Targocid[®]

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.

1. Why am I being given Targocid?

Targocid contains the active ingredient teicoplanin. Targocid injection is an antibiotic. It is used to kill bacteria responsible for infections which can occur in your blood, bones or joints. For more information, see Section 1. Why am I being given Targocid? in the full CMI.

2. What should I know before I am given Targocid?

Do not use if you have ever had an allergic reaction to Targocid or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, are pregnant or plan to become pregnant, or are breastfeeding or planning to breastfeed.** For more information, see Section 2. What should I know before I am given Targocid? in the full CMI. What if I am taking other medicines?

3. What if I am taking other medicines?

Some medicines may interfere with Targocid and affect how it works. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How will I be given Targocid?

• Targocid injection should be prepared and administered by a qualified health professional (doctor, pharmacist or nurse). More instructions can be found in Section 4. How will I be given Targocid? in the full CMI.

5. What should I know while being given Targocid?

Things you should do	 Call your doctor straight away if you notice any symptoms of serious skin reactions, including blistering of your skin, mouth, eyes or genitals, a red scaly widespread rash and blisters accompanied by a fever, or flu-like symptoms and a rash on your face and body with a fever. Remind any doctor, dentist or pharmacist that you visit that you are being given Targocid. 	
Things you should not do	 Do not receive more than the recommended dose unless your doctor or pharmacist tells you to. Do not stop receiving Targocid because you are feeling better, unless advised by your doctor or pharmacist. 	
Driving or using machines		
Looking after your medicine	Targocid is stored in the pharmacy or on the ward.	

For more information, see Section 5. What should I know while being given Targocid? in the full CMI.

6. Are there any side effects?

There are a number of side effects associated with this medicine. Not all of these side effects are listed here. It is important to be aware of them so that you can identify any symptoms if they occur (see Section <u>6</u>. Are there any side effects? in the full CMI for more details). Mild side effects include local pain and redness at the injection site, rash, dizziness, nausea, headache and stiffness. Very serious side effects which may indicate an allergic reaction include swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing, and hives or welts on the skin. Other very serious side effects include blistering of your skin, mouth, eyes or genitals, a red scaly widespread rash with bumps under the skin and blisters accompanied by a fever, flu-like symptoms and a rash on your face followed by an extended rash with a fever, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes, and kidney problems (shown in tests).

Targocid®

Active ingredient: teicoplanin

Consumer Medicine Information (CMI)

This leaflet provides important information about using Targocid. 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 Targocid.

Where to find information in this leaflet:

- 1. Why am I using Targocid?
- 2. What should I know before I use Targocid?
- 3. What if I am taking other medicines?
- 4. How do I use Targocid?
- 5. What should I know while using Targocid?
- <u>6.</u> <u>Are there any side effects?</u>
- 7. Product details

1. Why am I being given Targocid?

Targocid contains the active ingredient teicoplanin.

Targocid is an antibiotic. It is used to kill bacteria responsible for infections which can occur in your blood, bones or joints.

Targocid is generally used when the bacteria causing the infection are not satisfactorily eliminated by other antibiotics (e.g. penicillin), or when patients may be allergic to other antibiotics.

What should I know before I am given Targocid?

Warnings

Do not receive Targocid if:

 you are allergic to Targocid, 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 or have had any other medical conditions, especially kidney problems or liver problems
- take any medicines for any other condition
- have allergies to any other medicines, including to any other antibiotic (especially an antibiotic called vancomycin, also known as Vancocin*), or any other substances, such as foods, preservatives or dyes
- plan to have surgery

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

Do not receive Targocid if you are pregnant or intend to become pregnant. Targocid is not recommended to be used during pregnancy.

Do not receive Targocid if you are breastfeeding or planning to breastfeed. It is not known whether Targocid passes into breast milk.

