

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT
MITOXANA 1g and 2g Powder for Sterile Concentrate
Ifosfamide

Read all of this leaflet carefully before you start using 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 or nurse.
- 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 nurse. This includes any possible side effects not listed in this leaflet.

Throughout this leaflet, MITOXANA powder for sterile concentrate will be called MITOXANA.

Important things to know about MITOXANA

Your doctor has prescribed MITOXANA because you have cancer that can be treated.

MITOXANA is a medicine that kills cancer cells but, as a result, also attacks normal cells. It can therefore have a number of side effects. Your doctor will not give you MITOXANA unless he or she thinks that your cancer is more of a risk to you than any possible side effects. Your doctor will check you regularly and treat any side effects where possible.

MITOXANA:

- will reduce your blood cell count, which may make you feel tired and be more likely to get infections.
- can affect your kidneys and bladder. You may be given another medicine called UROMITEXAN to help prevent any damage. If you notice blood in your urine, tell your doctor immediately.
- can cause mental problems, such as confusion, feeling unusually sleepy and more seriously, fits and loss of consciousness. If you have these symptoms tell your doctor immediately.
- like most anti-cancer or chemotherapy medicines, you may lose your hair (anything from thinning to total loss), although it should start to grow back once your treatment has finished. It may also make you feel sick or be sick. Your doctor can give you advice or medicines to help.
- Men or women should not have a child during treatment with MITOXANA or for at least 6 to 12 months after treatment. You should use an effective contraceptive. Ask your doctor for advice.

Now read the rest of this leaflet. It includes other important information on the use of MITOXANA that might be especially important for you.

In this leaflet:

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

1 What MITOXANA is and what it is used for

MITOXANA is a cytotoxic drug or anti-cancer drug. It works by killing cancer cells, this is sometimes called 'chemotherapy'.

It is used to treat lots of different cancers. MITOXANA is often used together with other anti-cancer drugs or radiation therapy (radiotherapy).

2 What you need to know before you take MITOXANA:

You

will not be given MITOXANA if:

- if you are allergic to MITOXANA or any of the ingredients of this medicine listed in Section 6. An allergic reaction can include shortness of breath, wheezing, rash, itching or swelling of the face and lips
- you have a condition which decreases your ability to urinate (Urinary outflow obstruction)
- your bone marrow is not working properly (especially if you have previously had chemotherapy or radiotherapy). You will have blood tests to check how well your bone marrow is working

- you have problems passing urine or a urinary tract infection, which can be recognised as pain when passing urine (cystitis)
- your liver and kidneys are not working properly. You will have blood tests to check this.
- you currently have any infections
- you have had kidney or bladder problems as a result of previous chemotherapy or radiotherapy.
- you have condition which decrease your ability to urinate (Urinary outflow obstruction).

Warning and Precautions

Talk to your doctor or nurse before using MITOXANA if:

- you are already having, or have recently had, radiotherapy or chemotherapy
- you have diabetes
- you have liver or kidney problems
- if you have or had treatment with cisplatin before or during Mitoxana treatment
- you have poor general health or are frail
- you are elderly.

Take special care with MITOXANA :

- MITOXANA can have effects on your blood and immune system.
- Blood cells are made in your bone marrow. Three different types of blood cell are made:
 - red blood cells, which carry oxygen around your body
 - white blood cells, which fight infection, and
 - platelets, which help your blood to clot.
- After taking MITOXANA, your blood count of the three types of cells will drop. This is an unavoidable side effect of MITOXANA.. Your doctor will monitor your blood carefully.
- You may be more likely to get infections when your blood count drops. Try to avoid close contact with people who have coughs, colds and other infections.
- Your doctor will check that the number of red blood cells, white blood cells and platelets is high enough before and during your treatment with MITOXANA.
- MITOXANA can affect wound healing. Keep any cuts clean and dry, and check they are healing normally.
- It is important to keep your gums healthy, as mouth ulcers and infections can occur. Ask your doctor about this if you are unsure.
- MITOXANA can damage the lining of your bladder, causing bleeding into your urine. Your doctor knows this can happen and, if necessary, he or she will give you a medicine called UROMITEXAN which will protect your bladder.
- UROMITEXAN can either be given to you as a short injection, or mixed into the drip solution with your MITOXANA, or as tablets.
- More information on UROMITEXAN can be found in the Patient Information Leaflet for UROMITEXAN Injection and UROMITEXAN tablets.
- Most people having MITOXANA with UROMITEXAN do not develop any problems with their bladder, but your doctor may want to test your urine for the presence of blood using a 'dipstick' or microscope.
- If you notice that you have blood in the urine, you must tell your doctor right away.
- MITOXANA can damage your kidneys so that they do not work properly.
- This is more likely to happen if you only have one kidney or if your kidneys are already damaged.
- This is often temporary and they return to normal once MITOXANA therapy is stopped. Occasionally the damage is permanent and more severe.
- Your doctor will check your test results for signs of kidney damage.

