
Proposed suppression of the monograph on Ouabain (0048) from the Ph.
Eur.

Q1-4 (4004)

NPA:

Please choose country:

(52059)

Type: (/list-dropdown)

A10 - Estonia (EE)

Please choose:

(52060)

Type: (L/list-radio)

In favour of the suppression of the monograph on *Ouabain (0048)* from the Ph. Eur.

A1

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

(52061)

Type: (T/text-long)

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

This monograph is published in Pharmeuropa to inform all stakeholders that the text is proposed for suppression from the Ph. Eur.

Any stakeholders wishing either to share any important information or concerns directly related to this suppression process are requested to submit a detailed comment.

Ouabain (also known as g-strophanthin) is a cardiac glycoside that can be used to treat hypotension and some arrhythmias.

The monograph *Ouabain (0048)* was elaborated between 1971 and 1979 (first publication in the 2nd Edition) and since then only one correction has been made (6th Edition). The test for related substances in this monograph is not aligned with the current Ph. Eur. policy on impurities. A TLC procedure with a limit of maximum 2.0 per cent for any impurity is prescribed. Therefore, this monograph requires a complete revision.

No approved product in Europe containing ouabain and no manufacturers of this active substance currently active on the European market could be identified. It is therefore proposed to suppress the monograph on Ouabain (0048) from the European Pharmacopoeia

(52063)

Type: (Y/yes-no)

Yes

Remarks:

(52062)

Type: (T/text-long)

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