



Bundesamt für
Sicherheit im
Gesundheitswesen
BASG

Unternehmen/Frau/Herr
Organisationseinheit (optional)
(z. H.) Vorname Nachname
Straße
PLZ Ort

Datum: 14.04.2026
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Unser Zeichen: PHV-105402127-A-260414-EUIM

PHV-issue: Nitrate

Sehr geehrte Damen und Herren,

Bitte beachten Sie die Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh) Minutes for the meeting on 24-25 February 2026 im Anhang.

Bei Unklarheiten bezüglich der Implementierung oder wenn die Änderungen bereits aufgenommen worden sind, kontaktieren Sie uns bitte per E-Mail (pv-implementation@basg.gv.at).

Beachten Sie auch die aktuellen sicherheitsrelevanten Änderungen der Produktinformation unter: www.basg.gv.at/fuer-unternehmen/pharmakovigilanz/mustertexte

In der Begründung ist „**PHV-Issue: „Nitrate“**“ sowie die **Geschäftszahl (PHV-105402127-A-260414-EUIM)** anzugeben.

Mit freundlichen Grüßen
Für das Bundesamt

Ing. Veronika Heimlich BSc



Auszug aus den Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh) Minutes for the meeting on 24-25 February 2026

3.7. Contraindication regarding riociguat in SmPCs of nitrate products / DK

Following the CMDh discussion in January, the CMDh agreed to remind MAHs of all nitrate-containing medicinal products to ensure that their product information is kept up to date with current scientific knowledge regarding the contraindication for concomitant use with riociguat.

The CMDh agreed on the following wording to be included in sections 4.3 and 4.5 of the SmPC, provided this information is not already foreseen in the product information. The PL should be updated accordingly.

SmPC

Section 4.3:

"co-administration with riociguat (see section 4.5)."

Section 4.5:

"The use of <active substance> with riociguat, a stimulator of soluble guanylate cyclase, is contra-indicated (see section 4.3), since concomitant use can cause hypotension."

PL

Section 2, Do not take <X>:

"if you are also taking riociguat. See section "Other medicines and <X>."

Section 2, Other medicines and <X>:

"Do not use <X> at the same time as riociguat since this can cause hypotension (abnormally low blood pressure)."

Concerned MAHs are requested to implement the above changes at their earliest opportunity by submitting a type IB variation under C.3.b of the new classification guideline, in cases where the PI does not already include the contraindication for concomitant use with riociguat. No official translations or deadline for implementation will be provided. It is therefore recommended to update the product information of concerned products as soon as possible.

Heimlich Veronika
am 14.4.2026