

## Wording of the planned details for the package leaflet

### Package leaflet: Information for the user

#### Cystinol long Capsules

424.8 mg dry extract of Genuine Golden Rod herb, hard capsules

#### **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 long Capsules 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 any of the side effects gets serious, 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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4. Possible side effects
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6. Further information

#### **1. What Cystinol long Capsules are and what they are used for**

Cystinol long<sup>®</sup> Capsules are a herbal medicine for irrigation of the urinary tract.

Cystinol long<sup>®</sup> Capsules are used:  
for irrigation in case of inflammatory diseases of the lower urinary tract, in case of urinary stones and renal gravel  
for prophylactic treatment in case of urinary stones and renal gravel.

#### **2. Before you take Cystinol long Capsules**

- 2.1 Do not take Cystinol long Capsules,**  
if you are hypersensitive (allergic) to Genuine Golden Rod herb or to one of the other ingredients of Cystinol long<sup>®</sup> Capsules.

Please note:

No irrigation therapy in case of water retention (oedemas) due to impaired cardiac or renal function.

## **2.2 Take special care with Cystinol long Capsules**

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

In these cases a doctor should be consulted.

## **2.3 Children:**

There are no adequate data regarding the use in children. Therefore, Cystinol long<sup>®</sup> Capsules should not be taken by children under 12 years.

## **2.4 Taking other medicines:**

There are no known interactions.

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

## **2.5 Pregnancy and breast-feeding:**

No signs for risks in pregnancy and breast-feeding have resulted until now from the widespread use of Genuine Golden Rod herb as medicinal product. Results from experimental investigations are not available. Therefore, Cystinol long Capsules should not be taken during pregnancy and breast-feeding.

## **2.6 Driving and using machines:**

No special precautions are necessary.

## **3. How to take Cystinol long<sup>®</sup> Capsules**

Always take Cystinol long Capsules exactly as directed in this package leaflet. Please ask your doctor or pharmacist, if you are not quite sure.

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

Children from the age of 12 years and adults take 3 to 4 times daily 1 hard capsule.

### **3.2 Method of administration:**

Please take the hard capsules unopened and unchewed with plenty of liquid (approx. 1 glass of water) after the meals.

Do not take Cystinol long Capsules in lying position and only with sufficient liquid.

Your disease requires that you ensure a plentiful and consistent intake of liquid. Unless it does not conflict with cardiac or circulatory diseases, the daily intake of liquid should be 1.5 to 2 litres.

### **3.3 Duration of use:**

It is recommended to discuss the duration of treatment with your doctor.

Please also consult your doctor or pharmacist, if you have the impression that the effect of Cystinol long Capsules is too strong or too weak.

### 3.4 If you take more Cystinol long Capsules than you should:

Acute cases of intoxication by preparations of Genuine Golden Rod herb in humans have not yet been reported. However, it has to be expected that the symptoms described under "side effects" may increasingly occur.

Please consult a doctor, if you have taken Cystinol long<sup>®</sup> Capsules in large quantities.

### 3.5 If you forget to take Cystinol long Capsules:

Do not make up for a forgotten intake, but continue the intake of Cystinol long<sup>®</sup> Capsules at the next scheduled time, as described in the directions for use or as prescribed by your doctor.

### 3.6 If you stop taking Cystinol long Capsules:

Should your complaints noticeably improve, nevertheless continue the treatment in any case until the end.

If, however, an interruption of the treatment or a premature discontinuation is necessary from a medical point of view, this can be done at any time. Undesired consequences have not to be expected.

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

## 4. Possible side effects

Like all medicines, Cystinol long Capsules 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 patients of 10,000
Unknown:	frequency not assessable on the basis of the available data

Very rarely, allergic reactions (skin rash, swelling and itching) may occur.

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.

## 5. How to store Cystinol long Capsules

Keep out of the reach and sight of children!

Do not use Cystinol long Capsules after the expiry date which is stated on the carton and on the blister package after "use before". The expiry date refers to the last day of that month.

### Storage conditions:

Do not store above 30 °C.

## **6. Further information**

### **What Cystinol long Capsules contain:**

active substance:

1 hard capsule contains

424.8 mg dry extract of Genuine Golden Rod herb (5 – 7 : 1),

extractant: ethanol 30 % (m/m).

The other ingredients are:

powdered cellulose, magnesium stearate, colloidal anhydrous silica, colloidal anhydrous silica (methylated), starch;

capsule shell: gelatine, sodium dodecyl sulphate, indigocarmin E 132, titanium dioxide E 171, iron oxide E 172.

### **What Cystinol long Capsules look like and contents of the pack:**

Cystinol long Capsules are green-brown hard capsules.

Cystinol long Capsules are available in packs containing 60 and 120 hard capsules.

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

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