

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

UROMITEXAN 100 mg/ml Solution for Injection or infusion (Mesna)

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

Throughout this leaflet, UROMITEXAN 100 mg/ml Solution for Injection or infusion will be called UROMITEXAN.

What is in this leaflet:

1. What UROMITEXAN is and what it is used for
2. What you need to know before you are given UROMITEXAN
3. How UROMITEXAN is given
4. Possible side effects
5. How UROMITEXAN is stored
6. Contents of the pack and other information

1 What UROMITEXAN is and what it is used for

The name of your medicine is UROMITEXAN.

UROMITEXAN is used to help reduce and prevent bleeding in the bladder (haemorrhagic cystitis) caused by cyclophosphamide and ifosfamide. UROMITEXAN helps to protect the lining of the bladder from damage caused by these two drugs. The body breaks down these two drugs to form products that can harm the bladder. UROMITEXAN works by helping to make these breakdown products less harmful. UROMITEXAN should only be given when you are also given cyclophosphamide or ifosfamide.

The damage to your bladder may show up as blood in your urine. Very small amounts of blood may not be seen, so your doctor or nurse will test your urine with a 'dipstick' or microscope to check for blood. If a larger amount of blood is in your urine, you will notice that it is red and very occasionally you may be able to see blood clots in it.

2 What you need to know before you are given UROMITEXAN

You will not be given UROMITEXAN if:

- you are allergic (hypersensitive) to UROMITEXAN or any of the other ingredients (listed in section 6). An allergic reaction can include shortness of breath, wheezing, rash, itching or swelling of the face and lips.

If you are not sure if you are allergic talk to your doctor, nurse or pharmacist before having UROMITEXAN.

Warnings and precautions

Talk to your doctor, nurse or pharmacist before you are given UROMITEXAN if:

- you have any problems with your immune systems called 'autoimmune' disease, such as rheumatoid arthritis or lupus, where your body's immune system attacks itself. Patients with an autoimmune disease treated with cyclophosphamide and UROMITEXAN could have an increased risk of allergic (hypersensitivity) reactions.

- you have experienced any side effects in the past when given a thiol-containing compound as there could be an increased risk of experiencing side-effects with UROMITEXAN. Examples of thiol-containing medicines are amifostine (used to reduce the toxicity of some chemotherapy products), penicillamine (used to treat rheumatoid arthritis) and captopril (used to treat hypertension or heart failure).

If any of these applies to you your doctor will only give you UROMITEXAN following careful consideration of the risks and benefits to you.

Using other medicines

UROMITEXAN is given with ifosfamide and cyclophosphamide. It does not react with these medicines, and is not known to react with any others.

However, always tell your doctor, nurse or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you have obtained without a prescription.

Pregnancy, breast-feeding and fertility

UROMITEXAN is only taken with ifosfamide and cyclophosphamide. If you are pregnant and your doctor thinks that you need treatment with these medicines, you will also need to have UROMITEXAN. Discuss pregnancy with your doctor before having this medicine.

Do not breast-feed while being treated with these medicines.

Tests while you are being given UROMITEXAN

UROMITEXAN does not prevent the damage to the lining of the bladder in all patients. Your doctor or nurse will want to check your urine regularly for blood with a special 'dipstick' or look at it under a microscope.

Tell your doctor, nurse or pharmacist if you are having any other urine tests because your medicines can affect the results. 'Dipstick' and other types of tests frequently used to monitor diabetes can be used to detect 'ketones' or Vitamin C levels in your urine. UROMITEXAN can interfere with these types of urine tests.

UROMITEXAN can also interfere with the results of certain laboratory tests for the creatine phosphokinase (CPK) enzyme. Your doctor or nurse are aware of this interference and different test methods will be used while you are receiving UROMITEXAN.

UROMITEXAN with food, drink and alcohol

Food does not affect the absorption and urinary elimination of UROMITEXAN.

Driving and using machines

Some of the side effects of treatment with UROMITEXAN might affect your ability to drive and use machines safely. Your doctor will decide if it is safe for you to do so.

