PATIENT INFORMATION LEAFLET

MITOCYTE® (MITOMYCIN INJECTION USP 2mg, 10mg, 20mg, 40 mg)

Read all of this leaflet carefully before you start using this medicine.

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

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 MITOCYTE IS AND WHAT IT IS USED FOR

Mitomycin can be used to treat different types of cancers in many different parts of the body as described below:

• In bladder cancer Mitomycin can be administered by injection or, alternatively by instillation directly into the bladder after surgery to reduce the chances of a recurrence of the condition.

• In certain types of cancer of the stomach, pancreas, oesophagus, lower bowel, biliary tract and lung Mitomycin can be used in combination with other drug treatments.

• In a type of cancer of the anus, Mitomycin can be used in combination with other drug treatments or with radiotherapy.

• In a certain type of breast cancer, Mitomycin can be used as a single agent or in combination with other drug treatments.

2. BEFORE YOU USE MITOCYTE

Do not use MITOCYTE if you:

• are allergic (hypersensitive) to mitomycin or any of the other ingredients of MITOCYTE (listed in section 6)

• have certain types of blood disorders, e.g. if your bone marrow is not making enough blood cells (your doctor will check for this using blood tests), suffer from problems with blood clotting or bleeding, liver or kidney disorders, or have any active infections. Please tell your doctor if you have any of these problems and he will discuss with you whether this medicine is appropriate for you.

Take special care with MITOCYTE if you:

- have liver or kidney problems; side effects of mitomycin may be more noticable.
- are capable of child-bearing as mitomycin may affect your ability to have children in the future
- have bone marrow depression (your bone marrow is not able to make the blood cells you need); it may be made worse (especially in the elderly)
- have an infection (including chickenpox) it may be aggravated and may lead to fatal conditions.

Special attention will be paid if this product is administered to the elderly or to children due to the possible side effects in these groups.

Treatment with MITOCYTE will be administered to you under the supervision of a medical doctor who is experienced in cancer chemotherapy. This person will therefore take all the necessary precautions for the safe administration of this product to you.

Other medicines and MITOCYTE

Tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, or been given other treatments (e.g. radiotherapy).

Mitomycin may interact with certain other types of drugs:

• When given together with certain other cancer treatment there have been some reports of problems relating to bone marrow and the occurrence of cancer involving various types of blood cells.

• When given together with doxorubicin the potential for doxorubicin to cause heart damage may be made worse.

• When taken together with vinca alkaloid agents (such as vincristine) that are used in cancer treatment, shortness of breath, coughing, wheezing and tightness in the chest may occur.

Pregnancy and breast-feeding

Mitomycin should not be given if you are pregnant, may be pregnant, or to mothers who are breast-feeding because animal studies have shown a possible risk of abnormalities in the developing foetus. Ask your doctor for advice before taking any medicine.

Driving and using machines

Some people have reported that they feel tired or weak after the treatment. Do not drive or use any tools or machines if you are affected.

3. HOW TO TAKE MITOCYTE

The precise dosage and frequency of administration of MITOCYTE will depend on your age, weight, medical condition and whether MITOCYTE is being given in combination with other drug treatment.
The dosage may be decreased if side-effects are a problem. MITOCYTE is usually administered by injection or as an infusion (with a drip). However in the treatment or the prevention of the recurrence of bladder cancer, a solution of MITOCYTE will be instilled directly into the bladder through a catheter.

The recommended dose is given at 1-6 weekly intervals. A course ranging from 40-80 mg is often required for a satisfactory result when used alone or in combination with other treatments. The period of treatment could last from just a few weeks up to a number of months, depending on the condition being treated.

In the treatment of bladder cancer, the usual dose is 20-40 mg administered into the bladder, weekly or three times a week for a total of 20 doses. The dosage may be decreased if side effects are a problem.

If during treatment you develop a dry cough, breathlessness, rapid breathing or anything else which suggests your lungs might be affected, you may require to be monitored by X-rays of

your chest that could continue up to 4 weeks after the end of treatment.

