PATIENT INFORMATION LEAFLET

TİGENEX 50 mg Powder for Solution for Infusion
Administered intravenously.

Sterile

- ***Active Ingredient:*** Tigecycline…….50 mg
- ***Excipients:*** Maltose (monohydrate), hydrochloric acid (used to adjust pH), water for injection.

Before using this medicine, read all of this patient information leaflet carefully. Because, this leaflet includes important information for you.

- *Keep this patient information leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *During the use of this medicine, tell that you are using this medicine when you go to a doctor or hospital.*
- *Follow these instructions exactly as written. Do not use **higher or lower** dose other than your recommended dose.*

What is in this leaflet:

Headings are covered.

1. What TİGENEX is and what is it used for?

- TİGENEX is presented in packages of 10 vials. Orange in color, lyophilized (freeze-dried) cake or powder. The solution prepared by diluting for intravenous use is yellow-orange in color. Each vial contains 50 mg of tigecycline powder.
- TİGENEX is an antibiotic belonging to the glycylcycline group, which stops the growth of bacteria that cause infections.
- TİGENEX should only be used when other alternatives are known or suspected to be unsuitable.
- Your doctor has prescribed TİGENEX for you because you have one of the following serious infections:
  -Complicated skin and skin structure infections
  -Complicated intra-abdominal infections
  -Community-acquired bacterial pneumonia (lung infection transmitted outside the hospital setting)

TİGENEX should not be used in the treatment of diabetic foot infection.

2. What you need to know before you use TİGENEX?

DO NOT USE TİGENEX in below situations;
If;

- you are hypersensitive (allergic) to tigecycline or any of the other ingredients of this medicine. You are sensitive (allergic) to tetracycline class antibiotics such as minocycline, doxycycline, you may also be allergic to tigecycline.

USE TİGENEX CAREFULLY in the following situations
If;

- you have a wound that does not heal at all or heals slowly
- you develop signs of an allergic reaction, inform your doctor immediately.
- If severe abdominal pain, nausea and vomiting symptoms develop, inform your doctor immediately. These may be signs of acute pancreatitis.
- Before starting TİGENEX treatment, inform your doctor if you have diarrhea. If diarrhea develops during or after treatment with TİGENEX, inform your doctor immediately. Do not take any diarrhea medication without consulting your doctor.
- Inform your doctor if side effects (skin sensitivity to sunlight, staining of teeth during tooth development, pancreatic inflammation and changes in blood coagulation values in laboratory tests) have occurred due to the use of tetracycline class antibiotics before or during treatment.
- In some serious infections, your doctor may use TİGENEX with other antibiotics.
- Your doctor will monitor you closely for further bacterial infections. If another bacterial infection develops, your doctor may prescribe another antibiotic depending on the type of infection present.
- If you have or have had liver disease, inform your doctor about it. Depending on the condition of your liver, your doctor may reduce the dose to reduce possible side effects.
- Inform your doctor if there is obstruction of the bile ducts (cholestasis).
- While antibiotics, including TİGENEX, fight certain bacteria, other bacteria and fungi can continue to multiply. Your doctor will monitor you for possible infections and treat if necessary.
- TİGENEX should not be used in children and adolescents (under 18 years of age). Tigecycline should not be used in children under 8 years of age as it may cause permanent tooth damage such as staining of developing teeth.

In clinical studies, an increased rate of all-cause mortality has been observed in patients.

If these warnings apply to you, even at any time in the past, please consult your doctor.

Use of TİGENEX with food and drink
Due to the route of use, there is no data on its use with food and drink.

Pregnancy
Consult your doctor or your pharmacist before using the drug.

TİGENEX may harm the baby if administered during pregnancy. If you are pregnant or planning to become pregnant, consult your doctor before using TİGENEX.

Your doctor will recommend contraceptive measures due to your TİGENEX treatment.

If you notice you are pregnant during treatment, consult your doctor immediately.

Lactation
Consult your doctor or your pharmacist before using the drug.

It is not known whether TİGENEX passes into breast milk. Consult your doctor before breastfeeding your baby.

Driving and using machines
TİGENEX may cause dizziness. This may impair your ability to drive and use machines.

