PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

Uromitexan 400 mg injection

Mesna (sodium-2-mercaptoethane sulphonate)

Sugar free

Read all of this leaflet carefully before you are given UROMITEXAN

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. What UROMITEXAN is and what it is used for

UROMITEXAN contains the active substance mesna,

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 medicines. The body breaks down these two

medicines 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

UROMITEXAN should not be administered to you if:

- you are hypersensitive (allergic) to mesna, any other thiol containing medicines or any of the other ingredients of UROMITEXAN.
- you are pregnant or breastfeeding.

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

- Tell your doctor if you have previously been treated with UROMITEXAN or any other thiol containing medicine. Examples of medicines that are thiol compounds include amifostine (used to reduce the toxicity of some anti-cancer medicines), penicillamine (used to treat rheumatoid arthritis) and captopril (used to treat high blood pressure or heart failure).
- Tell your doctor if you have had an allergic reaction during previous treatment with UROMITEXAN or any other thiol containing medicine. These allergic reactions may have included any severe skin reactions (including severe rash, blisters, ulcers or peeling and swelling of the skin, skin reaction conditions (including Stevens-Johnson Syndrome, toxic epidermal necrolysis, erythema exudativum multiforme). These skin reactions may have been accompanied by fever, changes in blood pressure, irregular or fast heartbeats, difficulty in breathing, rapid breathing, cough, bloody sputum, blood abnormalities

(including the formation of blood clots in small vessels, decreased, increased or low levels of white blood cells, low levels of blood platelets, pancytopaenia (low levels of white blood cells, red blood cells, and platelets)), increased levels of liver enzymes in the blood, signs of kidney failure, nausea, vomiting, muscle or joint pain, generally feeling unwell, mouth sores or red and irritated eyes.

- Tell your doctor if you have any problems with your immune systems called 'autoimmune' disease, such as rheumatoid arthritis.

Take special care with UROMITEXAN

- Your doctor should take a urine sample before you are given UROMITEXAN to check for blood in your urine.
- Other laboratory tests may be performed to monitor your progress or to check for side effects. Be sure to keep all doctor and lab appointments.

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 whilst receiving UROMITEXAN, because it can affect the results. 'Dipstick' and other types of tests frequently used to monitor diabetes (to detect 'ketones' in the urine) or to check Vitamin C levels in your urine can be affected by UROMITEXAN.

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 URMITEXAN.

Children and adolescents

The safety of UROMITEXAN in children and adolescents (<16 years of age) has not been established.

Other medicines and UROMITEXAN

Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines).

UROMITEXAN is always given with oxazaphosphorines (cyclophosphamide or ifosfamide), UROMITEXAN does not react with these medicines.

UROMITEXAN does not affect the working of anti-cancer medicines like doxorubicin, carmustine (BCNU), methotrexate, vincristine or other medicines such as digitalis glycosides.

UROMITEXAN with food, drink and alcohol

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

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

You should not receive UROMITEXAN if you are pregnant or breastfeeding.

Driving and using machines

UROMITEXAN may cause light-headedness, drowsiness, dizziness, blurred vision or fainting, which could affect your ability to drive or use machines. Do not drive or perform other possibly unsafe tasks until you know how you react to treatment with UROMITEXAN.

UROMITEXAN contains sodium

UROMITEXAN contains approximately 59 mg of sodium per 400 mg mesna. This should be taken into consideration by patients on a controlled sodium diet.

3. How you will be given UROMITEXAN

You will not be expected to give yourself UROMITEXAN. It will be given to you by a person qualified to do so.

UROMITEXAN will be injected intravenously at the same time you receive your dose of oxazaphosphorine (cyclophosphamide or ifosfamide) medicine and then again four and eight hours later.

Your dose of UROMITEXAN will be determined by your doctor and will depend on the dose of oxazaphosphorine medicine that you have received.

You should be given UROMITEXAN on each day that you receive your oxazaphosphorine medicine.

If you receive more UROMITEXAN than you should

Since a healthcare professional will administer this medicine, he/she will control the dosage. However, in the event of overdosage, your doctor will manage the overdosage.

If you forget to take UROMITEXAN

Since a health care provider will administer UROMITEXAN, it is unlikely that the dose will be missed.

4. Possible side effects

UROMITEXAN can have side effects.

Not all side effects reported for UROMITEXAN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking UROMITEXAN, please consult your health care provider for advice.

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

If any of the following happens after you have received UROMITEXAN, tell your doctor immediately or go to the casualty department at your nearest hospital:

- A widespread skin rash with blisters, peeling skin and fever. These may be signs of Stevens-Johnson syndrome or toxic epidermal necrolysis.
- Anaphylaxis (a life-threatening allergic reaction). Signs of anaphylaxis include shortness of breath, wheezing, rash, itching or swelling of the face and lips. Severe allergic reactions could lead to difficulty in breathing or shock, with possible death.
- Hypersensitivity reactions that include skin eruption and abnormalities in your blood tests. These may be signs of a condition called drug rash with eosinophilia and systemic symptoms (DRESS).
- Yellowing of the skin and eyes, also called jaundice.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to UROMITEXAN. You may need urgent medical attention or hospitalisation.

