Package leaflet: Information for the user

TARGOCID® 200 mg powder for solution for injection/infusion or oral solution
TARGOCID® 400 mg powder for solution for injection/infusion or oral solution

teicoplanin

sanofi

Is this leaflet hard to see or read?
Phone 0800 035 2525 for help

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Targocid is and what it is used for

Targocid is an antibiotic. It contains a medicine called 'teicoplanin'. It works by killing the bacteria that cause infections in your body.

Targocid is used in adults and children (including newborn babies) to treat bacterial infections of:
- the skin and underneath the skin - sometimes called 'soft tissue'
- the bones and joints
- the lung
- the urinary tract
- the heart - sometimes called 'endocarditis'
- the abdominal wall - peritonitis
- the blood, when caused by any of the conditions listed above

Targocid can be used to treat some infections caused by '*Clostridium difficile*' bacteria in the gut. For this, the solution is taken by mouth.

2. What you need to know before you are given Targocid

Do not use Targocid if:
- you are allergic to teicoplanin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before you are given Targocid if:
- you are allergic to an antibiotic called 'vancomycin'
- you have had a flushing of your upper part of your body (red man syndrome)
- you have a decrease in platelet count (thrombocytopenia)
- you have kidney problems
- you are taking other medicines which may cause hearing problems and/or kidney problems. You may have regular tests to check if your kidneys and/or liver are working properly (see 'Other medicines and Targocid').

If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist or nurse before you are given Targocid.

Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP) have been reported with the use of teicoplanin. If you develop a serious rash or other skin symptoms as described in section 4, stop taking Targocid and contact your doctor or seek medical attention immediately.

Tests

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 loading doses (12mg/kg twice a day)
- you have a kidney problem
- you are taking or may take other medicines that may affect your nervous system, kidneys or hearing.

In people who are given Targocid for a long time, bacteria that are not affected by the antibiotic may grow more than normal - your doctor will check for this.

Other medicines and Targocid

Tell your doctor, pharmacist or nurse if you are using, have recently used or might use any other medicines. This is because Targocid can affect the way some other medicines work. Also, some medicines can affect the way Targocid works. In particular, tell your doctor, pharmacist or nurse if you are taking the following medicines:
- Aminoglycosides as they must not be mixed together with Targocid in the same injection. They may also cause hearing problems and/or kidney problems.
- amphotericin B - a medicine that treats fungal infections which may cause hearing problems and/or kidney problems
- ciclosporin - a medicine that affects the immune system which may cause hearing problems and/or kidney problems
- cisplatin - a medicine that treats malignant tumors which may cause hearing problems and/or kidney problems
- water tablets (such as furosemide) - also called 'diuretics' which may cause hearing problems and/or kidney problems.

If any of the above apply to you, (or you are not sure), talk to your doctor, pharmacist or nurse before being given Targocid.

Pregnancy, breast-feeding and fertility

If you are pregnant, think that you might be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before being given this medicine. They will decide whether or not you are given this medicine while you are pregnant. There may be a potential risk of inner ear and kidney problems.

Tell your doctor if you are breast-feeding, before being given this medicine. He/she will decide whether or not you can keep breast-feeding, while you are given Targocid.

Studies in animal reproduction have not shown evidence of fertility problems.

Driving and using machines

You may have headaches or feel dizzy while being treated with Targocid. If this happens, do not drive or use any tools or machines.

Targocid contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per vial and is essentially 'sodium-free'.

3. How to use Targocid

The recommended dose is

Adults and children (12 years and over) with no kidney problems

Skin and soft tissue, lung and urinary tract infections
- Starting dose (for the first three doses): 6 mg for every kilogram of body weight, given every 12 hours, by injection into a vein or muscle
- Maintenance dose: 6 mg for every kilogram of body weight, given once a day, by injection into a vein or muscle

Bone and joint infections, and heart infections
- Starting dose (for the first three to five doses): 12 mg for every kilogram of body weight, given every 12 hours, by injection into a vein
- Maintenance dose: 12 mg for every kilogram of body weight, given once a day, by injection into a vein or muscle

Infection caused by '*Clostridium difficile*' bacteria

The recommended dose is 100 to 200 mg by mouth, twice a day for 7 to 14 days.

