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).

* You are pregnant or trying to become pregnant.
* You are breast-feeding or plan to breast-feed.

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.

You are not suitable for treatment with Muphoran if:

* You are allergic to fotemustine or any other nitrosourea.

Tell your doctor straight away if:

* You have problems with the number of white cells or platelets in your blood.
* You have had other chemotherapy in the last 4-6 weeks.
* You have other health problems, including kidney disease.

Taking other medicines

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

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 to take different medicines.

Your doctor or pharmacist has more information about which medicines to be careful with or avoid while being treated with Muphoran.

For older people or children

* Older people can generally be treated with Muphoran.
However, additional care may be required to minimise side effects of treatment.
* Muphoran is not recommended for use in children.
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.

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 can have side effects. Muphoran may sometimes have unwanted 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 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.

Some side effects may not be apparent to you, but may be seen on the results of tests. 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.

Other side effects not listed above may also occur in some patients. Tell your doctor 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
ABN 54 004 838 500

The New Zealand contact address for Servier Laboratories is:
Servier Laboratories (New Zealand) Ltd
12th Floor, Citibank building
23 Customs Street
Auckland

Muphoran is registered on the Australian Register of Therapeutic Goods. Australian Register Number: AUST R 44019

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