

PATIENT INFORMATION LEAFLET FOR TIGEJEX

SCHEDULING STATUS **S4**

TIGEJEX lyophilised powder for injection

Tigecycline

Contains sugar (lactose monohydrate 100 mg)

Read all of this leaflet carefully before you are given TIGEJEX

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- TIGEJEX has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What TIGEJEX is and what it is used for

TIGEJEX contains the active substance tigecycline. Tigecycline is an antibiotic of the glycylcycline group that works by stopping the growth of bacteria that cause infections.

TIGEJEX is used in:

- Infection of the skin excluding diabetic foot infections
- Infection in the abdomen

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

2. What you need to know before you are given TIGEJEX

TIGEJEX should not be given to you:

- If you are hypersensitive (allergic) to tigecycline or any of the other ingredients of TIGEJEX (listed in section 6).
- If you are pregnant or are breastfeeding.

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

- If you are allergic to tetracycline class antibiotics (e.g., minocycline, doxycycline, etc.), you may be allergic to tigecycline.
- If you develop severe abdominal pain, nausea, and vomiting. These may be symptoms of acute pancreatitis.
- If you are suffering from diarrhoea before you are given TIGEJEX. 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. Pseudomembranous colitis may occur with most antibiotics including TIGEJEX. 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.
- In certain serious infections, your doctor may consider using TIGEJEX in combination with other antibiotics.
- If you suffer from a bleeding disorder or are on treatment with anticoagulant medicines, as TIGEJEX can interfere with blood coagulation (see Other medicines and TIGEJEX).
- 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.

- While antibiotics including TIG EJEX fight certain bacteria, other bacteria and fungi may continue to grow. This is called overgrowth. Your doctor will monitor you for any potential infections and treat you if necessary.
- If you have pneumonia that developed during your stay in hospital.
- If you have poor or slow wound healing.
- 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 blockage of the bile ducts (cholestasis).
- Although antibiotics including tigecycline, as in TIG EJEX, fight certain bacteria, other you bacteria and fungi may continue to grow. This is called overgrowth. Your doctor will monitor closely for any potential infections and treat you if necessary.

Children and adolescents

This medicine is not recommended for use in children or adolescents (under 18 years of age).

Other medicines and TIG EJEX

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

TIG EJEX may affect other medicines or be affected by them.

TIG EJEX 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 such as warfarin. If this is the case, your doctor will monitor you closely.

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

Other medicines may interfere with TIG EJEX. Examples of these are ketoconazole (used to treat fungal infections), ciclosporin (an immunosuppressant used during transplant surgery), tacrolimus (an immunosuppressant used following organ transplant) and rifampicin (used to treat tuberculosis). Please consult your doctor if you are taking any of these medicines.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before being given TIG EJEX.

Pregnancy:

TIG EJEX may cause foetal harm. TIG EJEX should not be used during pregnancy

Breastfeeding:

It is not known if TIG EJEX passes into breast milk in humans. Therefore, TIG EJEX should not be used during breastfeeding.

Driving and using machines

TIG EJEX may cause side effects such as dizziness. This may impair your ability to drive or operate machinery.

It is not always possible to predict to what extent TIG EJEX may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which TIG EJEX affects them.

TIG EJEX contains lactulose

If you have been told by your doctor that you have an intolerance to some sugars, contact your

doctor before taking this medicinal product.

3. How TIG EJEX is given

You will not be expected to give yourself TIG EJEX. It will be given to you by a person who is qualified to do so.

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

Your doctor will tell you how long your treatment with TIG EJEX will last.

A course of treatment usually lasts for 5 to 14 days.

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

If you have the impression that the effect of TIG EJEX is too strong or too weak, tell your doctor or pharmacist.

If more TIG EJEX is given to you than recommended

Since a health care provider will administer TIG EJEX he or she will control the dosage.

However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use TIG EJEX

Since a health care provider will administer TIG EJEX, it is unlikely that the dose will be missed.

4. Possible side effects

TIG EJEX can have side effects.

Not all side effects reported for TIG EJEX are included in this leaflet. Should your general health worsen or if you experience any untoward effects, please consult your health care provider for advice.

If any of the following happens to you, stop using TIG EJEX and tell your doctor immediately:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to TIG EJEX. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- 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,
- Nausea (feeling sick) or vomiting (being sick),
- Diarrhoea,
- Abscess (collection of pus),
- Infections,
- Laboratory measurements of decreased ability to form blood clots,
- Low platelet levels in the blood (which may lead to an increased bleeding tendency and bruising),
- Dizziness,
- Irritation at the site of injection, including pain, itching, swelling and redness,
- Pneumonia,
- Stomach pains, indigestion,
- Anorexia (loss of appetite),
- Increases in liver enzyme,
- Excess of bile pigment in the blood,
- Low protein levels in the blood,

- Low blood sugar,
- Itching,
- Headache,
- Impaired healing,
- Increase in amylase, which is an enzyme found in the salivary glands and pancreas,
- Increased blood urea.

Less frequent side effects:

- Acute pancreatitis (inflamed pancreas which may result in severe stomach pain, nausea (feeling sick) and vomiting (being sick),
- Jaundice (yellowing of your skin),
- Inflammation of the liver,
- Allergic reactions,
- Liver failure,
- Severe skin reactions, including Stevens-Johnson Syndrome (a skin rash, which may lead to severe blistering and peeling of the skin),
- Low fibrinogen levels in the blood (a protein involved in blood clotting).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of TIGEX.

5. How to store TIG EJEX

Store all medicines out of reach of children.

TIG EJEX will be stored in the hospital in the appropriate conditions [stored at or below 25 °C prior to being made into a solution and at room temperature (not to exceed 25 °C) for up to 24 hours or at 2 °C to 8 °C for up to 48 hours once transferred to the infusion bag].

Do not use after the expiry date stated on the vial.

Storage after preparation:

Once the powder has been made into a solution and diluted ready for use, it should be given to you almost immediately.

6. Contents of the pack and other information

What TIG EJEX contains:

The active substance is tigecycline.

Each 5 mL vial contains 50 mg tigecycline.

The other ingredients are hydrochloric acid (used to adjust pH), lactose monohydrate and sodium hydroxide (used to adjust pH).

What TIG EJEX looks like and contents of the pack

TIG EJEX is an orange coloured Lyophilised cake.

TIG EJEX is packed in a 5 ml clear glass tubular vial with 13 mm slotted grey bromobutyl sterile rubber stopper (RFU) and sealed with 13 mm flip-off seal glossy green packed in a printed unit carton along with a pack insert.

Pack size: 1 x 5 mL vial.

Holder of certificate of registration

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