swissmedic

Summary report on authorisation dated 17 April 2025

Hympavzi® (active substance: marstacimab)

Authorisation in Switzerland: 23 December 2024

Solution for injection in pre-filled pen for the routine prevention of bleeding episodes in patients aged 12 years and over with severe haemophilia A or B and a body weight of at least 35 kg

Information on authorisation

The medicinal product Hympavzi contains the active substance marstacimab.

Hympavzi is used to prevent or reduce bleeding in patients aged 12 years and older with a body weight of at least 35 kg who

- have severe haemophilia A (congenital factor VIII deficiency with a blood factor VIII level below 1%) without factor VIII inhibitors or
- have severe haemophilia B (congenital factor IX deficiency with a blood factor IX level below 1%) without factor IX inhibitors.

Haemophilia A and B are congenital diseases caused by a lack of clotting factors VIII and IX, respectively. Factor VIII and factor IX are important proteins[1], which are needed to clot the blood and stop bleeding.

Hympavzi contains the active substance marstacimab, which binds in a targeted manner to the protein TFPI (tissue factor pathway inhibitor), thereby inhibiting its effect. This promotes the formation of thrombin, which improves blood clotting and reduces bleeding in haemophilia patients.

Since haemophilia A and B are rare and life-threatening diseases, the medicinal product Hympavzi has been authorised as an orphan drug. "Orphan drug" is a designation given to medicinal products for rare diseases.

Hympavzi 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 2 of the 5 countries.

[1] Proteins are large, complex molecules made up of building blocks called amino acids. They have important roles in the body, e.g. as nutrients, messengers, or enzymes.

The authorisation application for Hympavzi was submitted to the drug regulatory authorities in Singapore, Australia, 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, Swissmedic has not produced a complete SwissPAR (Swiss Public Assessment Report) and therefore cannot issue a complete Summary report on authorisation. 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

Information for healthcare professionals: Information for healthcare professionals Hympavzi®

Information for patients (package leaflet): Information for patients Hympavzi®

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.