Frequent side effects are:

- itching (pruritus)
- rash (can be red, itchy or with small bumps)
- flushing

- fainting (syncope)
- difficulty in breathing or wheezing (bronchospasm)
- shortness of breath (dyspnoea)
- painful urination (dysuria)
- swelling of lymph nodes (lymphadenopathy)
- bleeding gums
- irritation of the lining of the mouth or rectum (mucosal irritation)
- decreased appetite or feeling dehydrated
- sleeplessness or nightmares
- disturbance in paying attention
- dizziness or light-headedness
- headache
- increased or abnormally painful sensitivity to touch (hyperaesthesia)
- reduced sensitivity to touch (hypoaesthesia)
- lack of energy or drowsiness
- sensation of tickling, tingling, burning, pricking (paraesthesia)
- blurred vision
- inflammation of the eye (conjunctivitis)
- sensitivity to light (photophobia)
- sensation that you have a “pounding” heartbeat (palpitations)
- coughing
- dry mouth
- nosebleeds (epistaxis)
- vocal cord discomfort (laryngeal discomfort)
- nasal congestion
- severe, sharp pain when breathing in (pleuritic pain)
- stomach pain or burning pain in the area of the stomach

- constipation
- diarrhoea
- flatulence
- nausea or vomiting
- increased levels of enzymes produced by your liver. Your doctor will do blood tests to test for these
- excessive sweating (hyperhidrosis)
- joint pain (arthralgia), back pain, jaw pain, muscle pain (myalgia), pain in the extremities (hands and feet)
- fatigue
- fever
- flu-like symptoms
- injection site reactions (rash, pain, itching, swelling)
- chills (rigors)
- feeling of discomfort (malaise)

The frequency of the following side effects are unknown:

- anaphylactoid (life threatening allergic reaction) or hypersensitivity (allergic) reactions
- rash which can develop into sores (erythema multiforme, erythema)
- ulceration or blistering of the skin, including conditions known as Stevens-Johnson syndrome and toxic epidermal necrolysis
- skin rash notable for pale red, raised, itchy bumps (urticaria)
- swelling of the face (facial oedema)
- swelling around the eyes (periorbital oedema)
- swelling of tissues, usually in the lower limbs, due to the accumulation of fluids (peripheral oedema)
- swelling of the deeper layers of the skin, caused by a build-up of fluid (angioedema)

- kidney failure (acute renal failure)
- inflammation of the liver which can cause jaundice (hepatitis)
- difficulty breathing
- coughing up blood or bloody sputum (haemoptysis)
- decrease levels of oxygen in your body (hypoxia, reduced oxygen saturation)
- rapid breathing (tachypnoea)
- fits (convulsions)
- abnormal test results for measurements of blood clotting
- decrease in red and white blood cells, as well as platelets (pancytopenia)
- decrease (leukopenia) or low levels (lymphopenia) of white blood cells - which fight infection
- decrease of platelets - which help your blood clot (thrombocytopenia)
- abnormally high amounts of eosinophils, a type of white blood cell that fights infections or diseases (eosinophilia)
- electrocardiogram (a test that checks for problems with the electrical activity of your heart) abnormalities
- rapid heartbeat (tachycardia)
- low or high blood pressure (hypotension, hypertension)
- bad taste in mouth (dysgeusia)
- inflammation of the lining of your mouth including ulcers (stomatitis)
- burning sensation
- sensitivity to light
- asthenia (lack of energy, exhaustion, weakness)
- reactions at the infusion site (skin irritation, inflammation of the vein).

Side effects may occur after the first exposure to UROMITEXAN. In some cases, symptoms are not observed until after the second or third exposure. In general, the complete spectrum of

symptoms developed over a period of several hours. Following re-exposure, some patients experienced no further reactions while others experienced definite reactions.

In some patients experiencing skin reactions at the infusion site after receiving UROMITEXAN, subsequent exposure caused skin reactions at other locations.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of UROMITEXAN.

5. How to store UROMITEXAN

Store at or below 25 °C.

Do not use UROMITEXAN after the expiry date given on the package.

Store all medicines out of reach of children.

6. Contents of the pack and other information

What UROMITEXAN contains

The active substance is mesna (sodium-2-mercaptoethane sulphonate). Each ampoule contains 100 mg/ml mesna (400 mg per 4 ml).

The other ingredients are: sodium edetate, sodium hydroxide and water for injections.

What UROMITEXAN looks like and contents of the pack

UROMITEXAN is a clear, colourless liquid in a 5 ml clear glass ampoule with a blue OPC point and a 2 colour ring code: upper ring blue; lower ring green. UROMITEXAN is available as 15 or 50 x 5 ml ampoules containing 400 mg mesna per 4 ml.

Holder of Certificate of Registration

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