

Public Summary SwissPAR dated 27 January 2023

Rapibloc[®] (active substance: landiolol hydrochloride)

First authorisation in Switzerland: 19 October 2022

Medicinal product (powder for solution for infusion) for the treatment of supraventricular tachycardia and non-compensatory sinus tachycardia.

Information on authorisation

The medicinal product Rapibloc, which contains the active substance landiolol hydrochloride, is a powder for solution for infusion.

Rapibloc is used for treating supraventricular tachycardia¹. It is used when rapid control of the ventricular rate in patients with atrial fibrillation or atrial flutter is required perioperatively², postoperatively or under other circumstances where short-term control of the ventricular rate with a short-acting agent is desirable.

Rapibloc is also used in non-compensatory sinus tachycardia³ if, in the doctor's opinion, the rapid heart rate calls for a special intervention.

Rapibloc is not suitable for treating chronic illness.

In deciding whether to authorise the medicinal product Rapibloc, containing the active substance landiolol hydrochloride, Swissmedic took account of certain aspects, such as the clinical data and the assessment of the Dutch drug regulatory authority as well as the corresponding product information.

Since the assessment of the clinical data was based on the assessment report of a foreign partner authority, the preconditions for a SwissPAR (Swiss Public Assessment Report) and a resulting Public Summary SwissPAR are not fully met. Swissmedic refers to the authorisation by the foreign reference authority.

¹Supraventricular tachycardia: increased heart rate ("racing" heart beat) owing to abnormal heart rhythms originating in the upper chambers of the heart (atria).

²Perioperatively: the perioperative period is the time immediately before, during or shortly after an operation.

³Sinus tachycardia: sinus tachycardia is an increased heart rate due to signals originating from the sinus node (tissue structure in the right atrium of the heart).

Further information on the medicinal product

At the time of publication of the Public Summary SwissPAR for Rapibloc, 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.