

20, AVENUE APPIA - CH-1211 GENEVA 27 - SWITZERLAND - TEL CENTRAL +41 22 791 2111 - FAX CENTRAL +41 22 791 3111 - WWW.WHO.INT

Tel_direct: Fax direct: +41 22 791 3695/1249

Email:

+41 22 791 4856

In reply please refer INN/RB/mrc

P5-180/19 (13878)

Your reference:

Ms Elena Vorobeva Avexima Diol LLC Ayaks settlement, 10, room 2-03 690922 Primorsky Krai, Vladivostok urban district, Russky Island Fédération de Russie

14 April 2025

Dear Ms Vorobeva,

I wish to refer to our letter of 29 January 2025 concerning your request for an International Nonproprietary Name (INN) "dioxaban", "teraxaban", "amidoxaban", "vitoxabanv" (13878).

I have been asked to inform you that "tedixaban" has been selected as the proposed INN for this substance. The selection was made by the members of the Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations designated to deal with the selection of nonproprietary names. This is in accordance with the "Procedure for the Selection of Recommended International Nonproprietary Names for Pharmaceutical Substances" and the "General Principles for Guidance in Devising International Nonproprietary Names for Pharmaceutical Substances".

The selected name, *tedixaban*, is a combination of your second and first submitted names. The submitted names could not be retained because of the following conflicts: dioxaban vs. dioxane, edoxaban (99)(61) and darexaban (104)(66) (especially in pronunciation); teraxaban vs. letaxaban (104)(66); amidoxaban vs. samidorphan (107)(68) and Laboratoires Amido (France); vitoxabanv / vitoxaban having the prefix vito- connoting vita (Latin for 'life'), which should be avoided according to the General Principles for guidance in devising International Nonproprietary Names for pharmaceutical substances.

Please note that if we do not hear from you prior to 16 May 2025, we shall assume that you agree to this selected name. Thus, "tedixaban" will be included in List 134 of proposed INN, to be published in WHO Drug Information, provided that all information has been validated by our experts. Kindly note that, although e-mail is very useful in speeding up communication, at WHO, it is not considered as official correspondence.

We would like to draw to your attention that in accordance with article 5 of the "Procedure for the Selection of Recommended International Nonproprietary Names for Pharmaceutical Substances", "a formal objection may be filed by any interested person within four months of the date of publication...". Should there be an objection, we will inform you within a month of the objection deadline. Should you not have heard from us by that time, you may assume that no objections have been raised and that the name will be included in the next list of recommended INN.

Yours sincerely

Dr Raffaella Balocco Mattavelli

Unit Head

International Nonproprietary Names (INN)

Programme and Classification of Medical

Products

Health Products Policy and Standards