upon the appearance of the first sign of hypersensitivity (allergic reaction) such as: Skin rash, itching skin, facial swelling.

Common side effects that appear in 1-10 out of 100 users of the medicine:
Gastrointestinal discomfort such as: Nausea, vomiting, diarrhea.

If a side effect appears, if one of the side effects worsens or if you suffer from a side effect that is not mentioned in this leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health via the link "Report side effects due to medication" which can be found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form of adverse events reporting or via the following link: https://sideeffects.health.gov.il
In addition, side effects can be reported to Dr. Samuelov Importing and Marketing via e-mail: drugsafety@drsamuelov.co.il

5. How to store the medicine?

Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach of children and/or infants to avoid poisoning.
Do not induce vomiting unless explicitly instructed to do so by the doctor.
Do not use the medicine after the expiry date (exp. date) stated on the package or blister.
The expiry date refers to the last day of that month.
Storage conditions: Do not store above 30°C.

6. Additional information

In addition to the active ingredients, this medicine also contains the following inactive ingredients:
Tablet core: lactose monohydrate; maize starch; povidone K 25; silica, colloidal anhydrous; magnesium stearate. Coating: sucrose; talc; calcium carbonate (E-170); dextrin; maize starch; glucose, liquid, spray-dried; titanium dioxide (E-171); shellac; riboflavin (E-101); povidone K 30; montan glycol wax; Iron oxide, red (E-172); castor oil, virgin.

What the medicine looks like and what the package contains: The medicine Canephron® looks like a round coated tablet, biconvex and orange-colored without a score line. The tablet diameter is 10.2-10.6 mm.
The coated tablets are packed in plastic trays (blisters), which are packed in carton boxes.

Package size: The medicine Canephron® is distributed in carton packages containing 2 plastic trays with 15 coated tablets in each one, 30 coated tablets in each package**.**

Registration holder and importer: Dr. Samuelov Importing and Marketing Ltd., Private company number 512260944, P.O. box 2486, Raanana 4365007,
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Drug registration number at the national drug registry at the Ministry of Health: 171-02-36663-00

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