Use with other medicines
If you are using certain drugs (anticoagulants) such as warfarin to prevent excessive coagulation of the blood and if laboratory tests detect changes in blood coagulation values, inform your doctor. In this case, your doctor will monitor you closely.

TİGENEX may interact with birth control pills. Discuss with your doctor whether an additional non-hormonal method is needed for birth control while using TİGENEX.

Inform your doctor if you are using a drug that can reduce the activity of an enzyme called P-gp (such as ketoconazole used in the treatment of fungal diseases and cyclosporine used to suppress the immune system) or increase it (such as rifampicin used in the treatment of tuberculosis). These drugs can change the effect (pharmacokinetics) of TİGENEX in your body.

If you are currently using any prescription or non-prescription medication or you have used it recently, please inform your doctor or pharmacist about them.

3. How to use TİGENEX?
Instructions for appropriate use and dose/administration frequency:
Your doctor will determine the dose of your drug and administer it to you depending on your illness.

The recommended dose is 100 mg initially, then 50 mg every 12 hours. The recommended duration of treatment in the treatment of complicated skin and skin structure infections and complicated intra-abdominal infections is generally 5-14 days. The recommended duration of treatment for community-acquired bacterial pneumonia is 7-14 days. Your doctor will tell you how long your treatment with TİGENEX will last.

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

Route and Method of administration:
TİGENEX is administered by your doctor or nurse into the vein as a drop in serum for about 30-60 minutes.

Various age groups:
Use in Children: TİGENEX should not be used in children and adolescents (under 18 years of age).

Use in Elderly: No dose adjustment is recommended in elderly patients.

Special use cases:
Renal Impairment:
No dose adjustment is recommended in patients with renal impairment or on hemodialysis.

Hepatic impairment:
No dose adjustment is recommended in patients with mild to moderate hepatic impairment. If you have severe liver failure, your doctor will check you while using TİGENEX.

Talk to your doctor or pharmacist if you have an impression that the effect of TİGENEX is too strong or weak.

If you use more TİGENEX than you should:
If you are concerned about taking too much TİGENEX, talk to your doctor or nurse immediately.

If you forget to use TİGENEX:
If you are worried that you have missed a dose of TİGENEX, talk to your doctor or nurse immediately.

Do not take a double dose to make up for forgotten doses.

Effects that may occur when treatment with TİGENEX is terminated:
Continue to use your medicine until your doctor terminates your treatment.

4. What are the possible side effects?
Like all medicines, there may be side effects in people who are sensitive to the substances contained in TİGENEX.

Other side effects seen with TİGENEX are as follows, and the side effects are listed as shown in the following categories.

Very Common: Effects seen in at least 1 in 10 patients
Common : Effects seen in less than one in 10 patients, but in more than one in 100 patients.
Uncommon : Effects seen in less than one in 100 patients, but in more than one in 1,000 patients.
Rare : Effects seen in less than one in 1,000 patients, but in more than one in 10,000 patients.
Very Rare :Effects seen in less than one in 10,000 patients.
Unknown : Cannot be estimated from the available data

Very common side effects:

- Nausea, vomiting, diarrhea

Common side effects:

- Abscess, infections
- Laboratory measurements of decreased blood clotting ability
- Dizziness
- Abdominal pain, stomach discomfort (stomach pain and indigestion), loss of appetite
- Elevated liver enzyme levels, increased bilirubin level in the blood (increased bile pigment in the blood)
- Itching, rash
- Slow or no healing of the wound
- Headache
- Increase in amylase, an enzyme found in the salivary glands and pancreas, increase in blood urea nitrogen
- Pneumonia (lung inflammation)
- Decreased blood sugar level
- Sepsis (serious infection in the body and blood)/septic shock (a serious illness that can lead to sepsis-related organ failure and death)
- Application site reactions (pain, redness, inflammation)
- Decreased protein levels in the blood

Uncommon side effects:

- Acute pancreatitis (inflammation of the pancreas that can result in severe abdominal pain, nausea and vomiting)
- Jaundice (may manifest as yellowing of the skin and whites of the eyes), inflammation of the liver
- Decreased number of platelets in the blood (increased bleeding tendency and bruising/hematoma)
- Injection-related irritations such as pain, swelling, and clot formation at the injection site