Important information about some of the ingredients of UROMITEXAN

This medicinal product contains approximately 59 mg of sodium per 400 mg of Mesna. To be taken into consideration by patients on a controlled sodium diet.

What to do if you see a different doctor, or have to go to hospital

If you see any other doctor or have to go to hospital for any reason, tell them what medicines you are taking. Do not take any other medicines unless your doctor knows you are taking Mesna.

3 How UROMITEXAN is given

Taking this medicine

UROMITEXAN can be given as an injection or by mouth.

- When UROMITEXAN is given by injection, it will be given to you by a doctor or nurse. They will check the injection solution is not discoloured, hazy or contain any particles before it is given to

you.

- When UROMITEXAN is given by mouth, it will be mixed in a flavoured drink such as orange juice or cola which will make it taste pleasant and easier to swallow.
- While you are taking UROMITEXAN you should drink enough fluid every day to maintain a urine output of 100 ml per hour.
- This helps to dilute your urine and keeps a good flow of urine. It will help to protect your bladder. You should pass urine (empty your bladder) as normal when you need to. Do not try to change your usual pattern.

The recommended usual dose

- Your doctor will decide how much of the medicine you will need and when you will need it. Always take the medicine exactly as your doctor tells you.
- The dose will depend on:
 - the dose and timing of your treatment with ifosfamide or cyclophosphamide
 - if ifosfamide or cyclophosphamide is being given to you as tablets or injection
 - if you suffer from water infections (urinary tract infections)
 - if you have ever had signs of bladder damage from Ifosfamide or Cyclophosphamide before
 - if you have had radiation therapy near your bladder.

Use in children

Children generally urinate more frequently than adults. For children your doctor may need to shorten the interval between doses and/or increase the number of individual doses.

If you are not sure how you will be given your injection or when you should drink it, ask your doctor, nurse or pharmacist.

If you take more UROMITEXAN than you should

It is unlikely that you will be given more UROMITEXAN as an injection than you should, because it will be given to you by a trained and qualified person. They would stop the injection straightaway if too much was given.

If you are drinking it, and think you have had too much or if a child has swallowed any of your medicine, talk to a doctor or go to a hospital straight away. Always take the labelled medicine container with you whether or not there is any medicine left.

Taking too much of UROMITEXAN can cause symptoms such as nausea, vomiting, abdominal pain, diarrhoea, headache, fatigue, limb and joint pains, rash, flushing, low blood pressure, slow or irregular heartbeat, feeling of pins and needles like tingling, fever, and breathing difficulties.

A specific antidote treatment for UROMITEXAN overdose is not known.

If you forget to take UROMITEXAN

It is very important to have UROMITEXAN at the times your doctor has told you: these times will have been carefully worked out to make sure that your bladder is fully protected against damage.

- If you are being given an injection by a doctor or nurse, it is very unlikely that you will miss a dose. If you think that you have missed an injection, talk to your doctor or nurse as soon as possible.
- If you are being given UROMITEXAN as drink and you miss a dose, drink it as soon as you remember and talk to your doctor or nearest hospital immediately for advice

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

4 Possible side effects

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

Some of these side effects may be caused by cyclophosphamide or ifosfamide rather than UROMITEXAN, as they are always taken together.

Tell your doctor straight away, if you notice any of the following side effects, you may need urgent medical attention:

- The most severe adverse reactions associated with use of UROMITEXAN are:
 - Anaphylaxis. Signs of this would be shortness of breath, wheezing, rash, itching or swelling of the face and lips (hypersensitivity). Severe allergic reactions could lead to difficulty in breathing or shock, with a possible fatal outcome (anaphylactic shock, anaphylactic/anaphylactoid reaction).
 - Stevens-Johnson syndrome or toxic epidermal necrolysis which are life-threatening conditions which cause:
 - rash,
 - ulcers,
 - sore throat,
 - fever,
 - conjunctivitis,
 - blistering of the skin.
 - Drug rash with eosinophilia and systemic symptoms (DRESS) which is a life-threatening hypersensitivity reaction to drugs which can cause:
 - rash,
 - fever,
 - pain and swelling of internal organs,
 - swollen and tender lymph nodes,
 - changes in blood cells (eosinophilia).
- The most frequently occurring adverse reactions associated with use of UROMITEXAN, are:
 - feeling sick, headache, diarrhoea,
 - fever, flushing, rash,
 - infusion site reactions such as pain, swelling, itching, redness or rash around the injection site,
 - waves of sudden abdomen or stomach pain (colic),
 - light headedness, lack of energy, tiredness,
 - flu-like illness.

