

Package leaflet: Information for the user

Ellura[®] hard capsules
Cranberry fruit juice refined dry extract

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ellura is and what it is used for
2. What you need to know before you take Ellura
3. How to take Ellura
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1. What Ellura is and what it is used for

Ellura is a traditional herbal medicinal product containing a refined dry extract from the juice of cranberry fruit.

Ellura is used to prevent recurrent uncomplicated acute urinary tract infections (UTIs) such as cystitis in adult women over the age of 18 years exclusively based on longstanding use.

Ellura is for use in women only.

Ellura is to be used if you suffer from recurrent uncomplicated acute 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. What you need to know before you take Ellura

2.1 Do not take Ellura

-If you are allergic (hypersensitive) to the active substance or any of the other ingredients of this medicine (listed in section 6).

-if you are a man

-If you are under 18 years old.

-If you are pregnant or breastfeeding

- 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, rivaroxaban, dalteparin, enoxaparin, tinzaparin or heparin. The effects of these medicines may be increased by cranberry. (**see Other medicines and Ellura**).

- If you are taking any immunosuppressant medicines such as tacrolimus or having chemotherapy (**see Other medicines and Ellura**).

2.2 Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Ellura.

- You should consult your doctor if 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 product is not suitable for use in men. Urinary symptoms in men should be treated by a doctor.

2.3 Other medicines and Ellura

You should not use Ellura if you are taking any anticoagulant medicines used to help prevent blood clots, immunosuppressant medicines such as tacrolimus or having chemotherapy (**see Do not take Ellura**).

If you are speaking to your doctor, pharmacist or nurse always remember to tell them about any medicines you are taking, including herbal remedies such as Ellura or any medicines bought without prescription.

2.4 Pregnancy and breast-feeding

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

2.5 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, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

You should take Ellura if you suffer from recurrent uncomplicated 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.

If these UTIs recur more often, a doctor should be consulted for advice including advice on how often you should take Ellura.

Recommended dose:

3.1 Adult women over 18y including the elderly:

Take one capsule of Ellura per day to prevent uncomplicated acute UTIs from recurring.

The capsule should be taken with a large glass of water.

This preventative treatment should be taken for at least 15 days after your last UTI.

Ellura should not be taken for longer than 6 months.

If symptoms of a urinary tract infection arise during the use of Ellura, a doctor should be consulted.

Do not take more than the recommended dose.

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, immediately consult 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

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects may occur:

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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse this includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance. Website: www.hpra.ie. 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 this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the outer carton and blister strip after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Ellura contains

One hard capsule contains 195.7-216.9 mg of extract (as dry extract, refined) from the juice of *Vaccinium macrocarpon* Ait., fructus (cranberry fruit), corresponding to 36 mg of proanthocyanidins (PAC), calculated as PAC A2.

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

What Ellura looks like and contents of the pack

Ellura are hard, colourless capsules containing a purple-coloured powder (natural colour). Ellura comes in blister packs of 15, 30, 60 and 90 capsules.

Not all pack sizes may be marketed.

Registration Holder and Manufacturer

Registration Holder

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