- MITOXANA can have toxic effect on the brain and spinal cord and cause encephalopathy (non-inflammatory brain disease). Tell your doctor immediately if you experience any of the following, which may be signs of brain and spinal cord toxicity:

. confusion, sleepiness, unconsciousness/coma, hallucination/delusion, blurred vision, perception disorders, extrapyramidal symptoms (like continuous spasms, muscle contractions, motor restlessness, slowness of movement, irregular movements), lack of control over passing urine and seizures.

Your doctor or nurse may monitor you for signs and symptoms of brain and spinal cord toxicity.

- Cancer medicines and radiation therapy can increase the risk of you developing other cancers; this can be a number of years after your treatment has stopped.
- MITOXANA can cause damage to your heart or affect the rhythm of it beating. This increases with higher doses of MITOXANA, if you are being treated with radiation or other chemotherapy medicines or if you are elderly. Your doctor will monitor your heart closely during treatment.
- MITOXANA can cause inflammation or scarring in your lungs. This can occur more than six months after your treatment. If you start having difficulty breathing tell your doctor straight away.
- MITOXANA can have life threatening effects on your liver. If you have sudden weight gain, liver pain and jaundice tell your doctor straight away.
- Hair thinning or baldness can occur. Your hair should grow back normally though it may be different in texture or colour.
- MITOXANA can make you feel sick or be sick. This can last for about 24 hours after taking MITOXANA. You may need to be given medicines to stop feeling or being sick. Ask your doctor about this.

Other medicines and Mitoxana

Tell your doctor or nurse if you are taking or have recently taken any other medicines, including medicines you have bought yourself.

In particular, tell them about the following medicines or treatments as they may not work well with MITOXANA:

The following medicines can increase the toxicity of MITOXANA:

medicines that can increase the toxic effects on your blood cells and immunity:

- ACE inhibitors (used to treat high blood pressure).
- Carboplatin (used to treat cancer)
- Cisplatin (used to treat cancer)
- Natalizumab (used to treat multiple sclerosis)

medicines that can increase the toxic effects on your heart:

- anthracyclines such as bleomycin, doxorubicin, epirubicin, mitomycin (used to treat cancer)
- radiation in the area of your heart

medicines that can increase the toxic effects on your lungs:

- Amiodarone (used to treat irregular heart beat)
- G-CSF, GM-CSF hormones (used to increase white blood cell numbers after chemotherapy)

medicines that can increase the toxic effects on your kidneys:

- Acyclovir (used to treat viruses)
- Aminoglycosides (used to treat bacterial infections)
- Amphotericin B (used to treat fungal infections)
- Carboplatin (used to treat cancer)
- Cisplatin (used to treat cancer)

medicines that can increase the toxic effects on your bladder:

- Busulfan (used to treat cancer)
- Irradiation of the bladder

medicines with an effect on the brain such as those against vomiting and nausea, sleeping pills, certain painkillers (opioids), or allergy medicines

• **the following medicines can increase the toxicity of MITOXANA:**

- Carbamazepine ,Phenytoin, Phenobarbital (used to treat epilepsy)
- Corticosteroids (used to treat inflammation)
- Rifampin (used to treat bacterial infections)
- St. John's (a herbal remedy for mild depression)

the following medicines can reduce how effective MITOXANA is:

- Ketoconazole, Fluconazole ,Itraconazole (used to treat fungal infections)
- Sorafenib (used to treat cancer)

other medicines and MITOXANA :

- Docetaxel (used to treat cancer)
- Coumarins such as warfarin (used to thin the blood)
- Vaccines
- Tamoxifen (used to treat breast cancer)
- Cisplatin (used to treat cancer).
- Irinotecan (used to treat cancer)

Using MITOXANA with food, drink, and alcohol

Drinking alcohol can increase the nausea and vomiting caused by MITOXANA.