If you are actually sick (vomit) after taking UROMITEXAN as a drink, you may need to have UROMITEXAN by injection instead.

Other possible side effects include:

Blood and Lymphatic System

- swollen/enlarged lymph nodes (lymphadenopathy),
- decrease in the number of cells in your blood:
 - of red and white blood cells, as well as platelets (pancytopenia),
 - of white cells - which fight infection (leukopenia, lymphopenia),
 - of platelets - which help your blood clot (thrombocytopenia),
- abnormally high amounts of eosinophils, type of white blood cell produced in the bone marrow, either the blood or in body tissues (eosinophilia).

Metabolism and Nutrition

- decreased appetite,
- feeling dehydrated.

Psychiatric

- insomnia,
- nightmares.

Nervous System

- dizziness,
- fainting (syncope),
- sensation of tickling, tingling, burning, pricking (paresthesia),
- increased or abnormally painful sensitivity to touch (hyperesthesia),
- reduced sensitivity to touch (hypoesthesia),
- disturbance in paying attention,
- fits (convulsions).

Eyes

- blurred sight,
- sensitivity to light,
- inflammation of the eye (conjunctivitis),
- swelling around the eyes (periorbital oedema).

Heart and Circulation

- changes in the electrical patterns of your heart seen as abnormal ECG heart tracing patterns,
- changes in your heartbeat (palpitation),
- faster heart beat (tachycardia),
- low or high blood pressure (hypotension, hypertension).

Lungs

- nasal congestion,
- cough,
- severe, sharp pain when breathing in (pleuritic pain),
- dry mouth,
- difficulty in breathing or wheezing (bronchospasm),
- shortness of breath (dyspnea),
- vocal cord discomfort (laryngeal discomfort),
- nosebleeds (epistaxis),
- severe difficulty breathing (respiratory distress),
- decrease levels of oxygen in your body (hypoxia, oxygen saturation decreased),
- rapid breathing (tachypnea),
- coughing up blood or bloody sputum (hemoptysis),

Digestive system

- irritation of the lining of the mouth and digestive system (mucosal irritation),
- flatulence,
- burning pain in the area of the stomach,
- constipation,
- bleeding gums,
- inflammation of the lining of your mouth including ulcers (stomatitis),
- bad taste in mouth,

Liver

- increased levels of certain proteins produced by your liver called enzymes. Your doctor will do blood tests to test for these.
- inflammation of the liver which can cause jaundice, weight loss and malaise (hepatitis).

Skin and Subcutaneous Tissue

- itching (pruritus),
- excessive sweating (hyperhidrosis),
- itchy, red rash which can develop in to sores (erythema multiforme, erythema),
- ulceration or blistering,
- swelling of the deeper layers of the skin, caused by a build-up of fluid (angioedema),
- skin rash notable for pale red, raised, itchy bumps (urticaria),
- burning sensation.

Musculoskeletal and Connective Tissue

- muscle or joint pain (myalgia, arthralgia),
- back pain,
- pain in hands or feet (pain in extremity),
- jaw pain.

Renal and Urinary

- painful urination (dysuria),
- kidney failure (acute renal failure).

General Disorders and Administrative Site Conditions

- chills (rigors),
- chest pain,
- swelling of the face (face oedema),
- swelling of tissues, usually in the lower limbs, due to the accumulation of fluids (oedema peripheral),
- muscle weakness (Asthenia).

Investigations

- abnormal test results for measurements of blood clotting.

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

Republic of Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

Malta
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

5 How UROMITEXAN is stored

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
- Do not store the ampoules above 30°C. Keep them in the outer carton to protect them from light.
- If UROMITEXAN has been mixed for drinking, store the mixture in a fridge in a sealed container for no longer than 24 hours.

