Professional information

BASED ON SCIENTIFIC EVIDENCE

SCHEDULING STATUS: S0

ELLURA®

CAPSULES

- Complementary medicine Category D33.6 (western herbal)
- This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

1. NAME OF MEDICINE

ELLURA® CAPSULE (Refined dry extract from the juice of cranberry fruit)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

ELLURA® CAPSULE: each capsule contains:
Vaccinium macrocarpon Ait Fructus (Cranberry) 206.3 mg [Refined Dry extract from the juice of cranberry fruit] standardised to Proanthocyanidins (PAC) 36mg*, calculated as PAC A2 *confirmed using the DMAC method.

Extraction solvent: Ethanol 70% (v/v)
Sugar free.
For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Hard capsule.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications:

ELLURA® is a natural medicine clinically researched to support urinary tract health and to help reduce the frequency of recurrent cystitis. It assists in preventing harmful E. coli bacteria adhesion to the urinary tract wall, allowing excretion from the body.

4.2. Posology and method of administration

Posology

Adults and children over 12 years:
ELLURA® is to be used in women who suffer from recurrent UTIs, meaning those who have had at least 3 or more episodes in the past 12 months or 2 or more episodes in the past 6 months.
One capsule of Ellura to be taken per day for 15 to 30 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.
If UTIs recur more often, a doctor should be consulted for advice on adjusting the frequency of treatment.
Children under 12 years:
Discuss dosage with your healthcare professional.

Method of administration

Oral use.
Capsules should be swallowed whole with some water.

4.3. Contraindications

Hypersensitivity to cranberry (Vaccinium macrocarpon Ait.) fruit or to any of the excipients.
Oedema secondary to heart failure or impaired renal function.
Current or previous kidney disease including kidney stones.
Conditions where a reduced fluid intake is recommended e.g. severe cardiac or renal diseases.
Concomitant use of warfarin and other anticoagulant medicines (see section 4.5).
Concomitant use of immunosuppressant drugs (see section 4.5)
Concomitant use with chemotherapy (see section 4.5).

4.4. Special warnings and precautions for use

Do not exceed the stated dose.
The use in children and adolescents under 12 years old is not recommended because data is not sufficient and medical advice should be sought.
Medical advice should be sought or usual treatment should be taken if the symptoms of a UTI appear. Medical advice should be sought if the patient is not sure if she has a UTI.
A doctor should be consulted immediately, if any of the following symptoms develop fever, rigors, abdominal pain, back pain, haematuria, urinary retention or urinary incontinence.

4.5. Interaction with other medicines and other forms of interactions

Individual case reports suggest a possible interaction between warfarin and cranberry juice, in most cases leading to an increase in INR or bleeding event.
Other vitamin K antagonists such as acenocoumarol and phenindione are occasionally used instead of warfarin and could also potentially interact with cranberry juice.
There are no reports to date of interactions between cranberry and the new direct-acting oral anticoagulants which are not vitamin K antagonists (such as apixaban, edoxaban, dabigatran, and rivaroxaban) or parenteral anticoagulants (such as heparin, dalteparin, enoxaparin and tinzaparin); however, a clinical study demonstrates a potential pharmacodynamic interaction between cranberry and warfarin.
Therefore the concomitant use of anticoagulant medicines and cranberry juice products is contraindicated (see section 4.3).
There is no evidence that cranberry juice has a clinically relevant effect on the pharmacokinetics of amoxicillin or cefaclor.
A recent case study reported that concurrent administration of tacrolimus and cranberry juice resulted in a significant reduction in tacrolimus levels. Therefore patients taking immunosuppressant drugs should not take cranberry preparations (see section 4.3).
An in vitro study has suggested that cranberry inhibits CYP2C8, an enzyme pathway for metabolizing many drugs, including paclitaxel. Although there are no human studies showing an interaction between cranberry and paclitaxel, patients receiving chemotherapy should not take cranberry products (see section 4.3).

4.6. Fertility, pregnancy and lactation

The safety of this product during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.
No studies on the effects on fertility have been performed.

4.7. Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8. Undesirable effects

Gastrointestinal disorders: nausea, or vomiting, diarrhoea, constipation, abdominal pain or discomfort.
Skin and subcutaneous tissue disorders: rash (hypersensitivity reaction)
The frequency is unknown and cannot be estimated from the available data.

4.9. Overdose

No cases of overdose have been reported.
Supportive and symptomatic treatment should be provided as appropriate.

5. PHARMACEUTICAL PARTICULARS

5.1. List of excipients

Magnesium stearate and anhydrous colloidal silica
Hypromellose (capsule shell)

5.2. Incompatibilities

Not applicable.

5.3. Shelf life

36 months

5.4. Special precautions for storage

Store at or below 25 °C.

5.5. Nature and contents of container

The capsules are packed into blisters consisting of transparent (PVC/ PVDC film) on one side and an aluminium foil on the other side. Pack sizes of 30 hard capsules. Not all pack sizes may be marketed.

6. REGISTRATION NUMBER

D540450

7. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be allocated.

8. DATE OF REVISION OF THE TEXT

July 2022.