Adults and elderly patients with kidney problems

If you have kidney problems, your dose will usually need to be lowered after the fourth day of treatment:
- For people with mild and moderate kidney problems - the maintenance dose will be given every two days, or half of the maintenance dose will be given once a day.
- For people with severe kidney problems or on haemodialysis - the maintenance dose will be given every three days, or one-third of the maintenance dose will be given once a day.

Peritonitis for patients on peritoneal dialysis

The starting dose is 6 mg for every kilogram of body weight, as a single injection into a vein, followed by:
- Week one: 20 mg/L in each dialysis bag
- Week two: 20 mg/L in every other dialysis bag
- Week three: 20 mg/L in the overnight dialysis bag.

Babies (from birth to the age of 2 months)
- Starting dose (on the first day): 16 mg for every kilogram of body weight, as an infusion through a drip into a vein.
- Maintenance dose: 8 mg for every kilogram of body weight, given once a day, as an infusion through a drip into a vein.

Children (from 2 months to 12 years)
- Starting dose (for the first three doses): 10 mg for every kilogram of body weight, given every 12 hours, by injection into a vein.
- Maintenance dose: 6 to 10 mg for every kilogram of body weight, given once a day, by injection into a vein.

How Targocid is given

The medicine will normally be given to you by a doctor or nurse.
- It will be given by injection into a vein (intravenous use) or muscle (intramuscular use).
- It can also be given as an infusion through a drip into a vein.

Only the infusion should be given in babies from birth to the age of 2 months.

To treat certain infections, the solution may be taken by mouth (oral use).

If you have more Targocid than you should

It is unlikely that your doctor or nurse will give you too much medicine. However, if you think you have been given too much Targocid or if you are agitated, talk to your doctor or nurse straight away.

If you forget to have Targocid

Your doctor or nurse will have instructions about when to give you Targocid. It is unlikely that they will not give you the medicine as prescribed. However, if you are worried, talk to your doctor or nurse.

If you stop having Targocid

Do not stop having this medicine without first talking to your doctor, pharmacist or nurse.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

Stop your treatment and tell your doctor or nurse straight away, if you notice any of the following serious side effects - you may need urgent medical treatment:

Uncommon (may affect up to 1 in 100 people)
- sudden life-threatening allergic reaction - the signs may include: difficulty in breathing or wheezing, swelling, rash, itching, fever, chills

Rare (may affect up to 1 in 1000 people)
- flushing of the upper body

Not known (frequency cannot be estimated from the available data)
- blistering of the skin, mouth, eyes or genitals - these may be signs 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 generalized exanthematous pustulosis (AGEP)'
- 'drug reaction with eosinophilia and systemic symptoms (DRESS)'. DRESS appears initially as 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.

Tell your doctor or nurse straight away, if you notice any of the side effects above.

Tell your doctor or nurse straight away, if you notice any of the following serious side effects - you may need urgent medical treatment:

Uncommon (may affect up to 1 in 100 people)
- swelling and clotting in a vein
- difficulty in breathing or wheezing (bronchospasm)
- getting more infections than usual - these could be signs of a decrease in your blood cell count

Not known (frequency cannot be estimated from the available data)
- lack of white blood cells - the signs may include: fever, severe chills, sore throat or mouth ulcers (agranulocytosis)
- kidney problems or changes in the way your kidneys work - shown in tests. Frequency or severity of kidney problems may be increased if you receive higher doses
- epileptic fits

Tell your doctor or nurse straight away, if you notice any of the side effects above.

Other side effects

Talk to your doctor, pharmacist or nurse if you get any of these:

Common (may affect up to 1 in 10 people)
- Rash, erythema, pruritus
- Pain
- Fever

Uncommon (may affect up to 1 in 100 people)
- decrease in platelet count.
- raised blood levels of liver enzymes
- raised in blood levels of creatinine (to monitor your kidney)
- hearing loss, ringing in the ears or a feeling that you, or things around you are moving
- feeling or being sick (vomiting), diarrhoea
- feeling dizzy or headache

Rare (may affect up to 1 in 1,000 people)
- infection (abscess).

