▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems .

MYLOTARG®

Gemtuzumab ozogamicin

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about MYLOTARG. It does not contain all the available information. It 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 taking MYLOTARG against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What MYLOTARG is used for

MYLOTARG contains the active ingredient gemtuzumab ozogamicin. It belongs to a group of medicines called antineoplastic agents that target cancer cells.

MYLOTARG is used to treat patients aged 15 years and above with acute myeloid leukaemia (AML). AML is a cancer of the blood and bone marrow in which the bone marrow makes immature white blood cells in high numbers. These abnormal cells crowd the bone marrow, preventing it from making normal blood cells.

This medicine works by stopping the abnormal growth of these cells and destroying them.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

Before you are given MYLOTARG

When you must not be given it

Do not receive MYLOTARG if you have an allergy to:

- any medicine containing gemtuzumab ozogamicin

- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction 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.

Do not receive this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not breast-feed if you are receiving this medicine.

It is not known if MYLOTARG passes into breast milk and there is a possibility that your baby may be affected.

MYLOTARG should not be used in children and adolescents under 15 years of age.

Limited information is available on MYLOTARG treatment in these patients.

Do not receive this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start receiving this medicine, talk to your doctor.

Before you start to be given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

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

- liver problems

MYLOTARG may cause, during or after treatment, a potentially life-threatening condition called hepatic venoocclusive disease, in which the blood vessels in the liver become damaged and obstructed by blood clots which may include fluid retention, rapid weight gain, increased liver size (which may be painful), and ascites (excessive accumulation of fluid in the abdominal cavity).

- kidney problems
- allergic reaction
- an infection
- bleeding
- anaemia
- an infusion reaction

Tell your doctor if you have had any of the following symptoms during or shortly after being given MYLOTARG

- fever, chills, hot flush, dizziness or lightheadedness, rash or trouble breathing

- nausea, vomiting, diarrhoea, changes in heartbeat, decreased urine or blood in urine, muscle weakness or cramps.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

It is unlikely that you will be given this medicine if you are pregnant or trying to become pregnant, as it may harm your unborn baby. Your doctor can discuss with you the risks and benefits involved.

You must avoid becoming pregnant or fathering a child if you are receiving MYLOTARG.

It is not known whether this medicine passes into breast milk.

You must not breast-feed during treatment with MYLOTARG and for at least 1 month after your last dose.

Seek advice from your doctor regarding fertility preservation before treatment.

Fertility may be compromised by treatment with MYLOTARG.

If you have not told your doctor about any of the above, tell him/her before you start receiving MYLOTARG.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including:

- all prescription medicines
- all medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a pharmacy, supermarket, naturopath or health food shop.

Some medicines may be affected by MYLOTARG or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

How MYLOTARG is given

MYLOTARG is given in "cycles". The first MYLOTARG treatment cycle is made up of a single MYLOTARG dose given on Day 1, Day 4 and Day 7 in Week 1 (Induction cycle).

The second and third MYLOTARG treatment cycles are made up of a single MYLOTARG dose given on Day 1 (Consolidation cycle).

A doctor or nurse will give you your MYLOTARG dose gradually over 2 hours through a drip in your vein (intravenous infusion).

How much is given

Your doctor will calculate how much you need to be given.

This will depend on your height and weight and may also depend on your condition and how you have responded to previous treatment.

Medicines given before each cycle

Before each treatment with MYLOTARG you will be given other medicines (premedication) to help reduce symptoms such as fever, chills or hot flush, known as infusion reactions, and other possible side effects.

How long it is given

You will receive between one and three cycles of MYLOTARG in combination with chemotherapy. The first cycle is called Induction. The second and third cycles are called Consolidation. If the medicine works well after the Induction cycle, you may receive the two Consolidation cycles. If you do not respond to the medicine after the first cycle your treatment will be stopped.

Your doctor will discuss with you how long your treatment will last.

If you forget a treatment

If you miss a treatment, contact your doctor or nurse as soon as possible to make a new appointment.

If you take too much (overdose)

It is unlikely that you will be given too much MYLOTARG, as your dose will be calculated and given to you in a specialised setting under the supervision of a doctor.

If an overdose is suspected, immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital.

You may need urgent medical attention.

