

Rispoval RS+PI3 IntraNasal

Authorised

- Bovine respiratory syncytial virus, strain 375, Live
- Bovine parainfluenza virus 3, strain RLB103, Live

Product identification

Medicine name:

Rispoval RS+PI3 IntraNasal

Active substance:

Bovine respiratory syncytial virus, strain 375, Live

Bovine parainfluenza virus 3, strain RLB103, Live

Target species:

Cattle

Route of administration:

Nasal use

Product details

Active substance and strength:

Bovine respiratory syncytial virus, strain 375, Live

5.00 log₁₀ 50% cell culture infectious dose / 1.00 Dose

Bovine parainfluenza virus 3, strain RLB103, Live

5.00 log₁₀ 50% cell culture infectious dose / 1.00 Dose

Pharmaceutical form:

Nasal spray, lyophilisate and solvent for suspension

Withdrawal period by route of administration:

Nasal use:

-

Cattle

- All relevant tissues. 0 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QI02AD07

Legal status of supply:

Veterinary medicinal product not subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Ireland

Available in:

Ireland

Package description:

Cardboard box with 1 glass vial of 5 doses of powder accompanied by 1 vial containing respectively 10 ml liquid component

Cardboard box with 1 glass vial of 25 doses of powder accompanied by 1 vial containing respectively 50 ml liquid component

Plastic box with 5 glass vial(s) of 1 dose of powder accompanied by 5 vial(s) containing 2 ml liquid component

Additional information

Entitlement type:

Marketing Authorisation

Legal basis of product authorisation:

Legal basis not covered by Directive 2001/82/EC

Marketing authorisation holder:

Zoetis Belgium S.A.

Marketing authorisation date:

9/12/2013

Manufacturing sites for batch release:

Zoetis Belgium

Responsible authority:

Health Products Regulatory Authority

Authorisation number:

VPA10387/064/001

Date of authorisation status change:

9/12/2013

Reference member state:

France

Procedure number:

FR/V/0335/001

Concerned member states:

Austria Belgium Bulgaria Czechia Estonia Germany Hungary Ireland Italy
Latvia Lithuania Luxembourg Netherlands Poland Portugal Romania Slovakia
Spain United Kingdom (Northern Ireland)

To consult adverse reactions on veterinary medicinal products please go to
www.adrreports.eu/vet

Documents

eu-puar-frv0335001-mr-rpe828-en.pdf