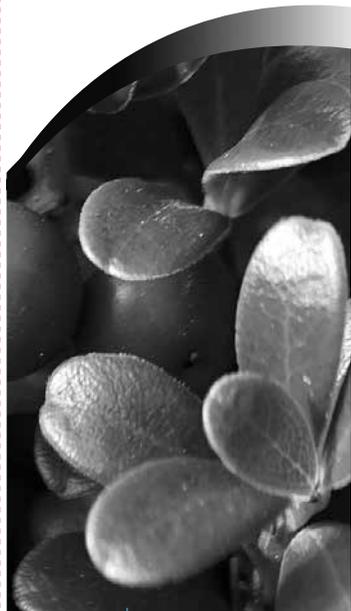




Package Leaflet:
Information for the user

A.Vogel
**Uva-ursi
& Echinacea**
Cystitis
oral drops

Tinctures of Bearberry herb and
Echinacea purpurea herb



pharma code

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

Always take this product 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 4 days.

What is in this leaflet

1. What A.Vogel Uva-ursi & Echinacea Cystitis is and what it is used for
2. What you need to know before you take A.Vogel Uva-ursi & Echinacea Cystitis
3. How to take A.Vogel Uva-ursi & Echinacea Cystitis
4. Possible side effects
5. How to store A.Vogel Uva-ursi & Echinacea Cystitis
6. Contents of the pack and other information

1. What A.Vogel Uva-ursi & Echinacea Cystitis is and what it is used for

A.Vogel Uva-ursi & Echinacea Cystitis is a traditional herbal medicinal product containing the tinctures of fresh Bearberry herb and fresh *Echinacea purpurea* herb.

It is used to help relieve minor urinary complaints associated with cystitis in women such as:

- Burning sensation when urinating
- Frequent urination

This is exclusively based on long-standing use.

A.Vogel Uva-ursi & Echinacea Cystitis is for use in women only.

You must talk to your doctor if you do not feel better or if you feel worse after 4 days.

2. What you need to know before you take A.Vogel Uva-ursi & Echinacea Cystitis

Do not take A.Vogel Uva-ursi & Echinacea Cystitis

- If you are **allergic** to
 - Echinacea or plants of the daisy (Asteraceae/ Compositae) family. Echinacea is a member of the daisy family

- Bearberry (also known as Uva-ursi or *Arctostaphylos uva-ursi*)
- Any of the other ingredients of this product (listed in section 6).
- 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 restricts your fluid intake e.g. severe heart or kidney disease
- 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

Warnings and precautions

- See your doctor if:
 - You have a high temperature (fever)
 - You have difficulty passing urine or have spasms
 - It is painful to pass urine
 - You become incontinent
 - You have blood in your urine
- Do not take this product for more than 7 days. See your doctor if your symptoms worsen or you do not feel an improvement within 4 days.
- If you have a tendency to allergies such as hives, allergic eczema or asthma consult your doctor before use. This product may not be suitable for you.
- This product is not suitable for use in men. Urinary complaints in men should be treated by a doctor.
- This product may make your urine appear greenish-brown in colour. This is a harmless effect.

Children and adolescents

- Do not give this product to children or adolescents under 18 years of age.

Other medicines and A.Vogel Uva-ursi & Echinacea Cystitis

- Do not take this product if you are already taking another medicine which is affected by alcohol, for example, the antibiotic metronidazole.
- Do not take this product if you are taking any medicine which affects your immune system.
- 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 A.Vogel Uva-ursi & Echinacea Cystitis.

Pregnancy and breast-feeding

- Do not take this product if you are pregnant or breast-feeding.

Driving and using machines

- This product contains alcohol (see below for alcohol content). Overdose of this product may result in alcohol intoxication.

Please turn over...

41530NXXUK

A.Vogel Uva-ursi & Echinacea Cystitis contains alcohol

- This traditional herbal medicine contains 213 mg of alcohol (ethanol) in each 15 drop dose.
- The amount in 15 drops of this medicine is equivalent to less than 6 ml beer (a teaspoon) or 3 ml wine (around half a teaspoon).
- The small amount of alcohol in this medicine will not have any noticeable effects.

3. How to take A.Vogel Uva-ursi & Echinacea Cystitis

Always take this product 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.

Recommended dose

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

It is advisable to drink plenty of liquids when treating the symptoms of cystitis.

For oral short-term use only. Do not take this product for more than 7 days. See your doctor if your symptoms worsen or you do not feel an improvement within 4 days.

Do not take more than the recommended dose.

pharma code

If you take more A.Vogel Uva-ursi & Echinacea Cystitis than you should

- If you take too much and feel ill, talk to your doctor.
- Overdose of this product may result in alcohol intoxication and should be treated accordingly.

If you forget to take A.Vogel Uva-ursi & Echinacea Cystitis

- Do not worry about a missed dose. Take the next dose as usual.
- Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product ask your doctor, pharmacist or nurse.

4. Possible side effects

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

Side effects

Allergic reactions

Echinacea can trigger allergic reactions in patients who have a tendency to allergic reactions. Allergic reactions which may occur are:

- Skin rash
- Red, itchy skin (hives)
- Swelling of the face or skin due to fluid (angioedema)

- Blistering of the skin, mouth, eyes or groin (Stevens-Johnson syndrome)
- Difficulty in breathing
- 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.