Pregnancy, breast-feeding and fertility

Do not become pregnant while taking MITOXANA. This is because it can cause miscarriage or damage your unborn baby. Tell your doctor if you are pregnant, think you might be pregnant or are trying to become pregnant.

- Men or women should not try to have a child during or for at least 6 to 12 months after treatment. You should use an effective contraceptive. Ask your doctor for advice.
- MITOXANA can affect your ability to have children in the future. Talk to your doctor about freezing sperm samples or eggs before your treatment starts.

Do not breast-feed while being treated with MITOXANA. Ask your doctor for advice.

Driving and using machines

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

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 MITOXANA.

3 How to take MITOXANA

MITOXANA will be given to you by a doctor or nurse.

- MITOXANA will normally be added to a large bag of fluid and will be slowly injected (infused) directly into your vein. The vein can be in your arm, the back of your hand or a large vein under your collar bone. Depending on your dose, the injection usually takes several hours but may be given over several days.
- MITOXANA is often given with other anti-cancer drugs or radiotherapy.

The usual dose

- Your doctor will decide how much of the medicine you need and when you should take it.
- The amount of MITOXANA you will need to take depends on:
 - the type of illness you have
 - how big you are (a combination of your height and weight)
 - your general health
 - whether you are being given other anti-cancer drugs or having radiotherapy.

MITOXANA is usually given as a series of courses of treatment. After a course there is a break (a period when no injections are given) before the next course.

If you are given too much MITOXANA

It is unlikely that you will be given more MITOXANA 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.

4. Possible side effects

Like all medicines, MITOXANA can cause side effects, although not everybody gets them. The following side effects may happen with this medicine.

Tell your doctor straight away, if you notice any of the following serious side effects:

- getting bruises without knocking yourself, being slow to stop bleeding or bleeding from your nose or gums. This may be a sign that the platelet levels in your blood are getting too low
- a lowering of your white blood cell count, your doctor will check this during your treatment. It will not cause any signs, but you will be more likely to get infections. If you think you have an infection (a high temperature, feeling cold and shivery, or hot and sweaty, or any signs of infection such as a cough, or stinging on passing water) you may need antibiotics to fight infections because your blood count is lower than usual
- very pale, lethargic and tired. This may be a sign of low red blood cells (anaemia). Usually, no treatment is required, your body will eventually replace the red blood cells. If you are very anaemic, you may need a blood transfusion
- blood in your urine, pain, or less being passed
- mental problems. In some people MITOXANA can affect the brain. Sometimes people on MITOXANA do not realise that they have been affected but friends and relatives may notice a change in them. If any of the following side effects are seen your doctor will stop your treatment with MITOXANA.

- confusion
- sleepiness
- unconsciousness/coma
- disorientation
- restlessness
- depression
- hallucinations
- delusions (false beliefs)
- blurred vision
- perception disorders
- extrapyramidal symptoms (like continuous spasms, muscle contractions, motor restlessness, slowness of movement, irregular movements)
- rapid speech
- repeating words
- being fixed on a task
- lack of control over passing urine
- seizures loss of consciousness

These side effects may be accompanied by a fever or rapid heartbeat.

Other possible side effects may be:

Immune system and Infections

- allergic reactions, 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)
 - reduction in the effectiveness of your immune system (immunosuppression).
 - increased risk and severity of bacterial, fungal, viral, protozoal or parasitic infections due to the effect of cyclophosphamide on your immune system
 - reactivation of infections you have had before (latent infections)
- severe infection spreading through the blood which may lead to a dangerous drop in blood pressure with a possible fatal outcome (sepsis, shock).
- swelling of the skin around the face, inside of the mouth and throat (angioedema) with a possible fatal outcome
 - a skin rash of red itchy swellings (urticaria)

Cancers

secondary tumours in various parts of the body, often in the area of the bladder

- progression of underlying cancers with a possible fatal outcome
- cancer of the bone marrow (myelodysplastic syndrome)
- cancer of your blood (leukaemia) with a possible fatal outcome
- cancer of the lymphatic system (Non-Hodgkin's lymphoma)

Blood and Lymphatic System

- decrease in the activity of your bone marrow (myelosuppression).

