

## Package leaflet: information for the user

### **Cystinol® N Solution**

Liquid for oral use

For use in adults and adolescents from the age of 12 years

Thick extract of bearberry leaves, thick extract of genuine golden rod herb

#### **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® N Solution 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 4 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:**

1. What Cystinol® N Solution is and what it is used for
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#### **1. What Cystinol® N Solution is and what it is used for**

Cystinol® N Solution is a herbal medicine for urinary tract infections.

Cystinol® N Solution is used as supportive therapy of sufficient intake of liquid and thermotherapy in case of inflammatory (also bacterially caused) diseases of the lower urinary tract, such as:

- inflammation of the ureter (ureteritis)
- inflammation of the bladder (cystitis), irritable bladder
- inflammations of the urethra (urethritis).

In case of blood in the urine, in case of fever or if the complaints persist longer than 4 days, you must consult a doctor.

#### **2. Before you take Cystinol® N Solution**

##### **2.1 Do not take Cystinol® N Solution:**

- if you are hypersensitive (allergic) to bearberry leaves and/or golden rod herb or to other composite plants or to one of the other ingredients of Cystinol® N Solution.
- if you have kidney disease

- if you suffer from water retention (oedemas) due to impaired cardiac function or if a reduced intake of fluids has been recommended to you because of the above mentioned disease.

## **2.2 Take special care with Cystinol® N Solution:**

See details regarding maltitol and ethanol under 2.8 "Important information about some of the other ingredients of this medicine".

## **2.3 Taking other medicines**

There are no known interactions.

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

## **2.4 Taking Cystinol® N Solution with food and drinks**

No limitations are known.

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

The safety during pregnancy and breast-feeding has not sufficiently been investigated.

Pregnant women should avoid taking Cystinol® N Solution. It has to be taken into account that the application in women of childbearing age who do not use contraceptives should be considered carefully as a possibly existing pregnancy might not yet be known.

Due to insufficient data the use of Cystinol® N Solution during breast-feeding is not recommended.

Please ask your doctor or pharmacist before taking/applying any medicine.

## **2.6 Children**

There are no adequate data regarding the use of Cystinol® N Solution in children. Therefore, Cystinol® N Solution should not be taken by children under 12 years.

## **2.7 Driving and using machines**

No limitations are known.

## **2.8 Important information about some of the other ingredients of Cystinol® N Solution**

This medicine contains maltitol solution. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Cystinol® N Solution.

10 ml liquid contain 6 g maltitol, corresponding to approx. 0.5 bread units (BU). If you have to comply with a diabetic diet, you should consider this. The calorie value is 2.3 kcal/g maltitol solution. Maltitol solution can have a mild laxative effect.

Warning:

This medicine contains 24 Vol.-% alcohol. If the dosage instructions are observed, up to 1.9 g alcohol will be ingested per 10 ml with each intake. A health risk exists among others for liver patients, patients suffering from alcoholic disease, epileptics, patients with organic diseases of the brain, pregnant and breast-feeding women and children. The effect of other medicinal products may be impaired or increased.

### **3. How to take Cystinol® N Solution**

Always take Cystinol® N Solution exactly as directed in this package leaflet.

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

*for adults and adolescents from the age of 12 years*

3 times daily 2 measuring caps with 5 ml liquid, corresponding to a daily dose of 30 ml liquid.

There are no sufficient data for exact dosage recommendations in case of impaired liver function.

#### **3.2. Method of administration**

Cystinol® N Solution should be taken with sufficient liquid after the meals. Please note that not only during the intake but during the whole day plenty of liquid has to be drunk, because otherwise Cystinol® N Solution cannot act properly.

#### **3.3. Duration of use**

Without medical advice, Cystinol® N Solution should not be taken for longer than one week at a time and no more than 5 times a year.

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

#### **3.4 If you take more Cystinol® N Solution than you should**

Do not take more Cystinol® N Solution per day than stated in the directions for use or prescribed by your doctor. If you have inadvertently taken 5 or 10 ml (corresponding to 1 or 2 measuring caps) more than you should, this will normally not have any negative effects. The ingestion of amounts far beyond the directions for use, however, may cause complaints (e.g. gastrointestinal complaints with nausea and vomiting). In this case, you should consult a doctor, even if you experience no symptoms yet.

#### **3.5 If you forget to take Cystinol® N Solution**

Do not make up for a forgotten intake, but continue the intake of Cystinol® N Solution at the next scheduled time, as described in the dosage instructions or as prescribed by your doctor.

#### **3.6 If you stop taking Cystinol® N Solution**

No specific features have to be observed.

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® N Solution can cause side effects, although not every treated person gets them.

#### **Possible side effects**

Gastrointestinal disorders or allergic reactions may occur. The frequency of the mentioned side effects is not known.

After first signs of a hypersensitivity reaction have occurred do not take Cystinol® N Solution again and consult your doctor.

If you notice any side effects, please inform your doctor or pharmacist. This also refers to side effects not listed in this package leaflet. You may also report side effects directly to Bundesinstitut für Arzneimittel und Medizinprodukte, Abt. Pharmakovigilanz, Kurt-Georg-Kiesinger Allee 3, D-53175 Bonn, Website: [www.bfarm.de](http://www.bfarm.de). Your reporting of side effects may contribute to making available more information on the safety of this medicine.

## 5. How to store Cystinol® N Solution

Keep out of the reach and sight of children.

Do not use Cystinol® N Solution after the expiry date which is stated on the carton and on the bottle label after "use before". The expiry date refers to the last day of that month.

### **Storage conditions:**

Do not store the medicine in the refrigerator.

### **Information on shelf life after opening:**

The shelf life after opening the bottle is 3 months.

Please shake before use!

## 6. Further Information

### **What Cystinol® N Solution contains:**

10 ml (corresponding to 12 g) liquid for oral use contain:

active substances:

0.66–1.06 g thick extract of bearberry leaves corresponding to 185 mg hydroquinone derivatives, calculated as anhydrous arbutin, extractant: water

0.6 g thick extract of genuine golden rod herb (3–7 : 1), extractant: ethanol 13 % (m/m)

The other ingredients are:

Ethanol 96 % (V/V), maltitol solution, acesulfame potassium, purified water.

Ethanol content: 24 Vol.-%

### **What Cystinol® N Solution looks like and contents of the pack:**

The liquid is dark brown.

Original packs with 100 ml and 200 ml liquid.

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

Schaper & Brümmer GmbH & Co. KG

Bahnhofstraße 35

38259 Salzgitter

Germany

Tel.: +49 53 41 3 07-0

Fax: +49 53 41 3 07-124

[info@schaper-bruemmer.de](mailto:info@schaper-bruemmer.de)

<http://www.schaper-bruemmer.com>

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