

Package leaflet: Information for the user
ellura[®] capsules
Cranberry fruit juice extract

Read all of this leaflet carefully because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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1. What ellura[®] is and what it is used for

ellura[®] is a traditional herbal medicinal product used to prevent recurrent uncomplicated acute urinary tract infections (UTIs) such as cystitis in women only, based on traditional use only. ellura[®] should only be used after a doctor has confirmed that there are no other serious conditions.

ellura[®] is to be used if you suffer from recurrent UTIs, meaning that you have had at least 3 or more episodes in the past 12 months or 2 or more episodes in the past 6 months.

2. Before you take ellura[®]

2.1 Do not take ellura[®]

If you are allergic (hypersensitive) to the active substance or any of the excipients (see section 6: Further information).

If you suffer from:

- Fluid retention caused by a kidney or heart problem
- Current or previous kidney problems including kidney stones
- A condition which requires you to restrict your fluid intake e.g. severe heart or kidney disease.
- If you are taking any anticoagulant medicine used to help prevent blood clots e.g. warfarin, acenocoumarol, phenindione, apixaban, edoxaban, dabigatran, rivaroxban, dalteparin, enoxaparin, tinzaparin or heparin. The effects of these medicines may be increased by cranberry. (**see Taking other medicines**). If you are taking any immunosuppressant medicines such as tacrolimus or having chemotherapy (**see Taking other medicines**).
- Kidney disorders and have experienced recurrent UTIs

2.2 Take special care with ellura[®]

Talk to your doctor, pharmacist or qualified healthcare practitioner before taking ellura[®].

- You should consult your doctor or take your usual treatment if the symptoms of a UTI appear.
- You should consult your doctor if you are not sure if you have a UTI.

- You should consult a doctor and seek medical advice **immediately**, if any of the following symptoms develop: high temperature (fever), difficulty passing urine or bladder spasms, pain when urinating, blood in your urine, abdominal pain, back pain or you become incontinent .

This medicine is not suitable for patients with kidney disorders who experience recurrent UTIs because medical supervision is required in these cases. This medicine is not suitable for patients with current or previous kidney disease including kidney stones. Cranberry contains oxalate and may increase risks of kidney stones in patients who have or have had kidney stones in the past.

2.3 Taking other medicines

You should not use ellura[®] or other cranberry products if you are taking any anticoagulant medicines used to help prevent blood clots, immunosuppressant medicines such as tacrolimus or having chemotherapy (see section 2.1 above). Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines This includes any bought without a prescription.

2.4 Pregnancy and breast-feeding

This medicine should not be used if pregnant or breast feeding.

2.5 Men

This medicine should not be used by men as lower urinary tract infections require medical supervision.

2.6 Driving and using machines

No special precautions are needed. This medicine should have no effect on your ability to drive and use machines.

3. How to take ellura[®]

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

You should take ellura[®] if you suffer from recurrent UTIs, meaning that you have had at least 3 or more episodes in the past 12 months or 2 or more episodes in the past 6 months.

3.1 Adult women including the elderly

Take one capsule of ellura[®] per day for 15 consecutive days, after the most recent UTI episode.

The capsules should then be used preventatively for up to a further 4 times per year to help avoid recurrence of the infection.

The capsule should be taken orally with a large glass of water (300 ml).

If UTIs recur more often than usual, you should consult your doctor for advice and on adjusting the frequency of your treatment.

3.2 Children and adolescents

This medicine is not recommended for use in children and adolescents under 18 years old.

3.3 If you take more ellura[®] than you should

If you have accidentally taken more than the recommended dosage of ellura[®], this usually will not have any side effects. Continue to take the usual dose at the usual time. However, if you feel unwell, contact your doctor as soon as possible.

3.4 If you forget to take ellura[®]

Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

The following side effects may occur:

- Gastrointestinal effects such as feeling or being sick, constipation, indigestion, vomiting, diarrhoea, abdominal pain or discomfort.
- Allergic skin reactions e.g. rash, hives.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store". By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store ellura®

This medicinal product does not require any special temperature storage conditions.

Store in the original package.

Keep out of the sight and reach of children.

Do not use the capsules after the expiry date on the outer carton, blister strip or bottle.

Medicines should not be thrown away in waste water or in household waste. Please ask your pharmacist how to throw away any medicine you do not need anymore. If you do this, you will help protect the environment.

6. Further Information

What ellura® contains

One hard capsule contains 195-216 mg of extract (as dry extract, refined) from the juice of cranberry fruit (*Vaccinium macrocarpon* Ait. Fructus), corresponding to 36 mg of proanthocyanidins (PAC), calculated as PAC A2.

Extraction solvent: Ethanol 70% (v/v).

The other ingredients are : mannitol, magnesium stearate, silica colloidal anhydrous, hyromellose (capsule shell).

What ellura® looks like and contents of the pack

ellura® capsules are hard, colourless capsules containing a purple coloured powder (natural colour).

ellura® comes in blister packs of 15 or 30 capsules.

Not all pack sizes may be marketed.

Traditional Herbal Registration Holder and Manufacturer

THR Holder : Laboratoire Pharmaceutique Pharmatoka S.A.S, 20-22 avenue de la République, 92500 Rueil Malmaison, France.

Manufacturer(s) :

Centre Spécialités Pharmaceutiques, 35 Rue de la Chapelle 63450 St Amant Tallante, France.

Or

Laboratoire Pharmaceutique Pharmatoka S.A.S, 20-22 avenue de la République, 92500 Rueil Malmaison, France.

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