Not known (frequency cannot be estimated from the available data)
- problems where the injection was given - such as reddening of the skin, pain or swelling
- low levels of all types of blood cells.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

United Kingdom
You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Targocid

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the carton and label of the vial after EXP. The expiry date refers to the last day of that month.
This medicine does not require any special storage conditions.
Information about storage and the time to use Targocid, after it has been reconstituted and is ready to use, are described in the 'Practical information for healthcare professionals on preparation and handling of Targocid'.

6. Contents of the pack and other information

What Targocid contains
- The active substance is teicoplanin. Each vial contains either 200 mg or 400 mg teicoplanin.
- The other ingredients are sodium chloride and sodium hydroxide.

What Targocid looks like and contents of the pack

Targocid is a powder for solution for injection/infusion or oral solution.
The powder is spongy, ivory and coloured homogeneous mass.
The powder is packaged:
- in a Type I, colourless glass vial of useful volume of 10 mL for 200 mg closed with bromobutyl rubber stopper and plastic flip-off top aluminium yellow overseal.
- in a Type I, colourless glass vial of useful volume of 22 mL for 400 mg closed with bromobutyl rubber stopper and plastic flip-off top aluminium green overseal.

Pack size:
- 1 powder vial
- 5x1 powder vials
- 10x1 powder vials
- 25x1 powder vials

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Sanofi, 410 Thames Valley Park Drive,
Reading, Berkshire, RG6 1PT, UK.
Tel: 0800 035 2525
email: uk-medicalinformation@sanofi.com

Manufacturer
Sanofi S.r.l., Via Valcanello 4
03012 Anagni (FR), Italy

This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark, Finland, Norway, Sweden, United Kingdom: Targocid

This leaflet was last revised in 05/2023.

The following information is intended for medical or healthcare professionals only:

Practical information for healthcare professionals on preparation and handling of Targocid.

This medicine is for single use only.

Method of administration

The reconstituted solution may be injected directly or alternatively further diluted.
The injection will be given either as a bolus over 3 to 5 minutes or as a 30-minutes infusion.
Only the infusion should be given in babies from birth to the age of 2 months.
The reconstituted solution may also be given by mouth.

Preparation of reconstituted solution

The solution is reconstituted by adding 3.14 mL of water for injection to the 200 mg and 400 mg powder vial. The water is slowly added to the vial which should be rotated until all the powder is dissolved to avoid foaming. If foam is developed, allow the solution to stand for approximately 15 minutes so that the foam disappears.
Only clear solutions should be used.
The colour of the solution may vary from yellowish to dark yellow.
The final solution is isotonic with plasma and has a pH of 7.2-7.8.

Nominal teicoplanin content of vial	200 mg	400 mg
Volume of powder vial	10 mL	22 mL
Volume containing nominal teicoplanin dose (extracted by 5 mL syringe and 23 G needle)	3.0 mL	3.0 mL

Preparation of the diluted solution before infusion

Targocid can be administered in the following infusion solutions:
- sodium chloride 9 mg/mL (0.9%) solution
- Ringer solution
- Ringer-lactate solution
- 5% dextrose injection
- 10% dextrose injection
- 0.18% sodium chloride and 4% glucose solution
- 0.45% sodium chloride and 5% glucose solution
- Peritoneal dialysis solution containing 1.36% or 3.86% glucose solution.

Shelf life of reconstituted solution

Chemical and physical in-use stability of the reconstituted solution prepared as recommended has been demonstrated for 24 hours at 2 to 8°C.
From a microbiological point of view, the medicine should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless reconstitution has taken place in controlled and validated aseptic conditions.

Shelf life of diluted medicine

Chemical and physical in-use stability of the reconstituted solution prepared as recommended has been demonstrated for 24 hours at 2 to 8°C.
From a microbiological point of view, the medicine should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless reconstitution/dilution has taken place in controlled and validated aseptic conditions.

Disposal

Any unused medicine or waste material should be disposed of in accordance with local requirements.

885991