

FONCITRIL®

4000

IDENTIFICATION OF THE MEDICINE

Name

FONCITRIL® 4000, granules, in a unit dose sachet.

Qualitative and quantitative composition:

Monohydrated citric acid

corresponding quantity of anhydrous citric acid.....1,189 g

Anhydrous monopotassium citrate.....1,730 g

Anhydrous monosodium citrate.....1,845 g

Excipients : Sodium saccharine, concentrated orange juice, sweet orange essential oil, mandarin essential oil, orange yellow S (E110), saccharose, for one unit dose sachet.

1 unit dose sachet contains 200,6 mg of sodium, 293 mg of potassium and 5,1 g of saccharose.

Medicinal form:

Granules - box of 30 unit dose sachets.

Pharmaco-therapeutic group:

URINE ALKALISER (G : Urology)

Name and address of developer and manufacturer:

S.E.R.P.

5 rue du Gabian

98000 MONACO

WHEN TO USE THIS MEDICINE

(Therapeutic indications)

This medicine is used to promote the alkalisation of urine.

WARNING!

When not to use this medicine:

(Contraindications)

This medicine **MUST NOT BE USED** in case of :

- a history of allergy to one of the components,
- alkalosis (insufficient blood acidity).

IF IN DOUBT, IT IS INDISPENSABLE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Precautions for use:

Medical surveillance is necessary if you are taking this medicine.

Urine pH will be tested regularly.

It is imperative to drink plenty of water during the treatment.

Urine alkalisation can be achieved through a diet that is low in protein and high in vegetables leaving an alkaline residue, in particular citrus fruits.

Take sodium content (200 mg per sachet) into account in case of salt-free or low-salt diets.

Take saccharose content (5,1 g per sachet) into account in case of diabetes or hypoglycemic (low-sugar) diets.

IF IN DOUBT, DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE

Drug interactions and other interactions:

IN ORDER TO AVOID POSSIBLE INTERACTIONS BETWEEN SEVERAL MEDICINES, YOU MUST ALWAYS INFORM YOUR DOCTOR OR PHARMACIST OF ANY OTHER TREATMENT UNDERWAY.

Pregnancy - Breastfeeding:

This medicine is only to be used during pregnancy upon your doctor's advice. Consult your doctor if you discover that you are pregnant during the treatment, since he alone can judge whether it needs to be continued.

IN GENERAL, DURING PREGNANCY OR IF YOU ARE BREASTFEEDING, YOU SHOULD ALWAYS SEEK ADVICE FROM YOUR DOCTOR OR PHARMACIST BEFORE TAKING MEDICATION.

List of excipients that need to be known for safe use in certain patients:

- Sodium (200 mg per unit dose sachet),
- Potassium (293 mg per unit dose sachet),
- Saccharose (5,1 g per unit dose sachet),
- Orange yellow S (E 110).

HOW TO USE THIS MEDICINE

Dosage

FOR ADULTS ONLY.

ALWAYS FOLLOW YOUR DOCTOR'S PRESCRIPTION EXACTLY

Usually :

- Short-term treatment : 3 to 4 sachets per day,
- Long-term treatment : 1 to 2 sachets per day.

Mode and route of administration:

Oral route

Sachet to be dissolved in a large glass of water. Take after meals.

Duration of treatment:

Follow your doctor's recommendations.

UNWANTED AND ADVERSE EFFECTS

(Side effects)

LIKE ANY ACTIVE SUBSTANCE, IN CERTAIN PERSONS THIS MEDICINE CAN PRODUCE SIDE EFFECTS SOME OF WHICH ARE MORE ADVERSE THAN OTHERS.

TELL YOUR DOCTOR OR YOUR PHARMACIST ABOUT ANY UNWANTED OR ADVERSE EFFECT NOT MENTIONED IN THIS INFORMATION LEAFLET.

STORAGE

Do not exceed the expiry date stated on the external packaging.

DATE OF REVISION OF THIS INFORMATION LEAFLET

June 2004