This can cause a decrease in the number of cells in your blood:

- white cells - which fight infection (leucopenia, agranulocytosis, granulocytopenia, lymphopenia, neutropenia). This may be associated with fever (febrile neutropenia) This may be associated with fever (febrile neutropenia)
- platelets - which help your blood clot (thrombocytopenia)
- red cells - which carry oxygen around the body (anaemia).

This may be associated with a decrease in their ability to carry oxygen (decreased haemoglobin)

- red cells white cells and platelets at the same time (pancytopenia)
- formation of small blood clots in your blood vessels disrupting the normal blood flow around your body (disseminated intravascular coagulation)
- haemolytic uremic syndrome – a condition causing abnormal break down of the red blood cells, decreased numbers of platelets in the blood and kidney failure.
- Endocrine System increase in the release of antidiuretic hormone from the pituitary gland. This affects the kidneys causing the low levels of sodium in your blood (hyponatremia) and water retention.

Metabolism and Nutrition

- loss or decrease of appetite (anorexia)
- changes to your metabolism caused by the breakdown of the dying cancer cells (Tumour lysis syndrome)
- increase of acidity of body fluids (metabolic acidosis)
- low blood levels of potassium which can cause abnormal heart rhythms , constipation, fatigue, muscle weakness or spasms, depression, psychosis, delirium, confusion, or hallucinations (hypokalemia).
- low blood levels of calcium which can cause muscle cramps and twitching, irregular heartbeat, overactive reflexes, and burning or tingling sensations in the hands and feet (hypocalcemia).
- low blood levels of phosphate which can cause bone pain, confusion and muscle weakness (hypophosphatemia)
- high blood sugar levels which can cause thirst, tiredness and irritability (hyperglycaemia)
- excessive thirst that is also accompanied by excessive fluid intake (polydipsia).

Digestive system

- feeling sick and being (nausea, vomiting).
- diarrhoea
- inflammation of the lining of your mouth including ulcers (stomatitis)
- inflammation of your intestines or bowel which may resulting in bleeding (enteritis, cecitis, enterocolitis)
- inflammation which causes abdominal pain or diarrhoea (colitis)
- bleeding in your stomach or intestines (gastrointestinal haemorrhage)
- severe tummy and back pain (inflammation of the pancreas).
- ulceration of the lining of the digestive system (mucosal ulceration)
- constipation
- increased saliva production

- abdominal pain

Nervous System

- a disorder of the nerves which can cause weakness, tingling or numbness (peripheral neuropathy). This could be in more than one set of nerves (polyneuropathy)
- having difficulties in controlling or coordinating the muscles you use when you speak, or weakness of those muscles (Dysarthria)
- fits (convulsions) with possible fatal outcomes
- a syndrome called Status epilepticus (convulsive and nonconvulsive) defined as one continuous, unremitting seizure lasting longer than 5 minutes, or recurrent seizures without regaining consciousness between seizures for greater than 5 minutes.
- a syndrome called Reversible posterior leukoencephalopathy syndrome, which can cause swelling of the brain, headache, confusion, fits and loss of sight
- effects on the brain (encephalopathy), signs of this can be problems in thinking or concentrating, reduced alertness, changes in personality, tiredness, fits, muscle twitching, and shaking
- dizziness
- movement disorders and gait disturbances (movement disorders, extrapyramidal disorder, gait disorder) effects on the spinal cord (Myelopathy), which can cause numbness, weakness and tingling in the hands, loss of motor skills
- flapping tremor of the hand (asterixis)
- pain from your nerves, which can also feel like an aching or burning sensation (neuralgia)
- tingling or numbness, often in the hands or feet (paresthesia)
- changes in your sense of touch (dysesthesia) or loss of sensation (hypoesthesia)
- inability to control bowel movements (fecal incontinence).