Medicines should not be disposed of via wastewater or household waste. If you have some UROMITEXAN in a drink left over, take them back to your hospital. These measures will help protect the environment.

6 Contents of the pack and other information

What UROMITEXAN contains

- Each 4 ml ampoule contains 400 mg mesna.
- Each 10 ml ampoule contains 1 g mesna.
- The other ingredients are: Disodium edetate, sodium hydroxide, sterile water (called 'water for injections').

What UROMITEXAN looks like and contents of the pack

The injection is a clear, colourless, sterile solution and is supplied in 4 ml and 10 ml clear glass ampoules. Each carton contains 15 ampoules.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation holder is:

Baxter Holding B.V.

Kobaltweg 49,
3542CE Utrecht,
Netherlands Send all enquiries to this address.

UROMITEXAN is manufactured by:

Baxter Oncology GmbH
Kantstrasse 2, 33790 Halle/Westfalen
Germany

Prasfarma SL
c/Sant Joan, 11-15
08560 Manlleu (Barcelona)
Spain

This leaflet was last revised in 06/2025.

For information about UROMITEXAN Injection or to request this leaflet in formats such as audio or large print please contact the Marketing Authorisation Holder: Tel: 01635 206345.

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TECHNICAL INFORMATION

UROMITEXAN 100 mg/ml Solution for injection for infusion

Presentation: Clear, glass ampoules containing a clear, colourless aqueous solution of mesna (sodium 2-mercaptoethane sulphonate) 400 mg in 4 ml and 1000 mg in 10 ml.

Indication: For the prophylaxis of urothelial toxicity, including haemorrhagic cystitis, microhaematuria and macrohaematuria in patients treated with MITOXANA or ENDOXANA in doses considered to be urotoxic.

Dosage and administration: For specific dosage information refer to the Summary of Product Characteristics.

Sufficient UROMITEXAN must be given to protect the patient adequately from the urotoxic effects of the oxazaphosphorine. The duration of UROMITEXAN treatment should equal that of the oxazaphosphorine treatment plus the time taken for the urinary concentration of oxazaphosphorine metabolites to fall to non-toxic levels. This usually occurs within 8-12 hours after the end of oxazaphosphorine treatment but may vary depending on the scheduling of the oxazaphosphorine. Urinary output should be maintained at 100 ml/hr (as required for oxazaphosphorine treatment) and the urine monitored for haematuria and proteinuria throughout the treatment period

Elderly: No specific information is available. Clinical trials have included patients over 65 years and no adverse reactions specific to this age group have been reported.

Children: Because of greater frequency of micturition, children may require shorter intervals between doses and/or to increase the number of individual doses.

Pharmaceutical precautions

Do not store above 30°C. Keep the container in the outer carton.

UROMITEXAN is chemically compatible with 0.9% saline or 5% dextrose for 36 hours and in dextrose/saline for 24 hours at room temperature.

UROMITEXAN and MITOXANA are chemically compatible with:

- (i) 0.9% saline and dextrose/saline solution for one week at room temperature
- (ii) Water for Injections for one week under refrigeration
- (iii) 5% dextrose solution for 24 hours at room temperature
- (iv) 0.9% saline solution for 28 days at room temperature

UROMITEXAN and ENDOXANA are chemically compatible with:

- (i) 10% dextrose solution for 2 hours at room temperature

UROMITEXAN is incompatible with platinum derivatives (e.g. Cisplatin, Carboplatin and nitrogen mustard) and must not be mixed in the same infusion solution.

UROMITEXAN does not contain a preservative. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours (less when combined with cyclophosphamide in dextrose, see above) at 2 to 8°C unless dilution has taken place in controlled and validated aseptic conditions.

When prepared for oral use UROMITEXAN can be stored in cola drinks or orange juice. The mixture should be kept in the fridge in a sealed container for not more than 24 hours.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. Any solutions which are discoloured, hazy, or contain visible particulate matter should not be used.

Further information is available to the medical and allied professions from the

Marketing Authorisation Holder:

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