If you are given more MITOCYTE than you should

If you have been accidentally given a higher dose you may experience symptoms such as fever, nausea, vomiting and blood disorders. Your doctor may give you supportive treatment for any symptoms that may occur

4. POSSIBLE SIDE-EFFECTS

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

If you notice any of the following severe reactions **tell your doctor immediately**:

• severe breathlessness
• fever, chills, shortness of breath or a cough
• severe allergic reaction – you may experience a sudden itchy rash (hives), swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing), and you may feel you are going to faint.
• intravenous injection site reactions - you may experience severe pain, redness of the skin, blisters or ulcers around the site of the injection.

If you experience any of the following **tell your doctor as soon as possible:**

• loss of appetite and weight loss
• tiredness, weakness and headache
• feeling or being sick
• sore mouth or mouth ulcers
• diarrhoea, abdominal pain or discomfort, constipation, or jaundice
• hair loss
• significant changes in the frequency of urination, passing blood in the urine or pain when urinating
• rapid weight gain or swelling of the legs
• any infections
• bleeding (including in the vomit or faeces) or bruising
• severe damage and potentially rupture of the wall of the bladder resulting in severe lower abdominal pain, difficulty or inability to pass urine, and possibly blood in the urine.
• severe damage to the penis resulting in pain in the penis, abnormal colour of the penis and potential difficulty in passing urine.

Treatment with MITOCYTE can result in blood disorders and bone marrow depression such as

• reduction in white and red blood cells and platelets (pancytopenia)
• reduction in red blood cells (anaemia)
• reduction in white blood cells (leucopenia),
• reduction in a type of white blood cell known as neutrophils (neutropenia),
• reduction in blood cells involved in clotting, known as platelets (thrombocytopenia), bleeding tendency, and disorders of the blood coagulation system (thrombotic thrombocytopenic purpura, haemolytic uraemic syndrome)

You may have symptoms such as weakness, tiredness, shortness of breath, bleeding or bruising or develop infections. If you develop any of these, please tell your doctor as soon as possible.

Various forms of blood cancer or serious bone marrow abnormalities have been reported including:

• acute leukaemia
• acute myeloid leukaemia

• myelodysplastic syndrome

These disorders may be associated with anaemia, bleeding, infections, feeling sick, having fevers, chills, night sweats and other flu-like symptoms, or feeling fatigued. Your blood will be monitored during the course of treatment for signs of undesirable effects on the blood, and the treatment amended accordingly.

Nausea, vomiting, are sometimes experienced immediately after treatment, but these are usually mild and of short duration.

Other possible side effects include:

Difficulty in breathing or cough, weight loss, constipation, pain in the abdomen, fever, chills, loss of hair, bleeding, rashes, mouth ulcers or inflammation, swelling, and inflammation of the lining of the mouth, general weakness and tiredness have been reported on rare occasions, so if you are affected you should not drive or operate machinery, loss of appetite and diarrhoea have also been reported

5. HOW TO STORE MITOCYTE

Keep out of the reach and sight of children.

Do not use MITOCYTE after the expiry date which is stated on the carton and on the vial label. The expiry date refers to the last day of that month.

Do not store above 25°C. Do not refrigerate or freeze.

For single use only. Discard any unused contents.

After reconstitution, the solution should be used immediately.

Do not use MITOCYTE if you notice signs of deterioration.

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

6. FURTHER INFORMATION

What MITOCYTE contains

- The active substance is mitomycin

Each vial of MITOCYTE contains 2mg, 10 mg, 20mg or 40mg of mitomycin.

The other ingredient is sodium chloride

What MITOCYTE looks like and contents of the pack

MITOCYTE is a powder for solution for injection. It is a blue/purple crystalline powder.

It is packaged in colourless glass vials with a rubber stopper and aluminium seal. The vials are packaged cardboard cartons and are available in packs containing 1 or 5 vials each. Not all pack sizes may be marketed.

Manufactured By:

TAJ PHARMACEUTICALS Ltd.
Mumbai, INDIA

Marketed By:

TAJ PHARMA INDIA LTD.
CRESCENT, SAHAR AIRPORT ROAD,
MUMBAI, MAHARASHTRA 400059
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