TEGADIS® 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 TEGADIS is and what it is used for
2.What you need to know before you receive TEGADIS
3.How TEGADIS is given
4.Possible side effects
5.How to store TEGADIS
6.Contents of the pack and other information

1.What TEGADIS is and what it is used for
TEGADIS is an antibiotic from the glycylcycline group ; it works by stopping the growth of bacteria that cause infections.
Your doctor has prescribed TEGADIS for you 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.
TEGADIS is only used when your doctor considers that other antibiotics are not suitable.

2.What you need to know before you receive TEGADIS
Do not use TEGADIS
•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 TEGADIS :
•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 change in results of certain lab tests that measure blood clotting).
•If you have, or previously have 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).
During treatment with TEGADIS :
•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 symptoms may be those of acute pancreatitis (inflammation of the pancreas which can lead to severe abdominal pain, nausea and vomiting).
•In certain serious infections, your doctor may consider combining TEGADIS 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 TEGADIS, fight certain bacteria, other bacteria and fungi may continue to grow. This is called microbial overgrowth. Your doctor will monitor you closely for any potential infections and treat you if necessary.
Children
TEGADIS 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 TEGADIS
Tell your doctor if you are taking, have recently taken or might take any other medicines.
TEGADIS may prolong certain tests that measure how well your blood is clotting. You should tell your doctor if you are taking medicines to prevent excessive clotting (medicines called anticoagulants). In this case, your doctor will monitor you closely.
TEGADIS may interfere with the contraceptive pill (birth control pill). Talk to your doctor about the need for an additional method of contraception while receiving TEGADIS.
Pregnancy and breastfeeding
TEGADIS may cause foetal harm. If you are pregnant or breast-feeding, think you may be pregnant or plan to become pregnant, ask your doctor for advice before taking TEGADIS.
It is not known whether TEGADIS passes into breast milk in humans. Ask your doctor for advice before breastfeeding your baby.
Driving and using machines
TEGADIS may cause side effects, such as dizziness, which may affect your ability to drive or operate machinery.

3.How TEGADIS is given
TEGADIS will be given to you by a doctor or 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 the blood stream) over a period of 3060-minutes.
The recommended dose in children aged 8 to < 12 years of age 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 5 to 14 days. Your doctor will decide how long you should be treated
If you receive more TEGADIS than you should :
If you think you have received too much TEGADIS, talk to your doctor or nurse straight away.
If you miss a dose of TEGADIS :
If you think an infusion has been missed, 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 TEGADIS. 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) are :
•Nausea, vomiting, diarrhea.
Common side effects (may affect up to 1 in 10 people) are :
•Abscess (collection of pus), infections
•Laboratory measurements of decreased ability to form blood clots
•Dizziness
•Irritation of the vein following the injection, including pain, inflammation, swelling and clotting
•Abdominal pain, dyspepsia (stomach ache and indigestion), anorexia (loss of appetite)
•Increases in liver enzymes, hyperbilirubinaemia in the blood (excess of bile pigments 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 in 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)
•Reaction at the injection site (pain, redness, inflammation)
•Low blood protein levels
Uncommon side effects (may affect up to 1 in 100 people) are :
•Acute pancreatitis (inflammation of the pancreas which can result in severe abdominal pain, nausea and vomiting).
•Jaundice (yellow discoloration of the skin), inflammation of the liver
•Low platelet levels in the blood (which may lead to an increased bleeding tendency and bruising/haematoma).
Not known side effects (cannot be estimated from the available data) are :
•Anaphylaxis/anaphylactoid reactions (that may range from mild to severe, including a sudden generalized allergic reaction which may lead to a life-threatening “shock” type reaction [characterized by difficulty in breathing, drop of blood pressure, a fast pulse]).
•Liver failure .
•Skin rash which may lead to severe blistering and peeling of the skin (Stevens-Johnson Syndrome)
•Low levels of blood fibrinogen (a protein involved in blood clotting)
KEEP MEDICINES OUT OF THE REACH OF CHILDREN
Reporting side effects
If you get any side effects, talk to your doctor or nurse. This also applies to any side effects not mentioned in this leaflet. You can also report side effects directly through the national reporting system. By reporting side effects, you help provide more information about the safety of the medicine.

5.How to store TEGADIS
Keep this medicine out of the sight and reach of children.
Store at a temperature below 25°C.
Do not use this medicine after the expiry date which is stated on the vial. The expiry date refers to the last day of that month.
Storage after preparation
Once the powder has been dissolved and diluted, ready for use, it should be given to you immediately.
The TEGADIS solution should be yellow-orange in color 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 TEGADIS contains
The active substance is tigecycline. Each vial contains 50 mg of tigecycline.
The other components are lactose monohydrate, hydrochloric acid and sodium hydroxide.
What TEGADIS looks like and contents of the pack
TEGADIS is supplied as a powder for solution in a vial. These vials are packaged for the hospital in boxes of 10 bottles and 1 bottle. 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 infusion bag or other suitable infusion container in the hospital.
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Supply Conditions : List 1
M.A. N° :
TEGADIS 50 mg, powder for solution for infusion, box of 1 vial : ST9234061H
TEGADIS 50 mg, powder for solution for infusion, box of 10 vials : ST9234062H
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This is a medicine
- A medicine is a product but not like any other product.
- A medicine is a product that affects your health.if it's not used properly : it can be health threatening.
- Strictly adhere to the prescription of you Doctor and the use instructions prescribed, follow your pharmacist advice.
- Your doctor and you pharmacist know the medicine, its use and side effect.
- Don't stop the use of the treatment on your own during the prescribed time.
- Don't retake, Don't increase the doses without doctor's advice.

Keep the medicines out of reach of children

The following information is intended for healthcare professionals only : Instructions for use and handling (see also 3. How TEGADIS is given in this leaflet)
The powder should be reconstituted with 5.3 ml of solution for injection containing sodium chloride 9 mg/ml (0.9%), dextrose 50 mg/ml (5%) or Lactated Ringer's solution for injection to achieve a concentration 10 mg/ml of tigecycline. Shake the vial gently 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 container for infusion (e.g. glass bottle).
For a 100 mg dose, reconstitute two vials and transfer to a 100 ml intravenous bag for infusion or other suitable infusion container (e.g. glass bottle).
Note : The bottle contains 6 % overage. Thus, 5 ml of the reconstituted solution is equivalent to 50 mg of the active substance. The reconstituted solution should be yellow-orange in color; if not, it should be discarded. Parenteral products should be visually inspected for particles and discoloration (e.g. green or black) prior to administration.
Tigecycline should be administered intravenously through a dedicated line or through a Y device. If the same intravenous infusion set 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%) or dextrose 50 mg/ml (5%). The injection should be made with an infusion solution compatible with tigecycline and any other medicinal product administered 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.
When TEGADIS is administered through a Y device, compatibility of tigecycline diluted in 0.9% sodium chloride for injection has been demonstrated with the following medicines and solutions : amikacin, dobutamine, dopamine, gentamicin, haloperidol, Lactated Ringer's , lidocaine, metoclopramide, morphine, norepinephrine, piperacillin/tazobactam (with EDTA), potassium chloride, propofol, ranitidine, theophylline and tobramycin.
TEGADIS must not be mixed with other medicinal products for which compatibility data are not available.
Once reconstituted and diluted in the infusion bag or other suitable infusion container (e.g. glass vial), tigecycline should be used immediately.
Intended for single use only, any unused solution should be discarded.

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