swissmedic

Public Summary SwissPAR dated 7 June 2024

Brukinsa® (active substance: zanubrutinib)

Indication extension in Switzerland: 1 February 2024

Hard capsules for third-line treatment of adults with relapsed or refractory grade 1–3a follicular lymphoma (FL)

Information on authorisation

Brukinsa, containing the active substance zanubrutinib, is used in combination with the active substance obinutuzumab to treat follicular lymphoma (FL) in adults when this disease recurs or when medicinal products given previously are no longer effective. Patients have previously received at least 2 lines of therapy, including an anti-CD20 antibody therapy.

Follicular lymphoma (FL) is a slow-growing form of cancer that affects the B cells. In FL, there are too many of these B cells in the lymph nodes, spleen and bone marrow.

The indication extension for Brukinsa was authorised under 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. The joint initiative coordinates the assessment of authorisation applications for new active substances that have been made in at least 2 of the 5 countries.

The application for indication extension for Brukinsa was submitted to the drug 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 authority in its decision on the authorisation. Accordingly, and since Swissmedic has not produced a complete SwissPAR (Swiss Public Assessment Report – a detailed report for professionals), it cannot issue a complete Public Summary SwissPAR. Swissmedic therefore refers to the relevant publications issued by the authority involved.

Swissmedic first authorised Brukinsa on 8 February 2022 for the treatment of Waldenström's macroglobulinaemia (also known as lymphoplasmacytic lymphoma) in adults when the disease recurs, when previous treatment has not been effective, or in patients who are unable to receive chemotherapy in combination with an antibody.

Brukinsa was also authorised for the treatment of chronic lymphatic leukaemia (CLL)

in adults whose disease recurred or did not respond to previous treatment on 29 August 2023.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Brukinsa

Information for patients (package leaflet): Information for patients Brukinsa

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.