PACKAGE LEAFLET: INFORMATION FOR THE USER

Tigecycline Viatris 50 mg powder for solution for infusion
Tigecycline

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

What is in this leaflet:

1. What <Invented name> is and what it is used for

<Invented name> is an antibiotic of the glycylcycline group that works by stopping the growth of bacteria that cause infections.

Your doctor has prescribed <Invented name> because you or your child at least 8 years old has one of the following types of serious infections:

- Complicated infection of the skin and soft tissues (the tissue below the skin), excluding diabetic foot infections.

- Complicated infection in the abdomen

<Invented name> is only used when your doctor thinks other antibiotics are not suitable.

2. What you need to know before you receive <Invented name>

Do not use <Invented name>
- If you are allergic to tigecycline, or any of the other ingredients of this medicine (listed in section 6). If you are allergic to tetracycline class antibiotics (e.g., minocycline, doxycycline, etc.), you may be allergic to tigecycline.

Warnings and precautions

Talk to your doctor or nurse before receiving <Invented name>:
- If you have poor or slow wound healing.
- If you are suffering from diarrhoea before you are given <Invented name>. If you develop diarrhoea during or after your treatment, tell your doctor at once. Do not take any diarrhoea medicine without first checking with your doctor.
- If you have or previously had any side effects due to antibiotics belonging to the tetracycline class (e.g., skin sensitization to sun light, staining on developing teeth,

pancreas inflammation, and alteration of certain laboratory values aimed at measuring how well your blood clots).
- If you have, or previously had liver problems. Depending on the condition of your liver, your doctor may reduce the dose to avoid potential side effects.
- If you have blockage of the bile ducts (cholestasis).
- If you suffer from a bleeding disorder or are in treatment with anticoagulant drugs, as this medicine can interfere with blood coagulation.

During treatment with <Invented name>:
- Tell your doctor immediately if you develop symptoms of an allergic reaction.
- Tell your doctor immediately if you develop severe abdominal pain, nausea, and vomiting.
- These may be symptoms of acute pancreatitis (inflamed pancreas which may result in severe abdominal pain, nausea, and vomiting).
- In certain serious infections, your doctor may consider to use <Invented name> in combination with other antibiotics.
- Your doctor will monitor you closely for the development of any other bacterial infections. If you develop another bacterial infection, your doctor may prescribe a different antibiotic specific for the type of infection present.
- Although antibiotics including <Invented name> fight certain bacteria, other bacteria and fungi may continue to grow. This is called overgrowth. Your doctor will monitor you closely for any potential infections and treat you if necessary.

Children
<Invented name> is not to be used in children less than 8 years of age due to the lack of data on safety and efficacy in this age group and because it may induce permanent dental defects such as staining on the developing teeth.

Other medicines and <Invented name>
Tell your doctor if you are taking, have recently taken or might take any other medicines.

Tigecycline may prolong certain tests that measure how well your blood is clotting. It is important that you tell your doctor if you are taking medicines to avoid an excess of blood clotting (named anticoagulants). If this were the case, your doctor will monitor you closely.

Tigecycline may interfere with the contraceptive pill (birth control pill). Talk to your doctor about the need for an additional method of contraception while receiving tigecycline.

Tigecycline may increase the effect of medicines used to suppress the immune system (such as tacrolimus or cyclosporine). It is important that you tell your doctor if you are taking these medicines so you can be closely monitored.

Pregnancy and breast-feeding
Tigecycline may cause foetal harm. If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor for advice before receiving <Invented name>.

It is not known if tigecycline passes into breast milk in humans. Ask your doctor for advice before breast-feeding your baby.

Driving and using machines
Tigecycline may cause side effects such as dizziness. This may impair your ability to drive or operate machinery.

<Invented name> contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially '*sodium- free*'.

3. How <Invented name> is given

<Invented name> will be given to you by a doctor or a nurse.

The recommended dose in adults is 100 mg given initially, followed by 50 mg every 12 hours. This dose is given intravenously (directly into your blood stream) over a period of 30 to 60 minutes.

The recommended dose in children aged 8 to <12 years is 1.2 mg/kg given every 12 hours intravenously to a maximum dose of 50 mg every 12 hours.

The recommended dose in adolescents aged 12 to <18 years is 50 mg given every 12 hours.

A course of treatment usually lasts for 5 to 14 days. Your doctor will decide how long you should be treated.

If you receive more <Invented name> than you should
If you are concerned that you may have been given too much <Invented name>, talk to your doctor or nurse immediately.

If you miss a dose of <Invented name>
If you are concerned that you may have missed a dose, talk to your doctor or nurse immediately

4. Possible side effects

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

Pseudomembranous colitis may occur with most antibiotics including <Invented name>. This consists of severe, persistent or bloody diarrhoea associated with abdominal pain or fever, which can be a sign of serious bowel inflammation, which may occur during or after your treatment.

Very common side effects (may affect more than 1 in 10 people):
- Nausea, vomiting, diarrhoea.

