PACKAGE LEAFLET: INFORMATION FOR THE USER

Tigecycline 50 mg

powder for solution for infusion

tigecycline

Read all of this leaflet carefully before you start using 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 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 TIGECYCLINE IS AND WHAT IT IS USED FOR

Tigecycline is an antibiotic of the glycylcycline group that works by stopping the growth of bacteria that cause infections.

Your doctor prescribed Tigecycline 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

Tigecycline is only used when your doctor thinks other antibiotics are not suitable.

2. WHAT YOU NEED TO KNOW BEFORE YOU RECEIVE TIGECYCLINE

Do not use Tigecycline
- 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 Tigecycline:
- If you have poor or slow wound healing.
- If you are suffering from diarrhoea before you are given Tigecycline. 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 Tigecycline:
Talk to your doctor or nurse before receiving Tigecycline:
- 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 Tigecycline 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 Tigecycline 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
Tigecycline 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 Tigecycline
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, talk to your doctor for advice before receiving Tigecycline.

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.

Tigecycline contains sodium
This medicinal product contains less than 1 mmol sodium per 5ml of solution, that is to say essentially 'sodium- free'.

3. HOW TIGECYCLINE IS GIVEN

Tigecycline will be given to you by a doctor or a nurse.

The recommended dose 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.

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The following information is intended for healthcare professionals only:

Instructions for use and handling (see also 3. How Tigecycline 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, dextrose 50 mg/ml (5 %) solution for injection, or Lactated Ringer's 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, dextrose 50 mg/ml (5 %) solution for injection, and Lactated Ringer's solution for injection.

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

If you miss a dose of Tigecycline
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 Tigecycline. 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 Yellow Card Scheme Website: 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 TIGECYCLINE

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 vial and the carton after EXP. The expiry date refers to the last day of that month.

Store below 25°C.

Storage after preparation
Chemical and physical in-use stability has been demonstrated for 48 hours at 2-8ºC once reconstituted with 0.9% Sodium chloride injection or Dextrose 5%.

From a microbiological point of view, the product 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 8ªC, unless reconstitution has taken place in controlled and validated aseptic conditions.

The Tigecycline 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 Tigecycline contains
The active substance is tigecycline. Each vial contains 50 mg of tigecycline.
The other ingredients are arginine, hydrochloric acid and sodium hydroxide (for pH-adjustment).

What Tigecycline looks like and contents of the pack
Tigecycline 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 10 vial 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:
Hikma Farmacêutica (Portugal), S.A.
Estrada do Rio da Mó, 8, 8A e 8B – Fervença
2705-906 Terrugem SNT
Portugal

Manufacturer:
Hikma Italia S.p.A.
Viale Certosa 10, 27100 – Pavia (PV)
Italy

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Consilient Health Ltd.
No.1 Church Road,
Richmond upon Thames,
Surrey, TW9 2QE.

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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, Lactated Ringer's, lidocaine HCl, metoclopramide, morphine, norepinephrine, piperacillin/tazobactam (EDTA formulation), potassium chloride, propofol, ranitidine HCl, theophylline, and tobramycin.

Tigecycline must not be mixed with other medicinal products for which compatibility data are not available.

Once reconstituted and diluted in the bag or other suitable infusion container (e.g. glass bottle) tigecycline should be used immediately.

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