MUPHORAN®

fotemustine (pronounced fo-te-mus-teen)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions about MUPHORAN. It does not contain all the available information. Reading this leaflet does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being treated with MUPHORAN against the expected benefits for you.

If you have any concerns about being treated with this medicine, ask your doctor, pharmacist, or oncology nurse.

Keep this leaflet in a safe place.
You may need to read it again.

What MUPHORAN is

The name of your medicine is MUPHORAN. The active ingredient of MUPHORAN is called fotemustine. Fotemustine is a type of chemotherapy that belongs to a group of anti-cancer agents called nitrosoureas (pronounced ni-tro-so-u-ree-as).

What MUPHORAN is used for

You have been prescribed MUPHORAN for melanoma (also known as malignant melanoma).
MUPHORAN is available only with a prescription - usually from an experienced cancer specialist (also known as an oncologist).

Why MUPHORAN is used for melanoma

Melanoma is a type of skin cancer. Sometimes melanoma spreads from the skin to the lung, liver, bowel, or brain.

MUPHORAN works by stopping the rapid growth of some types of cancer cells.

MUPHORAN treatment can shrink and slow the growth of melanoma tumours for some patients. Other patients may not have a useful treatment response from MUPHORAN.

Ask your doctor if you have any questions about why you are being treated with MUPHORAN.

Before you are treated with MUPHORAN

There are some people who shouldn't be treated with MUPHORAN. Please read the following lists. If you think any of these situations apply to you or you have any questions, please consult your doctor, pharmacist, or oncology nurse.

When you must not be treated with MUPHORAN

- **You are allergic to fotemustine or any other nitrosourea.**
  Symptoms of an allergic reaction to MUPHORAN may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin
- **You are pregnant or trying to become pregnant.**
  The affect of MUPHORAN on your developing baby if you are treated with it during pregnancy is unknown. Other medicines similar to MUPHORAN have been shown to affect the developing baby.
- **You are breast-feeding or plan to breast-feed.**
  It is unknown whether MUPHORAN is excreted in breast milk and therefore the risk to the breast-fed baby is unknown.
- **You have been or are intending to be vaccinated with the yellow fever vaccine.**
  The combination of MUPHORAN and the vaccine can result in a fatal reaction.
- **If you are a child or adolescent.**

Before you start to be treated with MUPHORAN

Tell your doctor if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially the following:

- You become pregnant while taking MUPHORAN.
- You have problems with the number of white cells or platelets

in your blood which you may notice as bleeding or bruising more easily than normal.
- You have had other chemotherapy in the last 4-6 weeks.
- You have other health problems, including kidney disease.
- You drink substantial quantities of alcohol or have an alcohol-related disorder.
- You have received or are intending to receive any vaccine.

Tell your doctor if you are breast-feeding or plan to breast-feed.
Your doctor or pharmacist will discuss the possible risks and benefits of using MUPHORAN during breast-feeding.

Taking other medicines

Tell your doctor, pharmacist or oncology nurse if you are taking any other medicines, including medicines that you buy without prescription from your pharmacy, supermarket or health food shop.

Some medicines and MUPHORAN may interfere with each other. These include:

- Phenytoin (a medicine used to treat epilepsy and/or convulsions).
- Certain vaccines while you are being treated with MUPHORAN is not recommended.
- Immunosuppressants (medicines which lower the body's resistance to disease).
- Dacarbazine (another medicine used to treat skin cancers).
- Medicines used to prevent blood clots, e.g. warfarin.

Being treated with MUPHORAN may change the effect of some medicines, and some medicines may affect how well MUPHORAN works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist may have more information about which medicines to be careful with or avoid while you are being treated with MUPHORAN.

For older people

Older people can generally be treated with MUPHORAN however, additional care may be required to minimise side effects of treatment.

How MUPHORAN is given

Only experienced cancer specialists treat patients with MUPHORAN. They select a dose depending on your height and weight. MUPHORAN may be given alone or with other chemotherapy drugs.

Treatment is divided into phases.

First phase of treatment:

- When MUPHORAN is the only chemotherapy used during treatment, then the first phase of treatment consists of one slow injection of MUPHORAN (a "drip") into a vein or an artery once a week for 3 consecutive weeks.
- When MUPHORAN is used with other chemotherapy then the first phase of treatment consists of one slow injection of MUPHORAN (as above) once a week for 2 consecutive weeks.

