

Public Summary SwissPAR dated 20 December 2022

Tavneos[®] (active substance: avacopan)

First authorisation in Switzerland: 19 September 2022

Medicinal product (hard capsule) for supportive treatment of adults with severe active anti-neutrophil cytoplasmic antibody (ANCA)-associated vasculitis with microscopic polyangiitis.

Information on authorisation

The medicinal product Tavneos contains the active substance avacopan. It is used for the treatment of adults with severe active anti-neutrophil cytoplasmic antibody (ANCA)-¹associated vasculitis² (granulomatosis with polyangiitis (GPA)) and microscopic polyangiitis (MPA)³. Tavneos is used as a supportive treatment alongside standard immunosuppressive treatment with rituximab or cyclophosphamide with glucocorticoids.

GPA and MPA are rare, inflammatory blood vessel disorders. Since these are rare, life-threatening diseases, the medicine has been authorised as an orphan drug. The term "orphan drug" is used to refer to important medicines for rare diseases.

Tavneos was authorised as part of the joint initiative of the Access Consortium. This joint initiative is a collaborative project between the drug regulatory authorities in Australia (Therapeutic Goods Administration, TGA),

Canada (Health Canada, HC), Singapore (Health Sciences Authority, HSA), the United Kingdom (Medicines & Healthcare products Regulatory Agency, MHRA) and Swissmedic and the pharmaceutical industry. The joint initiative coordinates the assessment of authorisation applications for new active substances that have been submitted in at least two of the five countries.

The authorisation application for Tavneos was submitted for assessment to the regulatory authorities in Canada and Switzerland. Each country assessed a part of the application and then shared and discussed the results. At the end of the process, each authority decided on the application independently.

Swissmedic considered the assessments by the foreign reference authorities in its decision on the authorisation. Accordingly, and

¹ Anti-neutrophil cytoplasmic antibody (ANCA): ANCAs are antibodies produced by the body which target a type of white blood cells involved in cellular immune defence. This leads to overactivation of the immune system.

² Vasculitis: Vasculitis is the general term for inflammation of the blood vessels (e.g. arteries, veins, capillaries).

³ Microscopic polyangiitis: Microscopic polyangiitis is a type of vasculitis affecting the small blood vessels (small arteries, arterioles, capillaries, venules) in multiple organs.

since Swissmedic has not produced a complete SwissPAR (Swiss Public Assessment Report), it cannot issue a complete Public Summary SwissPAR. Swissmedic therefore refers to the relevant publications issued by the authorities involved:

Further details of the Access joint initiative are published on the Swissmedic website. Access Consortium (swissmedic.ch).

Further information on the medicinal product

At the time of publication of the Public Summary SwissPAR for Tavneos, the Information for healthcare professionals was not yet available. As soon as the medicine becomes available in Switzerland, the Information for

healthcare professionals will be made available on the following website: www.swiss-medinfo.ch

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.