Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

Canephron®
coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 coated tablet contains:

Centaury powder *(Centaurium erythraea* Rafin s.l., herba)	36 mg
Lovage root powder *(Levisticum officinale* Koch, radix)	36 mg
Rosemary leaf powder *(Rosmarinus officinalis* L., folium)	36 mg

Excipients with known effect:

Glucose liquid, spray dried	2.17 mg
Lactose monohydrate	90.00 mg
Saccharose	120.86 mg

For a full list of the excipients see Section 6.1.

3. PHARMACEUTICAL FORM

Coated tablets
The coated tablets are orange, round, biconvex with a smooth surface. The coated tablet has a diameter of 10.2-10.6 mm.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Canephron® is a traditional herbal medicinal product for supportive treatment and as an adjuvant to specific measures in cases of mild complaints (such as frequent urination, burning micturition, and increased urge to urinate) caused by inflammatory diseases of the efferent urinary tract, in adults and children from the age of 12 years.

The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.

4.2 Posology and method of administration

Posology
The usual dose is:
Adults and adolescents from 12 years take 1 coated tablet 3 times a day.

There is insufficient data available for specific dosage recommendations for people with impaired kidney function/liver function.

Children

Canephron® is not indicated for children under 12 years of age.

Method of administration
A single dose of Canephron® should be taken 3 times a day (morning, noon, evening).

Take the coated tablet unchewed – preferably with a little liquid (e.g., a glass of water).

Make sure you drink plenty of fluids.

Duration of administration
The patient is advised in the package leaflet that if symptoms exacerbate or are still present after 3 days, a doctor must be consulted. The medicinal product must not be used longer than 2 weeks in self-medication.

4.3 Contraindications

Hypersensitivity to the active substances, to other apiaceae (umbellifers, e.g. anis, fennel), to anethole (component of essential oils) or to any of the other ingredients listed in section 6.1.

Peptic ulcer

Flushing therapy must not be used in the case of oedema due to impaired heart or kidney function and/or if a reduction of fluid intake has been recommended.

4.4 Special warnings and precautions for use

In case of persistent fever, pain in the lower abdomen, cramps, blood in the urine, discomfort while urinating and acute urinary retention, a doctor should be consulted immediately.

Patients with rare hereditary fructose intolerance, glucose-galactose malabsorption or saccharase-isomaltase deficiency, galactose intolerance or lactase deficiency should not take Canephron®.

Information for diabetics:
One coated tablet contains an average of 0.3 g of available carbohydrates.

Children
There have been insufficient studies on the use of this medicinal product in children under 12 years of age. Disorders affecting the urinary tract in children require medical attention (they have to be diagnosed, treated and supervised by a doctor). Canephron® should therefore not be used to treat children under the age of 12.

4.5 Interactions with other medicinal products and other forms of interaction

There are currently no known interactions with other medicinal products. No clinical studies on interactions with other medicinal products have been performed.

4.6 Fertility, pregnancy and lactation

Pregnancy
Further experience with pregnant women (between 300 and 1000 pregnancy outcomes) does not indicate a risk of malformation or of foetal/neonatal toxicity of Canephron®.

Available animal studies have not provided any evidence of reproductive toxicity (see section 5.3).

The use of Canephron® may be considered during pregnancy, if deemed necessary by the attending physician.

Breast-feeding
It is not known whether Canephron® or its active ingredients/metabolites pass into the breast milk. A risk to the newborn baby/child cannot be excluded. Canephron® should not be used during the lactation period.

Fertility
There is no data available relating to the influence on fertility in humans. No effects on female or male fertility have been observed in animal studies (see section 5.3).

4.7 Effects on ability to drive and use machines

Studies with Canephron® on the ability to drive and use machines have not been carried out.

4.8 Side effects

Gastrointestinal disorders
Common (≥ 1/100 to < 1/10): Gastrointestinal complaints (e.g. nausea, vomiting, diarrhoea)

Immune system disorders
Not known: Hypersensitivity reactions (rash, pruritus, facial oedema).

The patient is informed in the package leaflet that if these or other side effects are observed, the preparation should be discontinued immediately, and a doctor should be consulted.

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form: https://sideeffects.health.gov.il
In addition, suspected adverse events can be reported directly to Dr. Samuelov's drug safety department at: drugsafety@drsamuelov.co.il

4.9 Overdose

No cases of overdose have been reported up to now.
Treatment of overdoses: In case of overdose, symptomatic treatment should be initiated.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Traditional herbal medicinal product

5.2 Pharmacokinetic properties

No pharmacokinetic studies have been performed.

5.3 Preclinical safety data

Based on the conventional studies on safety pharmacology, single and multiple-dose toxicity, genotoxicity, reproductive and developmental toxicity, the non-clinical data does not indicate any particular risks to humans.
Neither in in-vitro-tests (Ames-test) nor in an in-vivo test (micronucleus test in rats) a relevant mutagenic potential was found for the drug mixture. No data is available on the carcinogenic potential of Canephron®.
No adverse effects on male or female fertility were observed in rats up to a dose of 1400 mg/kg bw/day. In available embryo-fetal studies, no evidence of teratogenic potential was observed in rats and rabbits up to doses of 1400 and 1000 mg/kg bw, respectively.
In a pre- and postnatal developmental study in rats, Canephron® had no adverse effects on either dams or pups up to the highest dose tested (1400 mg/kg bw).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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.

6.2 Incompatibilities

None known.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials

6.4 Special precautions for storage

Do not store above 30°C.

Type and contents of container

PVC/PVDC/aluminium blister pack.

Pack of 30 coated tablets

6.6 Special precautions for disposal

No special requirements for disposal.

7. MANUFACTURER

BIONORICA SE
Kerschensteinerstrasse 11-15
92318 Neumarkt, Germany

8. ISRAELI MARKETING AUTHORIZATION HOLDER AND IMPORTER:

Dr. Samuelov Importing & Marketing Ltd.
13 Hasadna st, POB 2486
Ra'anana 4365007 Israel

Phone: 09 7483769

9. REGISTRATION NUMBERS

171-02-36663-00

10. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

December 2022

10. DATE OF REVISION OF THE TEXT

December 2022

11. GENERAL CLASSIFICATION FOR SUPPLY

Over the counter, Available only in pharmacies

Canephron SmPc 1222