Package leaflet: Information for the patient

Tenkasi 400 mg powder for concentrate for solution for infusion
oritavancin

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.
- 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 Tenkasi is and what it is used for
2. What you need to know before you are given Tenkasi
3. How you will be given Tenkasi
4. Possible side effects
5. How to store Tenkasi
6. Contents of the pack and other information

1. What Tenkasi is and what it is used for

Tenkasi is an antibiotic that contains the active substance oritavancin. Oritavancin is a type of antibiotic (a lipoglycopeptide antibiotic) that can kill or stop the growth of certain bacteria.
Tenkasi is used to treat infections of the skin and underlying tissues.
It is for use in adults and paediatric patients aged 3 months and older.

Tenkasi can only be used to treat infections caused by bacteria known as Gram-positive bacteria. In mixed infections where other types of bacteria are suspected, your doctor will give you other appropriate antibiotics together with Tenkasi.

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

You must not be given Tenkasi
- if you are allergic to oritavancin or any of the other ingredients of this medicine (listed in section 6).
- if it is expected that you may need to be given a blood thinning medicine (unfractionated heparin sodium) within 5 days (120 hours) of the dose of Tenkasi.

Warnings and precautions
Talk to your doctor or nurse before receiving Tenkasi if you:
- have ever had an allergic reaction to another glycopeptide antibiotic (such as vancomycin and telavancin)
- have developed severe diarrhoea during or following antibiotic treatment in the past.
- have or are suspected to have a bone infection caused by bacteria (osteomyelitis). Your doctor will treat you as necessary

- have or are suspected to have a painful collection of pus on your skin (abscess). Your doctor will treat you as necessary.

Intravenous infusions of Tenkasi can cause flushing of the upper body, hives, itching and/or rashes. Infusion-associated reactions characterized by chest pain, chest discomfort, chills, tremor, back pain, neck pain, shortness of breath, abdominal pain, fever and headache, fatigue, somnolence that might be symptoms of hypoxia, have also been observed. If you experience these types of reactions, your doctor may decide to stop or slow the infusion.

Tenkasi may interfere with laboratory tests that measure how well your blood is clotting and may cause a false reading.

While antibiotics, including Tenkasi, fight certain bacteria, they may not be active against other bacteria or fungi, which may, therefore, continue to grow. This is called overgrowth. Your doctor will monitor you in case this happens and treat you if necessary.

After being given Tenkasi, you may get a new infection at another site on your skin. Your doctor should monitor you in case this happens and treat you as necessary.

Children and adolescents
Tenkasi should not to be used in children below the age of 3 months. The use of Tenkasi has not yet been studied in this age group.

Other medicines and Tenkasi
Tell your doctor if you are using, have recently used or might use any other medicines.

If you are going to be given a blood thinner called unfractionated heparin, then tell your doctor if you have received Tenkasi within the last 5 days (120 hours).

It is particularly important to tell your doctor if you are using medicines that prevent blood from clotting (oral anticoagulants, e.g.coumarin anticoagulants). Tenkasi may interfere with laboratory tests or self-test that measure how well your blood is clotting (INR) and may cause a false reading up to 12 hours after the infusion.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you are given this medicine.

You should not be given this medicine during pregancy unless the benefit is considered to be greater than the risk to the baby.

Driving and using machines
Tenkasi make you feel dizzy, which can influence your ability to drive or operate machines.

3. How you will be given Tenkasi

Tenkasi will be given to you by your doctor or nurse, by infusion (drip) into a vein.

In adults, the recommended dose for Tenkasi is one single infusion of 1,200 mg administered into a vein over 3 hours.

For paediatric patients aged 3 months and over the recommended dose for Tenkasi will be calculated based on the weight and age: one single infusion of 15 mg for each kg of body weight administered into a vein over 3 hours (maximum 1 200 mg). Please refer to section 6 for further details.

If you are given more Tenkasi than you should
Your doctor will decide how to treat you, including stopping the treatment and monitoring for signs of ill effects.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor or nurse immediately if you experience a reaction to the infusion including any of the following symptoms:
- Flushing of the face and upper body, hives, itching and/or rashes
- Wheezing;
- Shortness of breath;
- Swelling around throat or under the skin that develops over a short period of time;
- Shivering or trembling;
- Rapid or weak pulse;
- Chest pain or tightness;
- Decrease in blood pressure (which could make you feel faint or dizzy).

Such reactions may be life-threatening.

Other side effects occur with the following frequencies:

Common side effects (may affect up to 1 in 10 patients):
- Fewer red blood cells or less haemoglobin than normal;
- Feeling dizzy;
- Headache;
- Feeling sick (nausea) or being sick (vomiting);
- Diarrhoea;
- Constipation;
- Pain or irritation where the injection was given;
- Itching, skin rash;
- Muscle pain;
- More enzymes produced by your liver (as shown in blood tests);
- Heart racing or beating fast;
- Infection getting worse or new infection at another site on your skin;
- Swollen, red area of skin or underneath skin that feels hot and tender;
- Accumulation of pus underneath the skin.

Uncommon side effects (may affect up to 1 in 100 patients):
- Higher than normal levels of eosinophils, a type of white blood cell (eosinophilia);
- Low blood sugar;
- High uric acid levels in the blood;

- Increased blood bilirubin levels;
- Severe rash;
- Flushing;
- Inflammation surrounding a tendon (known as tenosynovitis);
- Bone infection caused by bacteria (known as osteomyelitis);
- Reduced blood platelet count below the normal lower limit (known as thrombocytopenia);
- Abdominal pain
- Chest pain
- Fever
- Shortness of breath

Rare side effects (may affect up to 1 in 1000 patients):
- Headache, fatigue, somnolence that might be symptoms of hypoxia;
- Back pain
- Neck pain
- Chills
- Tremor.

