MYLOTARG®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why am I using MYLOTARG?

MYLOTARG contains the active ingredient gemtuzumab ozogamicin. MYLOTARG is used to treat patients aged 15 years and above with acute myeloid leukaemia (AML). For more information, see Section 1. Why am I using MYLOTARG? in the full CMI.

2. What should I know before I use MYLOTARG?

Do not use if you have ever had an allergic reaction to MYLOTARG or any of the ingredients listed at the end of the CMI.

MYLOTARG may cause 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).

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use MYLOTARG? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with MYLOTARG and affect how it works. For more information, see Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use MYLOTARG?

- MYLOTARG is given in "cycles". Your doctor will calculate how much you need to be given.
- A doctor or nurse will give you your MYLOTARG dose gradually over 2 hours through a drip in your vein (intravenous infusion).

More instructions can be found in Section 4. How do I use MYLOTARG? in the full CMI.

5. What should I know while using MYLOTARG?

Things you should do	• Remind any doctor, nurse, dentist or pharmacist you visit that you are using MYLOTARG. • Tell your doctor if you have any of these symptoms during or shortly after being given MYLOTARG: fever, chills, hot flush, dizziness or lightheadedness, rash, trouble breathing, nausea, vomiting, diarrhoea, changes in heartbeat, decreased urine or blood in urine, muscle weakness or cramps.
Things you should not do	• Do not stop using this medicine suddenly.
Driving or using machines	• 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 or operate machinery.
Looking after your medicine	• MYLOTARG will be stored refrigerated at the hospital or clinic.

For more information, see Section 5. What should I know while using MYLOTARG? in the full CMI.

6. Are there any side effects?

There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur.

MYLOTARG may cause serious side effects including venoocclusive liver disease, infusion-related reactions, infections, 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, bruising easily or getting nose bleeds on a regular basis, tumour lysis syndrome.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ 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®

Active ingredient(s): *gemtuzumab ozogamicin*

Consumer Medicine Information (CMI)

This leaflet provides important information about using MYLOTARG. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using MYLOTARG.**

Where to find information in this leaflet:

1. Why am I using MYLOTARG?

MYLOTARG contains the active ingredient gemtuzumab ozogamicin.

MYLOTARG is used to treat patients aged 15 years and above with acute myeloid leukaemia (AML). It belongs to a group of medicines called antineoplastic agents that target cancer cells.

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.

2. What should I know before I use MYLOTARG?

Warnings

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).

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.

See additional information under Section 6. Are there any side effects?

Do not use MYLOTARG if:

- you are allergic to gemtuzumab ozogamicin, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions such as liver problems, kidney problems, an infection, bleeding, anaemia or have had an infusion reaction
- take any medicines for any other condition.

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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

You must avoid becoming pregnant or fathering a child if you are receiving MYLOTARG. Check with your doctor if you are pregnant or intend to become pregnant.

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.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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.

Adolescents under 15 years of age

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

There is limited information is available on MYLOTARG treatment in these patients.

3. What if I am taking other medicines?

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

Some medicines may interfere with MYLOTARG and affect how it works.

You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect MYLOTARG.

4. How do I use MYLOTARG?

How MYLOTARG is given

- You will receive MYLOTARG under the supervision of an experienced healthcare professional.

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

- 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.

When to use MYLOTARG

- MYLOTARG is given in "cycles".
- 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.
- 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).
- Your doctor will discuss with you how long your treatment will last.

Medicines given before each cycle of MYLOTARG

- 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.

If you forget to use MYLOTARG

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

If you use too much MYLOTARG

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.

In the unlikely event that you are given too much MYLOTARG (an overdose) your healthcare professional will check you for side effects.

5. What should I know while using MYLOTARG?

Things you should 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 effective contraception during treatment and for at least 7 months (women) or at least 4 months (men) after the last dose of MYLOTARG.

Remind any doctor, nurse, dentist or pharmacist you visit that you are using MYLOTARG.

- 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 you should not do

- Do not stop using this medicine suddenly.

Driving or using machines

Be careful before you drive or use any machines or tools 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.

Looking after your medicine

MYLOTARG is stored and administered by healthcare professionals so it is unlikely that you will store this medicine at home. 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.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

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

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Common side effects

Common side effects	What to do
Circulatory system issues: • high or low blood pressure • irregular or racing heart rhythm. **Gastrointestinal issues:** • nausea (feeling sick) • vomiting • mouth ulcer, redness or pain • diarrhoea • abdominal pain • decreased appetite • constipation. **Skin related issues:** • skin itching, redness, rash or blistering • a yellowish colour of the skin, eyes, and other tissues. **Metabolism and nutrition related issues:** • high blood sugar.	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Common side effects	What to do
General disorders and administration site conditions: • fatigue • headache • general weakness.	

Serious side effects

Serious side effects	What to do
Venoocclusive liver disease: • rapid weight gain, pain in the upper right side of your abdomen (stomach), swelling of your abdomen. **Infusion-related reactions:** • fever, chills, hot flush, dizziness or lightheadedness, rash or trouble breathing during or shortly after the MYLOTARG infusion. **Lung-related issues:**	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
• 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. **Infections:** • fever, sweating and chills. **Blood-related issues:** • bruising easily or getting nose bleeds on a regular basis • bleeding. **Tumour lysis syndrome:** • 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	

Serious side effects	What to do
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.	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

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.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What MYLOTARG contains

Active ingredient **(main ingredient)**	Gemtuzumab ozogamicin
Other ingredients **(inactive ingredients)**	Dextran 40 Dibasic sodium phosphate Monobasic sodium phosphate monohydrate Sodium chloride Sucrose
Potential allergens	This medicine contains less than 1 mmol sodium (23 mg) per dose.

Do not take this medicine if you are allergic to any of these ingredients.

What MYLOTARG looks like

MYLOTARG is a white to off-white cake or powder provided in an amber glass vial.

AUST R 316671.

Who distributes MYLOTARG

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229
www.pfizermedicalinformation.com.au

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