swissmedic

Summary report on authorisation dated 6 December 2024

Qdenga® (active substance: Dengue virus serotypes 1, 2, 3, and 4 (live, attenuated))

Authorisation in Switzerland: 29 July 2024

Powder and solvent for solution for injection in a pre-filled syringe for prevention of dengue fever in persons aged 4 years and older

About the medicinal product

Qdenga is a vaccine for prevention of dengue fever in persons aged 4 years and older. It contains attenuated (weakened) versions of dengue virus serotypes (variants) 1, 2, 3, and 4.

These weakened versions cannot cause the disease but trigger the immune system (the body's natural defences) to defend the body against the virus.
Dengue fever is a mosquito-borne viral disease that is common in tropical and subtropical regions. It can lead to flu-like symptoms, but in severe cases can also cause life-threatening complications such as dengue haemorrhagic fever or dengue shock syndrome.
Qdenga offers protection against fever and hospitalisation due to dengue caused by one of the 4 dengue virus serotypes.

Qdenga has been authorised by Swissmedic under Article 13 of the Therapeutic Products Act (TPA). This means that the medicinal product is already authorised in at least one other country with comparable medicinal product control.

In this case, Swissmedic takes into consideration the results of checks carried out by foreign regulatory agencies, provided certain requirements are fulfilled. These involve checks on the quality, efficacy, and safety of the medicinal product, and the extent to which the results can be accepted for Switzerland. The consideration of the results of foreign authorisation procedures is intended to help ensure that medicines that are already authorised abroad can be made available to patients in Switzerland as quickly as possible.

In deciding whether to authorise Qdenga in Switzerland, Swissmedic accepted the assessment and approval decision of the European Medicines Agency (EMA; reference number EMA/862552/2022) and has only conducted a limited scientific review.
Accordingly, in the SwissPAR (Swiss Public Assessment Report) and the resulting Summary report on authorisation, Swissmedic refers to the Assessment Report issued by the reference authority: www.ema.europa.eu.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Qdenga®

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 Summary report on authorisation.

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.