

Post Authorisation Assessments

July 2020 1. Change in the address of the marketing authorisation holder from GENERA Inc., Svetonedeljska 2, Kalinovica, 10436 Rakov Potok, Croatia to GENERA Inc., Svetonedeljska cesta 2, Kalinovica, 10436 Rakov Potok, Croatia. 2. Deletion of a non-significant in-process test applied during the manufacture of the finished product. 3. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. 4. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. 5. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. 6. Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer. 7. Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer. 17 May 2019 Change in the QPPV of an existing pharmacovigilance • system as described in the DDPS 02 April 2019 Change in the QPPV of an existing pharmacovigilance • system as described in the DDPS 16 May 2017 Change in the QPPV of an existing pharmacovigilance • system as described in the DDPS Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.

Canihelmin Plus 50 mg/144 mg/150 mg Tablets for Dogs