

TIGECYCLINE JUNO

Tigecycline

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about TIGECYCLINE JUNO. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking TIGECYCLINE JUNO against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What TIGECYCLINE JUNO is used for

TIGECYCLINE JUNO is an antibiotic of the tetracycline class in the glycylicycline subcategory that works by stopping the growth of bacteria that cause infections.

Your doctor has prescribed TIGECYCLINE JUNO because you have one of the following types of serious infections:

- Infection of the skin, including those with resistant bacteria
- Infection in the abdomen.

TIGECYCLINE JUNO is for use in adults aged 18 and over. There is no experience with the use of TIGECYCLINE JUNO in children under 18 years of age.

TIGECYCLINE JUNO, like other tetracyclines, may cause enamel loss and staining in developing teeth.

TIGECYCLINE JUNO will not work against viral infections such as colds or flu.

There is no evidence that TIGECYCLINE JUNO is addictive.

TIGECYCLINE JUNO is available only with a doctor's prescription.

Before you are given TIGECYCLINE JUNO

When you must not be given it

Do not have TIGECYCLINE JUNO if you are allergic to tigecycline.

Some of the symptoms of an allergic reaction may include rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or troubled breathing.

Do not have TIGECYCLINE JUNO after the expiry date (Exp. Date) printed on the pack has passed.

If you take this medicine after the expiry date it may not work.

Talk to your doctor if you are not sure whether you should be given TIGECYCLINE JUNO.

Before you are given it

You must tell your doctor if:

- **You are allergic to tetracycline antibiotics.**
You may have an increased chance of being allergic to TIGECYCLINE JUNO if you are allergic to tetracyclines.
- **You are pregnant or breastfeeding.**
As with many medicines, TIGECYCLINE JUNO may harm your

developing or breastfeeding baby. This may include permanent staining of the child's teeth.

- **You have or have had liver problems.**
Depending on the condition of your liver, your doctor may need to reduce your dose to avoid potential side effects.

If you have not told your doctor or nurse about any of the above, tell them before you are given TIGECYCLINE JUNO.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may interfere with TIGECYCLINE JUNO. These include:

- Medicines to treat infections that contain ketoconazole or rifampicin
- Medicines that contain cyclosporin
- Warfarin
If you are taking warfarin, your doctor or nurse will check your blood clotting time.
- Oral contraceptives (birth control pills)
TIGECYCLINE JUNO may interfere with birth control pills.

Talk to your doctor about the need for an additional method of contraception while receiving TIGECYCLINE JUNO.

How TIGECYCLINE JUNO is given

How TIGECYCLINE JUNO will be given

TIGECYCLINE JUNO is given as an injection into a vein and administered to you by your doctor or nurse.

How much you will be given

The recommended dosage is 100 mg for the first dose, followed by 50 mg every 12 hours.

How long you will receive TIGECYCLINE JUNO

It is very important that you continue to receive TIGECYCLINE JUNO for as long as your doctor prescribes it. Your doctor will decide how many days of treatment you need. How long you receive TIGECYCLINE JUNO will depend on how severe your infection is and how quickly you respond to treatment.

If you receive more TIGECYCLINE JUNO than you should (overdose)

Tell your doctor or nurse immediately if you are concerned that you may have been given too much TIGECYCLINE JUNO.

It is unlikely that you will receive an overdose of TIGECYCLINE JUNO because a trained nurse or doctor will give it.

If you miss a dose of TIGECYCLINE JUNO

Talk to your doctor or nurse immediately if you are concerned that you may have missed a dose.

While you are receiving TIGECYCLINE JUNO

Things you must do

If you get severe diarrhoea, tell your doctor or nurse immediately. Do this even if it happens several weeks after treatment with TIGECYCLINE JUNO has been stopped.

Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care.

Do not take any medicine for diarrhoea without first checking with your doctor.

Tell your doctor immediately if you realise that you are pregnant while taking TIGECYCLINE JUNO.