Common side effects (may affect up to 1 in 10 people):
- Abscess (collection of pus), infections
- Laboratory measurements of decreased ability to form blood clots
- Dizziness
- Vein irritations from the injection, including pain, inflammation, swelling and clotting
- Abdominal pain, dyspepsia (stomach ache and indigestion), anorexia (loss of appetite)
- Increases in liver enzymes, hyperbilirubinaemia (excess of bile pigment in the blood)
- Pruritus (itching), rash
- Poor or slow wound healing
- Headache
- Increase in amylase, which is an enzyme found in the salivary glands and pancreas, increased blood urea nitrogen (BUN).
- Pneumonia

- Low blood sugar
- Sepsis (severe infection in the body and blood stream)/septic shock (serious medical condition which can lead to multiple organ failure and death as a result of sepsis)
- Injection site reaction (pain, redness, inflammation)
- Low protein levels in the blood

Uncommon side effects (may affect up to 1 in 100 people):
- Acute pancreatitis (inflamed pancreas which may result in severe abdominal pain, nausea, and vomiting)
- Jaundice (yellow coloration of the skin), inflammation of the liver
- Low platelet levels in the blood (which may lead to an increased bleeding tendency and bruising/haematoma)

Rare side effects (may affect up to 1 in 1,000 people):
- Low fibrinogen levels in the blood (a protein involved in blood clotting)

Not known side effects (frequency cannot be estimated from the available data):
- Anaphylaxis/anaphylactoid reactions (that may range from mild to severe, including a sudden, generalised allergic reaction that may lead to a life-threatening shock [e.g. difficulty in breathing, drop of blood pressure, fast pulse]).
- Liver failure
- Skin rash, which may lead to severe blistering and peeling of the skin (Stevens-Johnson syndrome)

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <Invented name>

Keep this medicine out of the sight and reach of children.

Store below 25°C.

Do not use this medicine after the expiry date which is stated on the vial and the carton after EXP. The expiry date refers to the last day of that month.

Storage after preparation
Chemical and physical in-use stability has been demonstrated for tigecycline mixed with 0.9% Sodium chloride injection or Dextrose 5%. The product may be stored refrigerated at 2º to 8ºC for up to 48 hours following immediate transfer of the reconstituted solution into the intravenous bag.

From a microbiological point of view, the product should be used immediately.
If not used immediately, in-use storage times and conditions are the responsability of the user.

The <Invented name> solution should be yellow to orange in colour after dissolving; if it is not, the solution should be discarded.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What <Invented name> contains
The active substance is tigecycline. Each vial contains 50 mg of tigecycline.

The other ingredients are L-arginine, hydrochloric acid, and sodium hydroxide (for pH-adjustment).

What <Invented name> looks like and contents of the pack
<Invented name> is supplied as a cake or powder for solution for infusion in a vial and looks like an orange to orange-red compact powder before it is diluted. These vials are distributed to the hospital in a ten tray pack or 1 vial pack. Not all pack sizes may be marketed.
The powder should be mixed in the vial with a small amount of solution. The vial should be gently swirled until the medicine is dissolved. Thereafter, the solution should be immediately withdrawn from the vial and added to a 100 ml intravenous bag or other suitable infusion container in the hospital.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

Galenicum Health, S.L.U.
Sant Gabriel, 50,
Esplugues de Llobregat, 08950 Barcelona
Spain

Or

SAG Manufacturing S.L.U
Ctra. N-I, Km 36
San Agustín de Guadalix, 28750, Madrid,
Spain

Or

Mylan Germany GmbH
Zweigniederlassung Bad Homburg v. d. Höhe, Benzstrasse 1
Bad Homburg v. d. Hohe
Hessen, 61352,
Germany

Or

Hikma Italia S.p.A.
Viale Certosa, 10
27100, Pavia
Italy

This leaflet was last revised in
2026-02-25

Detailed information on this medicine is available on the web site of: {name of MS/Agency}

The following information is intended for healthcare professionals only:

Instructions for use and handling (see also 3. How <Invented name> is given, in this leaflet)

The powder should be reconstituted with 5.3 ml of sodium chloride 9 mg/ml (0.9 %) solution for injection or dextrose 50 mg/ml (5 %) solution for injection to achieve a concentration of 10 mg/ml of tigecycline. The vial should be gently swirled until the active substance is dissolved. Thereafter, 5 ml of the reconstituted solution should be immediately withdrawn from the vial and added to a 100 ml intravenous bag for infusion or other suitable infusion container (e.g. glass bottle).

For a 100 mg dose, reconstitute using two vials into a 100 ml intravenous bag for infusion or other suitable infusion container (e.g. glass bottle).

Note: The vial contains a 6 % overage. Thus, 5 ml of reconstituted solution is equivalent to 50 mg of the active substance. The reconstituted solution should be yellow to orange in colour; if not, the solution should be discarded. Parenteral products should be inspected visually for particulate matter and discolouration (e.g. green or black) prior to administration.

Tigecycline should be administered intravenously through a dedicated line or through a Y-site. If the same intravenous line is used for sequential infusion of several active substances, the line should be flushed before and after infusion of tigecycline with either sodium chloride 9 mg/ml (0.9 %) solution for injection or dextrose 50 mg/ml (5 %) solution for injection. Injection should be made with an infusion solution compatible with tigecycline and any other medicinal product(s) via this common line.

Compatible intravenous solutions include: sodium chloride 9 mg/ml (0.9 %) solution for injection and dextrose 50 mg/ml (5 %) solution for injection. The product was found not to be compatible with Ringer Lactate solution.

When administered through a Y-site, compatibility of tigecycline diluted in sodium chloride 0.9 % for injection is demonstrated with the following medicinal products or diluents: amikacin, dobutamine, dopamine HCl, gentamicin, haloperidol, lidocaine HCl, metoclopramide, morphine, norepinephrine, piperacillin/tazobactam (EDTA formulation), potassium chloride, propofol, ranitidine HCl, theophylline, and tobramycin.

<Invented name> must not be mixed with other medicinal products for which compatibility data are not available.

Chemical and physical in-use stability has been demonstrated for tigecycline mixed with 0.9% Sodium chloride injection or Dextrose 5%. The product may be stored refrigerated at 2º to 8ºC for up to 48 hours following immediate transfer of the reconstituted solution into the intravenous bag.

From a microbiological point of view, the product should be used immediately.
If not used immediately, in-use storage times and conditions are the responsability of the user.

For single use only, any unused solution should be discarded.