swissmedic

Public Summary SwissPAR dated 20 September 2021

Clofara® (active substance: clofarabine)

First authorisation in Switzerland: 15 July 2021

Medicinal product (solution for injection) for the treatment of acute lymphoblastic leukaemia (ALL) in paediatric patients who have relapsed or are refractory after receiving at least two prior regimens.

Information on authorisation

The medicinal product Clofara contains the active substance clofarabine. It is a solution for injection into the veins.

Clofara has been authorised in Switzerland for the treatment of acute lymphoblastic leukaemia (ALL[1]) in children and adolescents who have relapsed or are refractory[2] after receiving at least two prior regimens and if no other treatment options are available. The safety and efficacy of Clofara has been assessed in studies in patients who were ≤ 21 years old at initial diagnosis.

Clofara was authorised under Art. 14 para. 1 let. a^{bis} of the Therapeutic Products Act (TPA). The TPA enables certain categories of medicines to be authorised according to a simplified procedure, provided this is compatible with the quality, safety and efficacy requirements and there is no conflict with Swiss interests or international obligations.

At the time the application was submitted, clofarabine – the active substance in the medicine Clofara – had demonstrably been used in a medicinal product which had been authorised for at least 10 years in at least one EU or EFTA country and which is comparable in terms of indications, dosage and method of administration. The preconditions for simplified authorisation were therefore met.

Consequently, Swissmedic is not conducting its own comprehensive scientific review, and the preconditions for a SwissPAR (Swiss Public Assessment Report) and a resulting Public Summary SwissPAR do not apply. Swissmedic refers to the authorisation of the foreign comparator medicinal product: https://www.ema.europa.eu

The authorisation of Clofara is based on the medicinal product Evoltra, which contains

1 ALL: Acute lymphoblastic leukaemia is a cancer that begins in immature precursors of lymphocytes (cellular components of the blood, bone marrow, lymphatic and non-lymphatic tissues). This form of leukaemia occurs most frequently in children.

2 Refractory: In relation to cancer, refractory means that the cancer is resistant to treatment and does not recede or may even progress, despite treatment.

the same active substance and has been authorised in Germany for more than 10 years.

Further information on simplified authorisation according to Art. 14 TPA can be found in the Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA).

Further information on the medicinal product

At the time of publication of the Public Summary SwissPAR for Clofara, 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.swissmedicinfo.ch

Healthcare professionals (doctors, pharmacists and others) can answer any questions about this medicine.

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.