

Patient Information Leaflet



Uva-ursi & Echinacea

oral drops



Information

Important things you need to know

- This product is used to help relieve minor urinary complaints associated with cystitis in women.
- This product is suitable for women over 18 years.
- **Don't take** this product if you are allergic to any of the ingredients: see section 6.
- **Before you take this product:** read section 2.
- **Dosage instructions**: see section 3.
- Talk to your doctor if your symptoms worsen, or do not improve after 7 days.
- Side effects can occur when taking this product: see section 4.

Now read the rest of this leaflet

carefully. Keep this leaflet. You may need to read it again.

1. What this product is and what it is used for

Uva-ursi & Echinacea Cystitis oral drops is a traditional herbal medicinal product used to help relieve minor urinary complaints associated with cystitis in women such as:

- Burning sensation when urinating
- Frequent urination

This is based on traditional use only.

2. Before you take this product

Do not take this product

- If you are under 18 years of age.
- If you are **allergic** to
 - Echinacea or plants of the daisy (Asteraceae/ Compositae) family.
 Echinacea is a member of the daisy family.
 - Uva-ursi, also known as *Arctostaphylos uva-ursi*.
- Any of the ingredients of this product (listed in section 6).
- If you have a tendency to allergies such as hives, allergic eczema or asthma.

- If you **suffer** from
 - TB (the infection tuberculosis)
 - Sarcoidosis (a connective tissue disorder which causes the formation of clumps of cells mainly in the lymph nodes, lungs and liver)
 - An autoimmune disease such as collagenoses (inflammation of the connective tissue) or multiple sclerosis
 - HIV, AIDS or any other condition which decreases your resistance to infection
 - A disorder which affects your white blood cells such as agranulocytosis (low white blood cell count due to bone marrow disorders) or leukemia (blood cell cancer)
 - Impaired kidney function
 - A kidney disorder or if you have suffered from a kidney disorder in the past
 - Fluid retention caused by a heart or kidney problem
 - A condition which requires you to restrict your fluid intake e.g. severe heart or kidney disease

- If you are taking
 - Ciclosporin, methotrexate, or any other
 - immunosuppressant medicine.
 - Any medicine which is affected by alcohol.
- If you are having treatment to reduce the response of your immune system (immunosuppression) e.g. chemotherapy, radiotherapy.
- If you have had an organ or bone marrow transplant.
- If you are pregnant or breast-feeding.

You should also know

- This medicinal product contains 54 vol % ethanol (alcohol), i.e. up to 213 mg per 15 drop dose, equivalent to 5.4 ml beer (around half a tablespoon) or 2.25 ml wine (less than a teaspoon) per dose.
- If you suffer from alcoholism the alcohol content of this product may be harmful.
- If you are in a high-risk group (patients with liver disease or epilepsy) you should consider the alcohol content before taking this product.

3. How to take this product

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Adult women over 18 years: Take 15 drops in a little water two to five times daily.

Make sure you drink plenty of fluids whilst taking this product.

Not for use in children or those under 18.

For oral use only. Do not take more than the recommended dose.

If you feel this product isn't working

- See your doctor
 - If you have a high temperature (fever)
 - If you have difficulty passing urine or have spasms
 - If it is painful to pass urine
 - If you become incontinent
 - If you have blood in your urine
- If your symptoms worsen, or do not improve after 7 days, you should see your doctor to check your symptoms are not being caused by any underlying medical condition.

Using

If you take too much

- If you take too much and feel ill, talk to your doctor. Taking too much is unlikely to be harmful.
- Overdose of this product may result in alcohol intoxication and should be treated accordingly (see section 2 'You should also know' for alcohol content).

If you forget to take this product

 Do not worry about a missed dose. Take the next dose as usual.

Driving and using machines

• This product contains alcohol (see section 2 'You should also know' for alcohol content).

Side effects

4. Possible side effects

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

Side effects

This product may make your urine appear greenish-brown in colour. This is a harmless effect.

Digestive symptoms

Nausea

Feeling sick or vomitingStomach ache

These are often short-lived and should go away by themselves. However if they are troubling you, talk to your doctor or pharmacist.

Allergic reactions

If you already suffer from allergies you may be more likely to get them. Allergic reactions which may occur are:

- Skin rash
- Red, itchy spots (urticaria)

These are often short-lived and should go away by themselves. However if they are troubling you, talk to your doctor or pharmacist.

 Swelling of the skin due to fluid (angioedema) or swelling of the face (Quincke's oedema)

- Blistering of the skin and mucous membranes (Stevens-Johnson syndrome)
- Difficulty in breathing (bronchospasm with obstruction)
- Asthma or anaphylactic shock (a life-threatening allergic reaction)

Stop taking this product immediately if any of these occur. Seek medical advice and take this leaflet with you.

There have been isolated reports suggesting an association between Echinacea products and autoimmune diseases such as :

- Inflammation of the brain and spinal cord (disseminated encephalitis)
- Painful lumps on the shins (erythema nodosum)
- Low blood platelet count (immunothrombocytopenia)
- Destruction of blood cells by antibodies (Evans Syndrome)
- Dryness in the mouth and eyes with renal tubular dysfunction (Sjögren Syndrome)

A decrease in the number of white blood cells (leucopenia) may occur in long-term use (more than 8 weeks).

The frequency is not known. This means it is not known how often these reactions occur as there have not been enough reports to allow this information to be calculated.

If you are concerned about any side effect or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 the Yellow Card Scheme at: www.mhra.gov.uk/ yellowcard
- By reporting side effects you can help provide more information on the safety of this medicine.

You can get a larger print or audio version of this leaflet. Call this number: 0845 608 5858.



5. How to store this product

- Keep out of the sight and reach of children.
- Do not use this product after the expiry date which is stated on the packaging. The expiry date refers to the last day of that month.
- This product does not require any special storage conditions.
- Use within 4 months of opening.
- Do not use this product if you notice a change in appearance. It should be a clear to opalescent liquid that is brown-yellow to brown in colour.

6. Further Information

What this product contains

1 ml of oral liquid contains the tinctures of:

Fresh Uva-ursi herb715 mg(Arctostaphylos uva-ursi (L.) Spreng.)(1:4). Extraction solvent: Ethanol43% m/m

Fresh Echinacea herb 240 mg

(*Echinacea purpurea* (L.) Moench) (1:12). Extraction solvent: Ethanol 57.3% m/m

The other ingredients used for the liquid are ethanol and water.

1 ml of Uva-ursi & Echinacea Cystitis oral drops is equivalent to 30 drops.

What this product looks like and the contents of the pack

Uva-ursi & Echinacea Cystitis oral drops is a clear to opalescent liquid that is brown-yellow to brown in colour. It is available in 50 ml bottles.

Traditional Herbal Registration Holder and Manufacturer

Traditional Herbal Registration Holder and Batch Release

Bioforce (UK) Ltd, 2 Brewster Place, Irvine, Ayrshire, UK KA11 5DD

Manufacturer

Bioforce AG, CH-9325, Roggwil, Switzerland

THR 13668/0030



Certification Mark

This leaflet was last revised on 09/2015.

You should also know

Bioforce runs a helpline by phone and email which can provide you with further information.

E-mail: enquiries@avogel.co.uk

Phone: 0845 608 5858