Psychiatric conditions:

- sudden episode of intense fear that triggers severe physical reactions when there is no real danger or apparent cause (panic attack)
- feeling of being threatened in some way or false beliefs (paranoia, delusions)
- delirium and other changes in mental status
- slowness of thought processes and processing of information; inattentiveness (bradyphrenia)
- inability to speak (mutism), meaningless repetition of another person's spoken words (echolalia) or excessive and often incoherent talkativeness or wordiness (logorrhea)
- lack of movement and communication which can include agitation, confusion, and restlessness (catatonia)
- period of abnormally elevated, extreme changes in mood or emotions, energy level or activity level (mania)
- repetitive and continuous behaviour, speech or thought that occurs due to changes in memory or attention (perseveration)
- amnesia

Eyes and Ears

- blurring, reduction or loss of sight
- inflammation of the eye (conjunctivitis)
- irritation of the eyes
- deafness or hearing impairment
- ringing in the ears (tinnitus).
- Dizziness or feeling of spinning (vertigo)

Heart and Circulation

- damage to the heart muscle (cardiotoxicity) with possible fatal outcomes
- changes in your heart rhythm (arrhythmia) which may be noticeable (palpitations):
 - irregular heart beat (fibrillation)
 - faster heart beat (tachycardia), which may be life threatening (ventricular tachycardia)
 - slower heart beat (bradycardia)
- heart attack (myocardial infarction)
- decrease in your heart's ability to pump enough blood around your body which may be life threatening (cardiogenic shock, heart failure or cardiac arrest) with possible fatal outcomes
- disease of the heart muscle (cardiomyopathy, congestive cardiomyopathy) with possible fatal outcomes
 - bleeding into the muscles of the heart (myocardial hemorrhage)
 - chest pain from reduced blood supply to the heart (angina pectoris)
- inflammation of the tissues in or around your heart (myocarditis, pericarditis)
- build up of fluid in the sac around your heart (pericardial effusion). Increased pressure from this fluid can stop the heart filling properly (cardiac tamponade)
- abnormal ECG heart tracing .
- blood clot in the lungs which causes chest pain and breathlessness (pulmonary embolism)
- blood clot, usually in a leg, which causes pain swelling or redness (deep vein thrombosis)
- inflammation of the blood vessels (vasculitis)
- low or high blood pressure (hypotension, hypertension)
- reddening of the skin (flushing)

Lungs

- life-threatening decrease of your lungs ability to transfer oxygen into your blood (respiratory failure), some with fatal outcomes
- conditions causing inflammation of the lungs which can cause breathlessness, cough and raised temperature or scarring of the lungs (pneumonitis, acute respiratory distress syndrome, alveolitis allergic)
- scarring of the lungs which causes shortness of breath (pulmonary fibrosis, interstitial lung disease), some with fatal outcomes
- fluid in or around the lungs (pulmonary oedema, pleural effusion)
- increased blood pressure in the lungs which can cause shortness of breath, fatigue, cough, angina, fainting, peripheral oedema (pulmonary hypertension)
- difficulty in breathing or wheezing (bronchospasm)
- shortness of breath (dyspnea)
- decrease levels of oxygen in your body (hypoxia)
- cough

Liver

- a build up of toxins in the body due to liver failure (hepatotoxicity).
- liver failure
- blockage of the small veins in your liver (veno-occlusive liver disease) which can cause weight gain, increased liver size, pain and jaundice
- reduction of blood supply or blockage of the portal vein of the liver (portal vein thrombosis)
- Inflammation of the liver which can cause jaundice, weight loss and malaise (cytolytic hepatitis, fulminant hepatitis)
- conditions causing inflammation of the liver which can cause jaundice, weight loss and malaise (hepatitis)
 - disruption of the formation of bile by the liver which can cause itchiness, jaundice, pale coloured stools, dark urine (cholestasis)

Skin and Subcutaneous Tissue

- hair loss (alopecia).
- skin eruption or reaction consisting of small, round, raised bumps that have clear borders (popular rash)
- inflammation of this skin which may cause rash, blisters, itching, sores, oozing and scarring (dermatitis)
- life threatening conditions which cause rash, ulcers, sore throat, fever, conjunctivitis, separation of skin layers (toxic epidermal necrolysis, Stevens-Johnson syndrome)
- swelling, numbness, red lumps and peeling of skin on the hands and feet (Palmar-plantar erythrodysesthesia syndrome)
- redness and blistering of the skin appearing months or years after treatment (Radiation recall dermatitis)
 - red, warm, or swollen area of skin that results in the death of skin and nearby tissues (skin necrosis)