While you are being given MYLOTARG

Things you must do

If you (or your partner) become pregnant while you are being given this medicine, tell your doctor immediately.

You must avoid becoming pregnant or fathering a child.

Use a proven method of birth control (contraception) during treatment with MYLOTARG if you can become pregnant or if you can father a child.

You must continue to use 2 methods of effective contraception during treatment and for at least 7 months (women) or at least 4 months (men) after the last dose of MYLOTARG.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are being treated with MYLOTARG.

Tell all doctors, dentists and pharmacists who treat you that you are being given this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are being given this medicine.

It may affect other medicines used during surgery.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor will take regular blood tests to make sure MYLOTARG is working and to check for side effects.

In particular, your blood counts and liver function will need to be checked before each treatment.

Your doctor will also monitor you for signs and symptoms of infection, bleeding and respiratory effects.

Your doctor may change your dose, interrupt or completely stop treatment with this medicine if you have certain side effects.

Your doctor may also lower your dose based on your response to treatment.

Things to be careful of

Be careful driving or operating machinery until you know how MYLOTARG affects you.

This medicine may cause fatigue in some people. If you feel tired, do not drive, operate machinery or do anything else that could be dangerous.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are receiving MYLOTARG.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by this list of possible.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or nurse immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- rapid weight gain, pain in the upper right side of your abdomen (stomach), swelling of your abdomen

- These could be symptoms of a very serious and potentially fatal condition called venoocclusive liver disease.

- If you receive MYLOTARG either before or after a stem cell transplant (a process that involves replacing blood-forming cells called stem cells that are diseased or have been damaged by anti-cancer medicines) you have an increased chance of getting this side effect.

- If you have abnormal liver function you may have an increased chance of getting this side effect.

- fever, chills, hot flush, dizziness or lightheadedness, rash or trouble breathing during or shortly after the MYLOTARG infusion (infusion-related reactions)

- shortness of breath, wheezing, coughing, difficulty breathing, changes in the colour of your skin to a blue tinge, feeling of heaviness or congestion in lungs

- fever, sweating and chills

- These could be signs of an infection which may be serious and potentially fatal.

- bruising easily or getting nose bleeds on a regular basis

- symptoms in the stomach and intestines (for example, nausea, vomiting, diarrhoea), heart (for example, changes in the rhythm), kidney (for example, decreased urine, blood in urine), and nerves and muscles (for example, muscle spasms, weakness, cramps)

- These could be signs of a serious condition known as tumour lysis syndrome, which is caused by chemical disturbances in the blood due to the breakdown of dying cancer cells.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor as soon as possible if you notice any of the following:

- bleeding
- fatigue and shortness of breath
- fever
- pain in the abdomen.

The above list includes signs of serious side effects that may require urgent medical attention.

Tell your doctor or nurse if you notice any of the following:

- nausea (feeling sick)
- vomiting

- fatigue
- headache
- mouth ulcer, redness or pain
- diarrhoea
- abdominal pain
- decreased appetite
- general weakness
- constipation
- high or low blood pressure
- skin itching, redness, rash or blistering
- irregular or racing heart rhythm
- high blood sugar
- a yellowish colour of the skin, eyes, and other tissues.

The above list includes the more common side effects of your medicine.

Some side effects (for example, changes in your liver function) can only be found when your doctor does tests from time to time to check your progress.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After receiving MYLOTARG

Storage

MYLOTARG must be kept in the original packaging in a refrigerator, protected from light, before it is time to use it.

Your doctor, nurse or pharmacist will prepare the infusion for you before you are given it..

Your doctor, nurse and pharmacist have more information on how to store and prepare MYLOTARG

Disposal

Your doctor, nurse or pharmacist will dispose of any left-over medicine.

Product description

What it looks like

MYLOTARG is a white or off-white powder or cake supplied in a glass vial.

Before MYLOTARG is given, the powder is mixed with sterile water and diluted with a solution of sodium chloride.

Each MYLOTARG carton contains 1 vial.

Ingredients

MYLOTARG contains 5 mg of gemtuzumab as the active ingredient.

- dextran 40
- dibasic sodium phosphate
- monobasic sodium phosphate monohydrate
- sodium chloride
- sucrose

This medicine contains less than 1 mmol sodium (23 mg) per dose.

Supplier

MYLOTARG is supplied in Australia by:

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedinfo.com.au

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