swissmedic

Public Summary SwissPAR dated 15 March 2024

Tenkasi® (active substance: oritavancin)

First authorisation in Switzerland: 7 April 2022

Powder for concentrate for solution for injection for the treatment of adults with acute bacterial skin and skin structure infections (ABSSSI).

Information on authorisation

The medicinal product Tenkasi contains the active substance oritavancin and is a powder for solution for injection, which is administered into a vein.
Tenkasi is used in adults for the treatment of acute bacterial skin and skin structure infections (ABSSSI) where a microbiological sensitivity test determines or it is strongly suspected that the infection is caused by sensitive bacteria. Tenkasi may only be used for the treatment of ABSSSI if the antibiotics recommended for first-line treatment of these infections are considered not to be suitable.

Acute bacterial skin and skin structure infections are a major health problem and their severity can vary from mild to life-threatening. MRSA[1], a type of resistant bacteria, is a major cause of these infections worldwide. In recent years, MRSA infections have increasingly been observed outside of hospitals.

In deciding whether to authorise the medicinal product Tenkasi, Swissmedic took into account the assessments of the European Medicines Agency (EMA), the US Food and Drug Administration (FDA), and the corresponding medicinal product information texts.

Since the assessment of the clinical data was based on the assessment reports of these foreign authorities, the preconditions for a SwissPAR (Swiss Public Assessment Report – a detailed report for professionals) and a resulting Public Summary SwissPAR are not met. Swissmedic refers to the authorisations of the foreign reference authorities.

[1] MRSA: Methicillin-resistant *Staphylococcus aureus*

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Tenkasi®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.