- pinpoint, round spots that appear on the skin as a result of bleeding (petechiae)
- skin eruption in which the lesions are flat and less than 1 cm in diameter macular rash
- itching (pruritis)
- itchy, red rash which can develop into sores (erythema)
- changes in colour of your fingernails and skin.
- separation of the nail bed which can cause nails to fall off
- swelling of the face
- excessive sweating (hyperhidrosis)
- rash

Musculoskeletal and Connective Tissue

- abnormal muscle breakdown which can lead to kidney problems (rhabdomyolysis)
- softening of the bones that could cause severe bone pain, pain caused by slight crack in the bone back pain, partial or complete fractures and muscle weaknesses (osteomalacia, rickets)
- growth retardation
- muscle pain (myalgia) or joint pain (arthralgia).
- discomfort sensation in the upper or lower extremities (pain in extremity)
- muscle spasms

Renal and Urinary

- inflammation of the bladder lining which causes pain, bleeding, blood in the urine, reduced urine flow (haemorrhagic cystitis)
- blood in the urine (haematuria)
- life threatening decrease in the abilities of your kidney to adequately remove toxins and waste products from the blood (renal dysfunction, renal failure)
- changes to the structure of your kidneys which prevent them from working correctly (renal structural damage)
- kidney malfunction leads to excessive urine production and excessive thirst, resulting in deficits of water, calcium, potassium, magnesium, and other substances in the body (fanconi syndrome)
- inflammation of the kidneys (tubulointerstitial nephritis)
- glucose in the urine (nephrogenic diabetes insipidus)
- kidney malfunction causing urine to appear cloudy or murky color (phosphaturia)
- kidney malfunction causing Increased of total urine amino acids into urine(aminoaciduria).Your doctor will do urine tests to test for these.
- condition usually defined as excessive or abnormally large production or passage of urine (polyuria)
 - repeated inability to control urination (enuresis)
- feeling of residual urine

Pregnancy and Fertility

- infertility. Sperm production in men and egg production in women may be reduced or stop. In some cases this can be permanent
- loss of ovarian function before age 40 (ovarian failure , premature menopause)
- absence of menstrual periods (amenorrhea) or absence of ovulation (ovulation disorder)
- absence of measurable level of sperm in male semen (azoospermia) or less number of sperm in the ejaculate of the male (oligospermia)

Congenital, Familial and Genetic Disorders

- reduction in growth, deformity or death of a foetus while in the womb

General Disorders and Administrative Site Conditions

- inflammation of a vein, usually in the legs (phlebitis)
- development of a fever, commonly in conjunction with signs of infection (neutropenic fever)
- fatigue
- feeling of general discomfort or uneasiness (malaise)
- life threatening failure of multiple organs , some with fatal outcomes
- general physical deterioration
- appearance of skin changes and irritation or pain at the site of injection or infusion
- chest pain
- swelling

- inflammation of the linings of your body cavities (mucosal inflammation).
- flu-like symptoms such as headache, fever, chills, joint and muscle pain, weakness, tiredness

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

HPRA Pharmacovigilance

Website: www.hpra.ie

Malta

ADR Reporting

Website: www.medicinesauthority.gov.mt/adrportal

5 How to store MITOXANA

Because MITOXANA is usually given in hospital it will be stored safely and correctly by the hospital staff. If you do need the storage conditions they are given below.

- Keep this medicine out of the sight and reach of children.
- Do not use MITOXANA 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 above 25°C. Store in the original container.
- MITOXANA should be inspected visually for particulate matter and discoloration prior to administration.

6 Contents of the pack and other information

What MITOXANA contains

The active substance is Ifosfamide and each vial contains 1 g or 2 g.

There are no other ingredients.

What MITOXANA looks like and contents of the pack

MITOXANA is a dry white powder supplied in clear glass vials. Each carton contains 1 vial.

Nature and contents of container

Vials are packed with or without a protective plastic overwrap. Protective plastic overwrap does not come into contact with the medicinal product and provides additional transport protection, which increases the safety for the medical and pharmaceutical personnel.

The contents of each vial has to be mixed with sterile water (called 'water for injections') before use.

Appearance following reconstitution: clear and colourless solution. Do not use if solution does not match this description.

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.

MITOXANA is manufactured by:
Simtra Deutschland GmbH
Kantstrasse 2
33790 Halle/Westfalen Germany

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For information about MITOXANA or to request this leaflet in formats such as audio or large print please contact the Marketing Authorisation Holder: Tel: +44 1635 206345.

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