swissmedic

Public Summary SwissPAR dated 13 May 2022

Brukinsa® (active substance: zanubrutinib)

First authorisation in Switzerland: 8 February 2022

Medicinal product (hard capsule) for the treatment of Waldenström's macroglobulinaemia (WM) in adults.

Information on authorisation

Brukinsa, containing the active substance zanubrutinib, is used for the treatment of Waldenström's macroglobulinaemia (WM) in adults who have already received at least one prior treatment or if chemo-immunotherapy[1] is not possible.

Waldenström's macroglobulinaemia, also known as lymphoplasmacytic lymphoma, is a type of cancer of the B lymphocytes (white blood cells) that causes them to produce too much of a protein called IgM. Waldenström's macroglobulinaemia accounts for around 2% of all malignant blood disorders.

Since this is a rare, life-threatening disease, Brukinsa has been authorised as an orphan drug. "Orphan drug" is a designation given to important medicinal products for rare diseases.

Brukinsa was authorised under Article 13 of the Therapeutic Products Act (TPA). This means that the medicinal product is already authorised in another country with comparable medicinal product control. In this case, Swissmedic takes into consideration the results of checks carried out by the foreign regulatory agency, 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 Brukinsa in Switzerland, Swissmedic accepted parts of the assessment and approval decision of the Canadian authority (Health Canada) and has not conducted its own scientific review.

Accordingly, in the SwissPAR (Swiss Public Assessment Report) and the resulting Public Summary SwissPAR, Swissmedic refers to the Assessment Report and the short report issued by the reference authority:
(Health Canada - Canada.ca)

[1] Chemo-immunotherapy: In chemo-immunotherapy, cytostatics are administered in combination with an antibody. This means that the chemotherapy does not act generally on all rapidly dividing cells in the body but instead targets a specific feature of the tumour cells.

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.