Rest period:

- The first phase of treatment is followed by a period of 4 - 5 weeks where no MUPHORAN is given.

Second phase of treatment

- The second phase of treatment consists of one slow injection of MUPHORAN (as above) every 3 weeks for as long as the specialist thinks it is necessary.

Overdosage

As MUPHORAN is given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

However, if you experience any side effects after being given MUPHORAN tell your doctor immediately or go to Accident and Emergency at your nearest hospital.
You may need urgent medical attention.

While you are being treated with MUPHORAN

Things you must do

Tell all doctors, dentists and pharmacists who are involved with your treatment that you are being treated with MUPHORAN.
You are likely to have regular tests to check that your liver is working properly when you are treated with MUPHORAN.

If you become pregnant while taking MUPHORAN tell your doctor.

Ensure you are using effective contraception if you are a women of childbearing potential.

If you are male, you should use effective contraception while taking MUPHORAN.

Keep follow-up appointments with your doctor.
It is important to have your follow-up doses of MUPHORAN at the appropriate times to get the best effects from your treatments.

If you feel that your medicine is not helping your condition, talk to your doctor.

Things to be careful of

Driving is not advisable immediately following the administration of MUPHORAN. Be careful driving or operating machinery until you know how MUPHORAN affects you.

Side effects

If you do not feel well while you are being treated with MUPHORAN then tell your doctor, pharmacist, or oncology nurse as soon as possible.

All medicines including MUPHORAN, can have side effects. Sometimes they are serious, most of the time they are not. Side effects may happen at the start of treatment or they may happen after you have been taking your medicine for some time. You may need medical treatment if you get some of the side effects. These can include:

- Feeling quite sick or vomiting during the 2 hours following an injection.
- A reduced number of white cells in your blood - making you more vulnerable to infections.
- A reduced number of platelets in your blood - making you more vulnerable to bleeding or bruising.

Patients being treated with MUPHORAN have sometimes experienced:

- Swelling, redness and soreness at the site of injection.
- A rise in temperature.
- An itching sensation.
- Pain in the stomach.
- Diarrhoea.
- Feeling drowsy for a short time.
- Having temporary tingling feelings, numbness, or altered taste sensation.
- Hepatitis (a serious liver condition) which may cause nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, light coloured bowel motions and/or, dark coloured urine.
- Lung toxicity.

Anti-cancer medicines have a potential risk of blood disorders caused by a lack of new blood cells (myelodysplasic syndrome) and acute myeloid leukaemia. At high cumulated doses, rare cases of cancers have been reported following treatment with MUPHORAN. Some side effects may not be apparent to you, but may be seen on the results of tests. These may include moderate transient and reversible increases in liver enzymes (transaminases, alkaline phosphatases), bilirubin or transient increases in blood urea. You will usually have regular blood tests and your eyes examined regularly during treatment - more frequently if you have kidney problems or are an older person.

If you want to know more about the side effects of MUPHORAN ask your doctor, pharmacist or oncology nurse.

The possibility of a severe allergic reaction (anaphylaxis) exists with any medication.

While very rare, these are very serious side effects. You may need urgent medical attention or hospitalisation.

The following are general signs and symptoms of an allergic reaction

- itching, skin rash or hives
- shortness of breath, wheezing or trouble breathing
- swelling of the face, lips, tongue or other parts of the body.

Other side effects not listed above may also occur in some patients. Tell your doctor, pharmacist or oncology nurse if you notice anything else that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

What MUPHORAN looks like

MUPHORAN is a pale yellow powder packed inside a brown glass vial. It is dissolved in a liquid in the hospital pharmacy and usually diluted into a bag of weak glucose (sugar) solution before it is given to a patient. The solution is handled carefully and protected from light.

Ingredients

Each brown vial of MUPHORAN contains 208mg of fotemustine powder as the active ingredient.

Manufacturer

MUPHORAN is a product discovered by Servier Research International.

It is distributed in Australia by:

Servier Laboratories (Aust) Pty Ltd
8 Cato Street
Hawthorn Victoria, 3122
Telephone: 1800 153 590
Internet: www.servier.com.au

The New Zealand contact address for Servier Laboratories is:

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Auckland

MUPHORAN is registered on the Australian Register of Therapeutic Goods.

Australian Register Number:
AUST R 44019

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