PATIENT INFORMATION LEAFLET

TYGEPOL 50 mg lyophilized powder for solution for i.v. infusion

For intravenous administration.

Sterile

- ***Active Substance:*** Tigecycline……..50 mg
- ***Excipients:*** Maltose, water for injection, hydrochloric acid, sodium hydroxide

Read all of this PATIENT INFORMATION LEAFLET carefully before you start using this medicine because it contains important information for you.

- *Keep this **PATIENT INFORMATION LEAFLET.** You may need to read it again.*
- *If you have any additional questions, please contact your physician or pharmacist.*
- *This medicine has been prescribed personally for you. Do not pass it on to others.*
- *When you go to doctor or hospital while using this medicine, tell your doctor that you are using this medicine.*
- *Please completely follow the instructions in this information leaflet. Do not use **higher** or **lower** doses other than what is recommended to you.*

In this leaflet:

headlines are included.

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

- TYGEPOL is available in 10 vial packs. It is supplied as an orange lyophilized (freeze-dried) powder. The solution prepared by dilution for intravenous administration is clear, yellow or orange. Each vial contains 50 mg tygecycline powder.
- Tigecycline is an antibiotic of the glycylcycline group that works by stopping the growth of bacteria that cause infections.
- TYGEPOL should be used only where it is known or suspected that other alternatives are not suitable.
- Your doctor prescribed TYGEPOL because you have one of the following types of serious infections:
  - Complicated infection of the skin and soft tissues
  - Complicated infection in the abdomen

- Community-Acquired Bacterial Pneumonia (Lung infection developed outside a hospital)

TYGEPOL should not be used to treat diabetic foot infection.

2. What you need to know before you use TYGEPOL

Do not use TYGEPOL in the following conditions

If,

- you are hypersensitive (allergic) to tigecycline or any of the other ingredients of this medicine, you are allergic to tetracycline class antibiotics e.g., minocycline, doxycycline, etc., you may be allergic to tigecycline.

Take special care with TYGEPOL in the following conditions

- If you have poor or slow wound healing.
- 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.
- If you have diarrhea before starting TYGEPOL treatment, inform your doctor. If you develop diarrhea during or after your treatment with TYGEPOL, tell your doctor at once. Do not take any diarrhea 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).
- In certain serious infections, your doctor may consider to use TYGEPOL 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.
- If you have, or previously had liver problems, inform you doctor. 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).
- Although antibiotics including Tigecycline fight certain bacteria, other bacteria and fungi may continue to grow. Your doctor will monitor you closely for any potential infections and treat you if necessary.
- TYGEPOL should not be used in children and adolescents (less than 18 years of age). Tigecycline is not to be used in children less than 8 years of age because it may induce permanent dental defects such as staining on the developing teeth.

Clinical studies have shown an increase in all-cause mortality rates.

Please consult your doctor even if these warnings apply to you at any time in the past.

Using TYGEPOL with food and drink

Due to the route of administration, there is no data on the use with food and beverages.

Pregnancy
Before using this medicine consult your doctor or pharmacist.

TYGEPOL may cause fetal harm if used during pregnancy. If you are pregnant or are planning to have a baby, talk to your doctor for advice before receiving TYGEPOL.

Your doctor will prescribe contraceptive measures due to your TYGEPOL treatment.

If you notice that you have been pregnant during treatment, consult immediately your doctor.

Breastfeeding
Before using this medicine consult your doctor or pharmacist.
It is not known whether TYGEPOL is excreted in breast milk. You should consult your doctor before you breastfeed your baby.

Driving and using machinery
TYGEPOL may cause dizziness. This may impair your ability to drive or operate machines.

Important information on some excipients present in TYGEPOL
This medicinal product contains less than 1 mmol (23 mg) sodium per ml, i.e. it is essentially "sodium free". No adverse effect associated with sodium is expected.

Taking with other medicines
If you are using some drugs (such as warfarin) to avoid an excess of blood clotting, and if there is a change in blood clotting values in laboratory tests, tell your doctor. If this were the case, your doctor will monitor you closely.

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

Tell your doctor if you are taking a medication that can reduce (such as ketoconazole for the treatment of fungal diseases and cyclosporin used for the suppression of the immune system) or can increase (such as rifampicin used in the treatment of tuberculosis) the effectiveness of an enzyme called p-gp. These drugs can change the effect (pharmacokinetics) of TYGEPOL on your body.

If you are taking or have recently taken any other medicines, including medicines without a prescription, tell your doctor or pharmacist.

3. ***How to use TYGEPOL?***

Instructions for proper use and dosage/administration frequency:
Your doctor will determine the dosage of your drug depending on your illness and will apply it to you.

The recommended dose is 100 mg given initially, followed by 50 mg every 12 hours. The recommended duration of treatment for complicated skin and skin structure infections or for complicated intra-abdominal infections is usually 5 to 14 days. The recommended duration of treatment for community-acquired bacterial pneumonia is 7 to 14 days. Your doctor will inform you on the duration of your treatment with TYGEPOL.

Consult your doctor or pharmacist if you have other questions about the use of this medicine.