Side effects with an unknown frequency:

- Anaphylaxis/anaphylaxis-like reactions (may range from mild to severe, including sudden onset of widespread allergic reaction [e.g., difficulty in breathing, drop in blood pressure, rapid heart rate] that can lead to life-threatening shock)
- Hepatic failure
- Severe skin reactions, including inflammation of the skin with swelling, redness and peeling (Steven-Johnson Syndrome)
- Low levels of fibrinogen (protein involved in blood clotting) in the blood

Pseudomembranous colitis (inflammation of the large intestine) may occur with many antibiotics, including TİGENEX. This picture may occur during or after your treatment; it presents as severe, persistent or bloody diarrhea with abdominal pain or fever and may be a sign of a serious bowel infection.

If you experience any side effect not mentioned in this patient information leaflet, inform your doctor or your pharmacist.

Reporting of suspected adverse reactions

If you get any side effects not listed in this leaflet, talk to your doctor or pharmacist. You can also report side effects directly to your doctor or pharmacist. You can also report side effects directly

to your country's related health authority. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store TİGENEX?

Keep TİGENEX out of the reach and sight of children and within its packaging.

TİGENEX will be stored in hospitals under appropriate conditions.

Use in compliance with the expiry date.

Store at room temperature below 25ºC.

Storage after reconstitution
After TİGENEX is prepared for use, it can be stored for up to 24 hours at room temperature (25ºC) and 48 hours in the refrigerator (2-8ºC).

Do not use TİGENEX after the expiration date stated on the packaging.

Do not throw away expired or unused drugs! Give it to the collection system determined by the Ministry of Environment, Urbanization and Climate Change.

***Marketing Authorization Holder*:**	Haver Trakya İlaç San. ve Tic. A.Ş. Ulaş OSB Mah. D100 Cad. No:28/1, Ergene 2 OSB Ergene/TEKİRDAĞ Phone: (0282) 655 55 05
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THE FOLLOWING INFORMATION IS FOR THE HEALTHCARE PROFESSIONALS WHO ADMINISTER THIS MEDICINE.

Preparation and usage information:
The lyophilized powder is mixed with 5.3 ml, 9 mg/ml (0.9%) sodium chloride solution for injection or 50 mg/ml (5%) dextrose solution for injection to obtain tigecycline at a concentration of 10 mg/ml. The vial should be rotated slightly to allow the medicine to dissolve completely. Then, 5 ml of the prepared solution in the vial is immediately taken and transferred to a 100 ml I.V. bag for infusion.

For the 100 mg dose, 2 vials of medication should be prepared and transferred into a 100 ml I.V. bag. **The prepared solution should be yellow-orange in color, otherwise the solution should not be used and discarded.** Parenteral products must be inspected for discoloration (eg green or

black) and particulates prior to administration. When reconstituted in the IV bag, tigecycline can be stored for up to 24 hours at room temperature (25^{o}C) and 48 hours in the refrigerator (2-8^{o}C).

Any unused solution should be discarded.

TİGENEX can be administered alone on a separate I.V. line or on a common I.V. line. Where the same I.V. line is used for sequential infusions of several drugs, the vein line should be flushed with sodium chloride 9 mg/ml (0.9%) solution for injection or dextrose solution 5 mg/ml (5%) for injection before and after administration of TİGENEX. An infusion solution compatible with tigecycline should be used and care should be taken to ensure that the drug(s) administered through the same vascular line are compatible with tigecycline.

Compatible drugs and solutions
Suitable intravenous solutions are: 9mg/ml (0.9%) sodium chloride solution (USP) for injection and 50mg/ml (5%) dextrose solution (USP) and Lactated Ringer's injection (USP) for injection. When TİGENEX is administered with 0.9% sodium chloride (USP) or 5% dextrose solution (USP), it can be given in the same set with the following drugs or solutions: Amikacin, dobutamine, dopamine HCl, gentamicin, haloperidol, Lactated Ringer's solution, lidocaine HCl, metoclopramide, morphine, norepinephrine, piperacillin/tazobactam (EDTA formulation) potassium HCl, propofol, ranitidine HCl, theophylline, tobramycin.