Additional side effects in children and adolescents

Side effects in paediatric patients are similar to those seen in adults. The side effects seen only in paediatric patients are: irritability, changes in ECG heart tracing (transitory, asymptomatic and not associated to other changes in heart tracing), infection of the bowel (*Clostridioides difficile* colitis).

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tenkasi

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
Do not store above 25°C.

Do not throw away any medicines via wastewater. 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 Tenkasi contains
- The active substance is oritavancin. Each vial contains oritavancin diphosphate equivalent to 400 mg oritavancin.

- The other ingredients are mannitol and phosphoric acid.

What Tenkasi looks like and contents of the pack
- Tenkasi is a powder for concentrate for solution for infusion
- Tenkasi is a white to off white powder, supplied in a 50 ml glass vial.
- Tenkasi is available in cartons containing 3 vials.

Marketing Authorisation Holder

Menarini International Operations Luxembourg S.A.
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Manufacturer

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The following information is intended for healthcare professionals only:

Tenkasi is intended for intravenous (IV) administration, only after reconstitution and dilution. Tenkasi should be prepared under aseptic techniques in a pharmacy.

The powder must be reconstituted with water for injections and the resulting concentrate must be diluted in a glucose 5% intravenous infusion bag prior to use. Both the reconstituted solution and the diluted solution for infusion should be clear, colourless to pale yellow solution. Parenteral medicinal products should be inspected visually for particulate matter after reconstitution. Aseptic procedures should be used for the preparation of Tenkasi.

Adults

Three Tenkasi 400 mg vials need to be reconstituted and diluted to prepare a single once-only 1,200 mg IV dose.
Reconstitution: Aseptic technique should be used to reconstitute three Tenkasi 400 mg vials.
- 40 mL of water for injections (WFI) should be added using a sterile syringe to reconstitute each vial to provide a 10 mg/mL solution per vial.
- To avoid excessive foaming, it is recommended that WFI should be added carefully, along the walls of the vials.

- Each vial should be swirled gently to avoid foaming and ensure that all Tenkasi powder is completely reconstituted in solution.

The reconstituted solution should be further diluted in glucose 5% intravenous infusion bag immediately.

Dilution: Three reconstituted vials are needed for dilution for administration of a single 1,200 mg IV infusion. Only glucose 5% intravenous bag (D5W) should be used for dilution.

To dilute:
- Withdraw and discard 120 mL from a 1,000 mL D5W intravenous bag.
- Withdraw 40 mL from each of the three reconstituted vials and add to D5W intravenous bag to bring the bag volume to 1,000 mL. This yields a concentration of 1.2 mg/mL of oritavancin. PP (Polypropylene) or PVC (Polyvinyl chloride) bags should be used for administration preparation.

Use in the paediatric population (aged 3 months to < 18 years),

Calculate the dose of oritavancin required based on patient's weight (one single infusion of 15 mg/kg administered intravenously over 3 hours).
Determine the number of oritavancin vials that are required for the patient (each vial is 400 mg).

Reconstitution:
- 40 mL of water for injections (WFI) should be added using a sterile syringe to reconstitute each vial to provide a 10 mg/mL solution per vial.
- To avoid excessive foaming, it is recommended that WFI should be added carefully, along the walls of the vials.
- Each vial should be swirled gently to avoid foaming and ensure that all of the powder is completely reconstituted in solution.

Dilution: Only glucose 5% intravenous bag (D5W) should be used for dilution. Sodium chloride solution should not be used for dilution (see section 6.2).

Dilution:
Withdraw the necessary volume of oritavancin with a sterile syringe and add to the IV bag containing sterile D5W (please refer to table 1 for relevant example). The size of the IV bag will be based on the total volume administered. For small volumes a syringe pump may be used.

Table 1: 15 mg/kg Oritavancin: 3-Hour Infusion (Concentration of 1.2 mg/ml)

Patient's Weight (kg)	**Calculated Oritavancin Dose (mg)**	**Total Infusion Volume (ml)**	**Volume of Reconstituted Oritavancin (ml)**	**Volume of D5W to add to IV Bag (ml)**
5	75	62.5	7.5	55
10	150	125	15	110
15	225	187.5	22.5	165

20	300	250	30	220
25	375	312.5	37.5	275
30	450	375	45	330
35	525	437.5	52.5	385
40	600	500	60	440

Calculations
1) Use Patient's Actual Weight—ROUND ONLY TO THE NEAREST WHOLE NUMBER
2) Dose: Weight (kg) x 15 mg/kg = _____ mg (Maximum Dose 1200 mg)
3) Total Infusion Volume: Dose (mg) ÷1.2 mg/ml = _____ ml
4) Volume of Reconstituted Oritavancin: Dose (mg) ÷ 10 =_____ ml
5) Volume of D5W to add to IV bag: Total Infusion Volume (C) – Volume of Reconstituted Oritavancin (D) = _____ ml

The diluted solution should be used immediately.

From a microbiological point of view, the product should be used immediately. If not used immediately storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 12 hours at 25°C and 24 hours at 2-8°C for Tenkasi diluted in glucose 5% intravenous infusion bag, unless reconstitution and dilution has taken place in controlled and validated aseptic conditions.