3. What if I am taking other medicines?

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

Some medicines may interfere with Targocid and affect how it works. These include:

- aminoglycoside antibiotics, medicine used to treat bacterial infections
- amphotericin B (amphotericin), medicine used to treat fungal infections
- ciclosporin, medicine used to help control your body's immune system
- cisplatin, a medicine used in the treatment of some cancers
- furosemide (frusemide), a medicine used to remove excess fluid in the body
- etacrynic acid, a medicine used to help the kidneys get rid of salt and water

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

4. How will I be given Targocid?

How much you will be given

- On the first day of treatment most patients generally receive two doses of Targocid, 12 hours apart
- During the following days, most patients receive ONE dose each day
- After the first day, the daily dose varies between 6 mg and 12 mg for each kilogram you weigh, depending on what type of infection you have. An adult of normal weight (around 70 kg) would therefore receive a single daily dose of between 400 mg and 800 mg
- Patients with kidney problems may need lower doses (or doses less often) than other patients. Your doctor can calculate how much Targocid you require if you have kidney problems.
- If you have an infection in your blood, you will probably need to receive a daily injection of Targocid for 2 to 4 weeks. If you have an infection in any bones or joints, you may require a daily injection of Targocid for 3 to 6 weeks.

 Follow the instructions provided and continue to receive Targocid for as long as prescribed by your doctor.

How it is given

- Targocid injection should be prepared and administered by a qualified health professional (doctor, pharmacist or nurse).
- The vial of Targocid powder should be mixed carefully with the sterile water, which is included in the pack, to form a clear solution.
- The solution may be injected into a vein directly over about 5 minutes, or it may be mixed with other sterile solutions and delivered into a vein from a 'drip' bottle or bag over about 30 minutes.
- Targocid solution may also be injected directly into a muscle.

If you receive too much Targocid

As Targocid is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you think you have received too much, or if you experience any unexpected or worrying side effects, you may need urgent medical attention.

You should immediately:

- Phone the Poisons Information Centre (by calling 13 11 26 in Australia or 0800 764 766 in New Zealand), or
- Contact your doctor, or
- Go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Targocid?

During treatment you may have tests to check your blood, your kidneys, your liver and/or your hearing. This is more likely if your treatment will last for a long time, you need to be treated with high doses, you have a kidney problem, you are taking or may take other medicines that may affect your nervous system, kidneys or hearing.

Things you should do

- Remind any doctor, dentist or pharmacist that you visit that you are being given Targocid.
- If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are being given Targocid.
- If you become pregnant while you are being given Targocid, stop receiving it and tell your doctor or pharmacist immediately.

Call your doctor straight away if you notice:

 blistering of the skin, mouth, eyes or genitals, which may be symptoms of severe skin reactions called 'Stevens-Johnson Syndrome', or 'Toxic Epidermal Necrolysis', or

- a red scaly widespread rash with bumps under the skin and blisters accompanied by a fever, which may be symptoms of a severe skin reaction called 'Acute Generalised Exanthematous Pustulosis', or
- flu-like symptoms and a rash on your face, then an extended rash with a high temperature, which may be symptoms of a condition called 'Drug Reaction with Eosinophilia and Systemic Symptoms'.

Things you should not do

- Do not receive more than the recommended dose unless your doctor or pharmacist tells you to.
- Do not use this medicine to treat any other complaints unless your doctor or pharmacist tells you to.
- Do not stop receiving Targocid because you are feeling better, unless advised by your doctor or pharmacist.

Driving or using machines

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

Looking after your medicine

Targocid is stored in the pharmacy or on the ward.

6. Are there any side effects?

All medicines have some unwanted 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.

Less serious side effects

Less serious side effects	What to do
Injection-related:	Speak to your doctor or pharmacist if you notice any of these less serious side
local pain and redness at the injection site	
Other side effects:	
• rash	effects and they worry
• dizziness	you.
• nausea	•
headache	
• stiffness	

Serious side effects

Serious side effects	What to do
 fever vomiting diarrhoea balance problems ringing in the ears problems hearing if you suspect you have a second infection 	Speak to your doctor or nurse as soon as possible if you notice any of these side effects.

