swissmedic

Public Summary SwissPAR dated 26 March 2024

Tenkasi® (active substance: oritavancin)

Indication extension in Switzerland: 15 November 2023

Powder for concentrate for solution for injection for the treatment of adults and children over 3 months 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 children over 3 months and 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.

Tenkasi was approved by Swissmedic on 7 April 2022 for the treatment of adults with acute bacterial skin and skin structure infections (ABSSSI). The present indication extension means that children over three months can now also be treated with Tenkasi.

In deciding whether to authorise the indication extension for Tenkasi, Swissmedic took into account the assessment of the European Medicines Agency (EMA) and the corresponding medicinal product information texts.

Since the assessment of the clinical data was based on the assessment reports of the foreign authority, 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 authorisation of the foreign reference authority.

[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.