

## Package leaflet: information for the user

### **Cystinol akut® Coated Tablets**

coated tablets  
for use in adults and adolescents from the age of 12 years  
dry extract of bearberry leaves

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

This medicine is available without prescription. However, you still need to take Cystinol akut® Coated Tablets carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 5 days.
- If you are considerably affected by any of the side effects, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **In this leaflet:**

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#### **1. What Cystinol akut® Coated Tablets are and what they are used for**

Cystinol akut® Coated Tablets are a herbal medicine for urinary tract infections.

Cystinol akut® Coated Tablets are used in case of inflammatory diseases of the lower urinary tract.

#### **2. Before you take Cystinol akut® Coated Tablets**

##### **2.1 Do not take Cystinol akut® Coated Tablets,**

- if you are allergic (hypersensitive) to dry extract of bearberry leaves or any of the other ingredients of Cystinol akut® Coated Tablets,
- if you are pregnant or nursing,
- if the patient is younger than 12 years.

##### **2.2 Take special care with Cystinol akut® Coated Tablets,**

- in case of blood in urine,
- in case of fever,
- if the complaints persist longer than 5 days.

In these cases you must consult a doctor.

## 2.3 Taking other medicines

Cystinol akut® Coated Tablets should not be taken together with drugs causing the production of acidic urine (such as methionine) since it cannot be excluded that this decreases the antibacterial effect of bearberry leaves. In case of doubt please ask your doctor or pharmacist.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

## 2.4 Pregnancy and breast-feeding

Cystinol akut® Coated Tablets must not be taken during pregnancy and breast-feeding (see 2.1 „Do not take Cystinol akut® Coated Tablets ...“).

## 2.5 Driving and using machines

No special precautions necessary.

## 2.6 Important information about some of the other ingredients of Cystinol akut® Coated Tablets

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

## 3. How to take Cystinol akut® Coated Tablets

Always take Cystinol akut® Coated Tablets exactly as directed in this package leaflet. Please check with your doctor or pharmacist if you are not sure.

### 3.1 Unless otherwise prescribed by the doctor, the usual dose is:

Adults and adolescents from the age of 12 years take **2 coated tablets 3 times daily**. The coated tablets should be taken with sufficient liquid, preferably water, after the meals.

### 3.2 Duration of use

Without medical advice, Cystinol akut® Coated Tablets should not be taken for longer than one week and no more than 5 times a year.

Please ask your doctor or pharmacist if you have the impression that the effect of Cystinol akut® Coated Tablets is too strong or too weak.

### 3.3 If you take more Cystinol akut® Coated Tablets than you should

Do not take more Cystinol akut® Coated Tablets per day than suggested in the directions for use or prescribed by your doctor. If you have accidentally taken a double dosage, this will normally not have any negative effects.

The ingestion of amounts far beyond the directions for use, however, may cause considerable complaints such as gastrointestinal complaints with nausea and vomiting, but also bloody urine and liver damage.

In this case, you should immediately discontinue Cystinol akut® Coated Tablets and consult a doctor, even if you experience no symptoms yet.

### 3.4 If you forget to take Cystinol akut® Coated Tablets

Do not take a double dose, but continue the intake as described in the directions for use or as prescribed by your doctor.

### 3.5 If you stop taking Cystinol akut® Coated Tablets

Your doctor should examine you and determine if the treatment has been successful at this point, i.e. no bacteria should be present in the urine and the symptoms of an inflammation should have subsided to a large extent.

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

## 4. Possible side effects

Like all medicines, Cystinol akut® Coated Tablets can cause side effects, although not everybody gets them.

Assessment of side effects is based on the following frequency rates:

very common:	more than 1 treated patient of 10
common:	1 to 10 treated patients of 100
uncommon:	1 to 10 treated patients of 1,000
rare:	1 to 10 treated patients of 10,000
very rare:	less than 1 treated patient of 10,000
unknown:	frequency not assessable on the basis of the available data

### Possible side effects

Rarely: sensitive patients may experience gastrointestinal complaints (nausea and vomiting).

Very rarely: allergic reactions

Please inform your doctor or pharmacist if any of the listed side effects considerably impairs you, or if you notice any side effects not listed in this leaflet.

After first signs of a hypersensitivity reaction or other side effects have occurred Cystinol® akut Coated Tablets must not be taken again.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via (...*the national reporting system*). By reporting side effects you can help to provide more information on the safety of this medicine.

## 5. How to store Cystinol akut® Coated Tablets

Keep out of the reach and sight of children.

Do not use Cystinol akut® Coated Tablets after the expiry date which is stated on the carton and on the blister after "use before". The expiry date refers to the last day of that month.

### Storage conditions:

Do not store above 25° C.

## 6. Further Information

### **What Cystinol akut® Coated Tablets contain:**

The active substance is:

1 coated tablet contains

238.7–297.5 mg dry extract of bearberry leaves (3.5–5.5 : 1), corresponding to 70 mg hydroquinone derivatives, calculated as anhydrous arbutin (Photometrie Ph. Eur. 1998), extractant: ethanol 60 % (V/V).

The other ingredients are:

microcrystalline cellulose, long-chain partial glycerides, hypromellose, lactose monohydrate, macrogol 6000, magnesium stearate (Ph.Eur.), colloidal anhydrous silica, quinoline yellow E 104, indigocarmine E 132, titanium dioxide E 171.

### **What Cystinol akut® Coated Tablets look like and contents of the pack:**

Cystinol akut® Coated Tablets are light green.

Cystinol akut® Coated Tablets are available in packs containing 60 and 100 coated tablets.

### **Marketing authorization holder and manufacturer:**

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