Route and method of administration:
TYGEPOL is given by your doctor or nurse into a vein drop by drop over a period of 30 to 60 minutes.

Different age groups:
Use in children: TYGEPOL should not be used in children and adolescents (less than 18 years of age).

In elderly: No dosage adjustment is required in elderly.

Special conditions of use:
Renal impairment
No dosage adjustment is necessary in patients with renal impairment or in patients undergoing hemodialysis.

Hepatic impairment
No dosage adjustment is required in patients with mild to moderate liver impairment. If you have severe liver impairment, your doctor will monitor you while using TYGEPOL.

If you have the impression that the effect of TYGEPOL is too strong or weak, talk with your doctor or pharmacist.

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

If you used more TYGEPOL than was prescribed, tell your doctor or pharmacist.

If you miss a dose of TYGEPOL:
If you are concerned that you may have missed a dose of TYGEPOL, talk to your doctor or nurse immediately.

Do not take double dose to make up the dose you have missed.

Effects that may occur if you stop receiving TYGEPOL:
Continue to use your medication until your doctor terminates your treatment.

4. Possible side effects
Like all medicines TYGEPOL may cause side effects in patients sensitive to its ingredients.

Other side effects seen with TYGEPOL are as follows and are listed in the following categories.

Very common	: may be seen in at least 1 of 10 patients;
Common	: may be seen in less than one of 10 patients but more than one of 100 patients;
Uncommon	: may be seen in less than one of 100 patients but more than one of 1000 patients.
Rare	: may be seen in less than one of 1,000 patients but more than one of 10,000 patients;
Very rare	: may be seen in at least one of 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 ability to form blood clots
- Dizziness
- Abdominal pain, dyspepsia (stomach ache and indigestion), loss of appetite
- Increases in liver enzymes, increase in blood bilirubin (excess of bile pigment in the blood)
- Pruritus, 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
- Pneumonia (lung inflammation)
- 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:

- 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/hematoma)
- Injection-induced irritations such as pain at the injection site, swelling and clot formation

Unknown side effects:

- Anaphylaxis/anaphylactoid reactions (that may range from mild to severe, including a sudden, generalized allergic reaction that may lead to a life-threatening shock [e.g. difficulty in breathing, drop of blood pressure, fast pulse])
- Hepatic failure
- Skin rash, which may lead to severe blistering and peeling of the skin (Stevens-Johnson syndrome)
- Low fibrinogen levels in the blood (a protein involved in blood clotting)

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

Tell your doctor or pharmacist if you notice any other effects not listed in this leaflet.

5. *How to store TYGEPOL?*

Store TYGEPOL in its original packaging and keep out of the reach and sight of children.

TYGEPOL is stored in hospital under adequate conditions.

Store at room temperature below 25ºC.

Storing after reconstitution

Once prepared, TYGEPOL can be stored at room temperature (25ºC) for up to 24 hours (up to 6 hours in the vial, 18 hours in the IV bag) and 48 hours in the refrigerator (2-8ºC).

Shake/swirl until product is completely dissolved during reconstitution.

Use in compliance with the expiry date.

Do not throw away drugs that have expired or are not used! Deliver to the collection system determined by the Ministry of Environment and Urbanism.

Do not use TYGEPOL after the expiry date which is stated on the packaging.

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FOLLOWING INFORMATION IS FOR HEALTHCARE PROFESSIONALS ONLY:

Instructions for preparation and use:
Lyophilized powder should be reconstituted with 5.3 mL of 9 mg/ml (0.9%) Sodium Chloride Solution for Injection or 50 mg/ml (5%) Dextrose Solution for Injection to achieve a concentration of 10 mg/mL of tigecycline. The vial should be gently swirled until the drug dissolves. Withdraw 5 mL of the reconstituted solution from the vial and transfer into to a 100 mL IV bag for infusion.

For a 100 mg dose, reconstitute two vials and transfer in 100 ml I.V bag. (Note: Each vial contains a 6% overage. Thus, 5 mL of reconstituted solution is equivalent to 50 mg of the drug.) **The reconstituted solution should be yellow to orange in color; if not, the solution should be discarded.** Parenteral drug products should be inspected visually for particulate matter and discoloration (e.g., green or black) prior to administration. Once reconstituted in IV bag, TYGEPOL can be stored at room temperature (25ºC) for up to 24 hours (up to 6 hours in the vial, 18 hours in the IV bag) and 48 hours in the refrigerator (2-8ºC).
Shake/swirl until product is completely dissolved during reconstitution.

Any unused solution must be discarded

TYGEPOL may be administered intravenously through a dedicated I.V line or through a Y-site. If the same intravenous line is used for sequential infusion of several drugs, the line should be flushed before and after infusion of TYGEPOL with 9 mg/ml (0.9%) Sodium Chloride Solution for Injection or 50 mg/ml (5%) Dextrose Solution for Injection. Injection should be made with an infusion solution compatible with tigecycline and with any other drug(s) administered via this common line.

Compatible drugs and solutions
Compatible intravenous solutions are: 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 administered with sodium chloride 0.9% for injection (USP) or 5% dextrose solution (USP), TYGEPOL may be given through the same Y-site 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), propofol, ranitidine HCl, theophylline.