Serious side effects		What to do
	low levels of all types of blood cells (pancytopenia) – the symptoms may include shortness of breath, fatigue, fever, chills, and bruising	

Very serious side effects

Allergic reaction-related: swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing hives or welts on your skin blistering of the skin, mouth, eyes or genitals - these may be symptoms of something called 'Toxic Epidermal Necrolysis' or 'Stevens-Johnson Syndrome' red scaly widespread rash with bumps under the skin (including your skin folds, chest, abdomen (including stomach), back and arms) and blisters accompanied by fever - these may be symptoms of something called 'Acute Generalised Exanthematous Pustulosis' flu-like symptoms and a rash on the face then an extended rash with a high temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes. These may be signs or symptoms of 'Drug Reaction with Eosinophilia and Systemic Symptoms' Other very serious side effects: kidney problems - shown in tests. Frequency or severity of kidney problems may be increased if you receive higher doses	Ver	Very serious side effects What to do			
 swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing hives or welts on your skin blistering of the skin, mouth, eyes or genitals - these may be symptoms of something called 'Toxic Epidermal Necrolysis' or 'Stevens-Johnson Syndrome' red scaly widespread rash with bumps under the skin (including your skin folds, chest, abdomen (including stomach), back and arms) and blisters accompanied by fever - these may be symptoms of something called 'Acute Generalised Exanthematous Pustulosis' flu-like symptoms and a rash on the face then an extended rash with a high temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes. These may be signs or symptoms of 'Drug Reaction with Eosinophilia and Systemic Symptoms' Other very serious side effects: kidney problems - shown in tests. Frequency or severity of kidney problems may be increased if you receive higher 	-				
 Skin reactions: blistering of the skin, mouth, eyes or genitals - these may be symptoms of something called 'Toxic Epidermal Necrolysis' or 'Stevens-Johnson Syndrome' red scaly widespread rash with bumps under the skin (including your skin folds, chest, abdomen (including stomach), back and arms) and blisters accompanied by fever - these may be symptoms of something called 'Acute Generalised Exanthematous Pustulosis' flu-like symptoms and a rash on the face then an extended rash with a high temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes. These may be signs or symptoms of 'Drug Reaction with Eosinophilia and Systemic Symptoms' Other very serious side effects: kidney problems - shown in tests. Frequency or severity of kidney problems may be increased if you receive higher 	•	swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing	doctor or nurse straight away, or go straight to the Emergency Department at		
increased if you receive higher	•	blistering of the skin, mouth, eyes or genitals - these may be symptoms of something called 'Toxic Epidermal Necrolysis' or 'Stevens-Johnson Syndrome' red scaly widespread rash with bumps under the skin (including your skin folds, chest, abdomen (including stomach), back and arms) and blisters accompanied by fever - these may be symptoms of something called 'Acute Generalised Exanthematous Pustulosis' flu-like symptoms and a rash on the face then an extended rash with a high temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes. These may be signs or symptoms of 'Drug Reaction with Eosinophilia and Systemic Symptoms'	your nearest hospital if you notice any of these very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very		
·		increased if you receive higher			

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

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 in Australia or in New Zealand at

https://pophealth.my.site.com/carmreportnz/s/.

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 Targocid contains

Active ingredient	Teicoplanin
(main ingredient)	
Other ingredients	Sodium chloride
(inactive ingredients)	Water for injections
Potential allergens	Targocid does not contain gluten, dyes or preservatives.

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

What Targocid looks like

Targocid injection is presented in a glass vial as a white powder which your doctor, pharmacist or nurse will mix with the ampoule of sterile water, included in the pack. A clear solution is formed when the powder is mixed with the water.

Who distributes Targocid

Distributed in Australia by: sanofi-aventis australia pty ltd 12-24 Talavera Road

Macquarie Park NSW 2113

Freecall: 1800 818 806

Email: medinfo.australia@sanofi.com

Distributed in New Zealand by:

Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics

PO Box 62027

Sylvia Park Auckland 1644 Freecall: 0800 283 684

Email: medinfo.australia@sanofi.com

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