Digestive symptoms

- Feeling sick (nausea)
- Sickness
- Stomach ache

Stop taking this product if you find these are troubling you. Talk to a doctor or pharmacist if you are concerned.

Other effects

You may find that when you take A.Vogel Uva-ursi & Echinacea Cystitis you feel tingling, irritation or numbness in your mouth. This is due to the presence of alkylamides which are a natural part of one of the plant extracts in A.Vogel Uva-ursi & Echinacea Cystitis oral drops.

Association between Echinacea products and autoimmune disease have been reported such as:

- Inflammation of the brain and spinal cord (multiple sclerosis)
- Painful lumps on the shins (erythema nodosum)
- Low blood platelet count

- Destruction of blood cells by antibodies (Evans Syndrome)
- Dryness in the mouth and eyes with kidney dysfunction (Sjögren Syndrome)

The frequency of these side effects is not known as the frequency cannot be estimated from the available data.

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
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
E-mail: medsafety@hpra.ie

- By reporting side effects you can help provide more information on the safety of this traditional herbal medicine.

5. How to store A.Vogel Uva-ursi & Echinacea Cystitis

- Keep this product out of the sight and reach of children.
- Do not use this product after the expiry date which is stated on the label and carton. 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.
- Do not throw away any medicines via wastewater or household waste. 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 A.Vogel Uva-ursi & Echinacea Cystitis contains

One dose (15 drops) of oral liquid contains 357.5 mg of tincture from fresh *Arctostaphylos uva-ursi* (L.) Spreng, herba (Bearberry herb) (1:4.0-5.2). Extraction solvent: Ethanol 43% m/m and 120 mg of tincture from fresh *Echinacea purpurea* (L.) Moench herba (Purple Coneflower herb) (1:12-13). Extraction solvent: Ethanol 57.3% m/m.

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

What A.Vogel Uva-ursi & Echinacea Cystitis looks like and contents of the pack

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

Traditional Herbal Registration Holder

A.Vogel Ireland Ltd,
48 Upper Drumcondra Road,
Dublin 9, Ireland
Tel: 1 890 930 070
enquiries@avogel.ie

Manufacturer

A.Vogel Ltd,
2 Brewster Place,
Irvine, Ayrshire, KA11 5DD - UK
Tel: +44 (0)1294 277344
enquiries@avogel.co.uk

TR 2309/021/001

This leaflet was last revised in MM/YYYY

You should also know

A.Vogel Ireland runs a helpline by phone and email which can provide you with further information.

Email: enquiries@avogel.ie
Phone: **1 890 930 070**

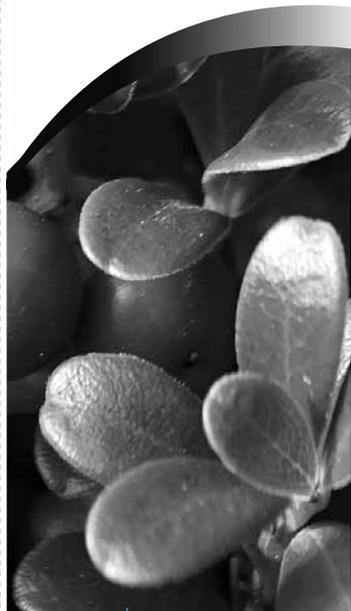
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Package Leaflet:
Information for the user

A.Vogel
**Uva-ursi
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Cystitis
oral drops

Tinctures of Bearberry herb and
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pharma code

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- Burning sensation when urinating
- Frequent urination

This is exclusively based on long-standing use.

A.Vogel Uva-ursi & Echinacea Cystitis is for use in women only.

You must talk to your doctor if you do not feel better or if you feel worse after 4 days.

2. What you need to know before you take A.Vogel Uva-ursi & Echinacea Cystitis

Do not take A.Vogel Uva-ursi & Echinacea Cystitis

- If you are **allergic** to
 - Echinacea or plants of the daisy (Asteraceae/ Compositae) family. Echinacea is a member of the daisy family

- Bearberry (also known as Uva-ursi or *Arctostaphylos uva-ursi*)
 - Any of the other ingredients of this product (listed in section 6).
 - 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)
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 - A condition which restricts your fluid intake e.g. severe heart or kidney disease
 - If you are having treatment to reduce the response of your immune system (immunosuppression) e.g. chemotherapy, radiotherapy
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- Warnings and precautions**
- See your doctor if:
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Children and adolescents

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Other medicines and A.Vogel Uva-ursi & Echinacea Cystitis

- Do not take this product if you are already taking another medicine which is affected by alcohol, for example, the antibiotic metronidazole.
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- 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 A.Vogel Uva-ursi & Echinacea Cystitis.

Pregnancy and breast-feeding

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Please turn over...

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pharma code

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- Difficulty in breathing
- 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.

Digestive symptoms

- Feeling sick (nausea)
- Sickness
- Stomach ache

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48 Upper Drumcondra Road,
Dublin 9, Ireland
Tel: 1 890 930 070
enquiries@avogel.ie

Manufacturer

A.Vogel B.V.
J.P. Broekhovenstraat 16,
8081 HC Elburg,
Netherlands

TR 2309/021/001

This leaflet was last revised in MM/YYYY

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Email: enquiries@avogel.ie
Phone: **1 890 930 070**

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