Things to be careful of

Tell your doctor if you get thrush (a fungal infection which can affect the mouth and/or vagina) or any other infection while having, or soon after stopping, TIGECYCLINE JUNO.

Although antibiotics, including TIGECYCLINE JUNO fight certain bacteria, other bacteria and fungi may continue to grow. Your doctor will check you for any possible infections and, if necessary, will give you treatment.

Protect your skin when you are in the sun, especially between 10 am and 3 pm. If outdoors, wear protective clothing and use a 15+ sunscreen.

TIGECYCLINE JUNO may cause your skin to be much more sensitive to sunlight than it is normally. Exposure to sunlight may cause a skin rash, itching, redness, or severe sunburn.

Be careful driving or operating machinery until you know how TIGECYCLINE JUNO affects you.

Whilst it is unlikely that you will drive or operate machinery when having TIGECYCLINE JUNO, you need to be aware that TIGECYCLINE JUNO may cause side effects such as dizziness. This may affect your ability to drive or operate machinery.

Side Effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are having TIGECYCLINE JUNO.

TIGECYCLINE JUNO is effective against certain serious infections for most people but it may have unwanted side effects in some.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

The most common side effects of TIGECYCLINE JUNO are:

- Nausea
- Vomiting
- Diarrhoea

Other less common side effects include:

- Dizziness
- Headache
- Loss of appetite
- Stomach pain or heartburn
- Increased bleeding tendency

- Skin rash and itchiness
- Yellowing of the skin or eyeballs also called jaundice
- Injection site reaction (pain, redness, inflammation, swelling)
- Swelling and/or clotting; and redness along a vein which is very tender when touched
- Abscesses or other infections
- Abnormal healing

Elevated levels of proteins or liver enzymes in the blood may also be observed by your doctor.

Less often, serious effects have occurred in people taking TIGECYCLINE JUNO.

Tell your doctor immediately if you notice any of the following:

- Sepsis (rapid heartbeat, rapid breathing and fever)
- Inflammation of the pancreas (severe upper stomach pain, often with nausea and vomiting)
- Stevens-Johnson Syndrome (a skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals)
- Pneumonia (fever, chills, shortness of breath, cough, phlegm and occasionally blood)
- Low sugar levels in the blood (sweating, weakness, hunger, dizziness, trembling, headache, flushing or paleness, numbness, having a fast, pounding heart beat)
- Low blood platelet count (bleeding or bruising more easily than normal)
- Sudden onset of signs of allergy such as:
 - rash, itching or hives on the skin,
 - swelling of the face, lips, tongue or other parts of the body,
 - shortness of breath, wheezing or trouble breathing

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

After finishing it

Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after stopping treatment with TIGECYCLINE JUNO.

- Severe abdominal cramps or stomach cramps
- Watery and severe diarrhoea, which may also be bloody
- Fever in combination with one or both of the above.

These are rare but serious side effects. You may have a serious condition affecting your bowel. Therefore, you may need urgent medical attention. However, this side effect is rare.

Do not take any medicine for this diarrhoea without first checking with your doctor.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After receiving TIGECYCLINE JUNO

Storage

The hospital will store TIGECYCLINE JUNO under the correct conditions.

TIGECYCLINE JUNO must be kept out of the reach and sight of children.

TIGECYCLINE JUNO will be given to you only within the "Exp. Date" date of the product.

Product description

What it looks like

TIGECYCLINE JUNO is an orange to orange-red powder or cake supplied in glass vials. Dissolving the powder in a sterile liquid makes a solution for injection. After mixing, the solution is an orange to orange-red colour.

Ingredients

Each TIGECYCLINE JUNO vial contains 50 mg of tigeicycline powder for intravenous infusion.

TIGECYCLINE JUNO also contains L-arginine. It does not contain any preservatives.

Supplier

TIGECYCLINE JUNO is supplied in Australia by:

Juno Pharmaceuticals Pty Ltd
Level 2, 6 Bond Street,
South Yarra, VIC – 3141
Australia

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