



Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021,
please refer to the [EMA](#) website.

Increxxa 25 mg/ml Solution for Injection for Pigs

Vm 52127/5031

• 10 May 2024	Unlimited renewal
• 21 November 2023	Change to in-process tests or limits applied during the manufacture of the finished product.
• 20 September 2023	Deletion of a manufacturing site for an active substance.
• 28 July 2023	Minor changes to an approved test procedure for the finished product.
• 11 March 2022	Change in the SPC, labelling or package leaflet following assessment of the same change for the reference product.
• 22 February 2022	Extension of a re-test period of the active substance. Minor change to the restricted part of an Active Substance Master File. Minor change to an approved test procedure for the active substance used in the manufacturing process of the active substance. Minor change to the restricted part of an Active Substance Master File. Minor change to the restricted part of an Active Substance Master File. Minor change to the restricted part of an Active Substance Master File. Minor change to the restricted part of an Active Substance Master File. Minor change to the restricted part of an Active Substance Master File. Minor change to the restricted part of an Active Substance Master File.
• 11 January 2022	Minor change to an approved test procedure for the active substance used in the manufacturing process of the active substance. Changes to the quality control testing arrangements for the active substance – addition of a site where testing takes place. Addition of a site where batch control/testing takes place.
• 09 September 2021	Change in the SPC, labelling or package leaflet following assessment of the same change for the reference product.