

PATIENT INFORMATION LEAFLET
CYSTOPURIN® 3g Granules for Oral Solution

Potassium Citrate

EFFECTIVE RELIEF FROM THE SYMPTOMS OF CYSTITIS

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 Cystopurin 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.
- If you have any unusual effects after using this product, tell your doctor or pharmacist.

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1. What is Cystopurin and what is it used for

Cystopurin is used to relieve the symptoms of cystitis.

The active substance in Cystopurin is potassium citrate. Potassium citrate helps to relieve the symptoms of cystitis by making your urine less acidic, reducing the discomfort caused by acidic urine.

Cystitis is a distressing condition caused by an infection and/or inflammation of the bladder. It is normally no more than a painful nuisance and only rarely becomes more serious. Cystitis will occur in 4 out of 5 women at least once in their lifetime so it is a very common complaint and the attacks usually cause no lasting damage.

Cystitis can also occur in men and children, but this is quite rare and medical advice should be sought.

There are two types of cystitis: bacterial cystitis and non-bacterial cystitis.

- Bacterial cystitis is caused by bacteria that reach the bladder from the bowel. This may occur during sexual intercourse, or be due to ineffective/infrequent hygiene.
- Non-bacterial cystitis can be caused by a number of triggers including certain soaps, deodorants, insufficient water-based liquid intake, or even tight trousers.

The most common symptoms of cystitis are:

- A sharp stinging sensation on passing water
- An urge to pass water more frequently.

2. BEFORE YOU TAKE CYSTOPURIN

DO NOT take Cystopurin:

- If you are allergic (hypersensitive) to potassium citrate or any of the other ingredients in Cystopurin (listed in section 6, Further Information).
- If you have a history of kidney disease,

Before taking Cystopurin, consult your doctor if any of the following apply to you:

- A history of heart problems
- Urine that is dark or cloudy, or has blood in it
- Unusually heavy vaginal discharge
- Stomach, groin or back pain
- High body temperature and general tiredness
- You suffer from phenylketonuria, since this product contains aspartame.

Important information about some of the ingredients of Cystopurin:

The granules contain aspartame, a source of phenylalanine. This may be harmful to people with phenylketonuria.

Taking other medicines:

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

In particular, tell your doctor or pharmacist if you are taking ACE inhibitors (for high blood pressure) or diuretics that retain potassium (such as amiloride).

Taking Cystopurin with food and drink:

Cystopurin granules should be diluted in water. They can be taken with or without food.

While suffering from cystitis avoid alcohol, fruit juices, coffee and strong tea. You should also try to drink as much water as possible (at least 8 glasses per day).

Pregnancy and breast-feeding:

As with all medicines, Cystopurin should not be taken during pregnancy or breast-feeding, unless you are advised to do so by your doctor.

3. HOW TO TAKE CYSTOPURIN

Follow the directions below closely. You should ask your doctor or pharmacist if you are unsure how to use this medicine. Cystopurin is taken as a drink.

Adults and the elderly:

- Take the contents of one sachet dissolved in a small glass of cold water (200ml), three times daily for two days.
- All six sachets must be taken to complete the course of treatment.

Children over 6 years:

- Use only after advice from your doctor, and follow his/her directions carefully.

Cystopurin is not recommended for children under 6 years.

While suffering from cystitis avoid alcohol, fruit juices, coffee and strong tea. You should also try to drink as much water as possible (at least 8 glasses per day).

You should consult your doctor if symptoms return or persist after 48 hours of treatment.

If you take more Cystopurin than you should:

Tell your doctor straight away or contact the Accident and Emergency Department of your nearest hospital.

How to avoid Cystitis in the future:

- ✓ Try to drink plenty of fluids every day
- ✓ Take care of your personal hygiene. It can help if you and your partner wash carefully before and after sexual intercourse.
- ✓ Always go to the toilet as soon as you feel the need to pass water. Keeping your bladder flushed will help it work normally.
- X Try to avoid washing with perfumed soaps or using deodorants or perfumes around the vaginal area.

If you are still worried or have any questions about the symptoms or the treatment of cystitis, ask your doctor or pharmacist for advice.

4. POSSIBLE SIDE EFFECTS

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

Some people may experience stomach irritation. This can be minimised by diluting the content of the sachets with extra water or by taking it with or after meals.

If you react badly to the product in any way, tell your doctor or pharmacist immediately.

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 HPRC 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 medicine.

5. HOW TO STORE CYSTOPURIN

Keep out of the reach and sight of children.

Do not store above 25°C. Store in the original container.

Do not take Cystopurin after the expiry date which is stated at one end of the carton and on the sachet. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Cystopurin contains:

- The active substance is potassium citrate (3g).

The other ingredients are mannitol (E421), citric acid (anhydrous), aspartame (E951), natural flavouring cranberry type 14666: maltodextrin, Natural Flavouring Substances, Flavouring Preparations (including natural cranberry juice concentrate), silicon dioxide (E551), carmine (E120) and triacetin (E1518).

What Cystopurin looks like and contents of the pack:

Cystopurin granules are available in packs of 6 sachets for oral solution.

Cystopurin is manufactured by: Pharmapac UK Ltd, Bidston, Wirral CH41 7EL, UK.

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation Holder:

PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath

PARALLEL PRODUCT AUTHORISATION NUMBER: PPA 465/280/1

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Date of leaflet preparation by PCO Manufacturing: July 2014