
Proposed suppression of the monograph on Difloxacin hydrochloride trihydrate for veterinary use (2239) from the Ph. Eur.

Q1-4 (4463)

NPA: (55848)

Type: (!/list-dropdown)

A10 - Estonia (EE)

Please choose: (55849)

Type: (L/list-radio)

In favour of the launch of a process to suppress the monograph on *Difloxacin hydrochloride trihydrate for veterinary use* (2239) from the Ph. Eur.

A1

If you are opposed, please justify your answer and/or provide details of any marketing authorisations for medicinal products containing substances covered by this monograph that may exist in your country.

(55850)

Type: (T/text-long)

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Do you approve the accompanying note outlining the reason for suppression, as reproduced below? This note will be used for the public consultation:

Difloxacin hydrochloride trihydrate is an active substance, a broad-spectrum fluoroquinolone antibiotic, used in veterinary medicine.

The test for related substances in this monograph does not comply with the current European Pharmacopoeia (Ph. Eur.) policy on impurities: it contains a limit test with an inappropriate quantitative expression for the acceptance criterion for total impurities. Therefore, this monograph requires a revision.

Since no approved products in Europe containing difloxacin hydrochloride trihydrate and no manufacturers of this active substance currently active on the European market could be identified, it is proposed to suppress the monograph on *Difloxacin hydrochloride trihydrate for veterinary use (2239)* from the Ph. Eur.

(55852)

Type: (L/list-radio)

Yes

A1

Comments : (55851)

Type: (T/text-long)

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