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# ROTAGAL BG Emulsion for injection for cattle (pregnant cows and heifers)

Authorised

- Escherichia coli, serotype O9:K35 (fimbrial adhesins F5 and F41), strain EC/17, Inactivated
- Bovine coronavirus, strain C-197, Inactivated
- Bovine rotavirus A, type G6P1, strain TM-91, Inactivated

# **Product identification**

#### **Medicine name:**

РОТАГАЛ БГ Инжекционна емулсия за говеда (бременни крави и юници) ROTAGAL BG Emulsion for injection for cattle (pregnant cows and heifers)

#### **Active substance:**

Escherichia coli, serotype O9:K35 (fimbrial adhesins F5 and F41), strain EC/17, Inactivated

Bovine coronavirus, strain C-197, Inactivated

Bovine rotavirus A, type G6P1, strain TM-91, Inactivated

# **Target species:**

Cattle

#### Route of administration:

Intramuscular use

# Product details

# **Active substance and strength:**

Escherichia coli, serotype O9:K35 (fimbrial adhesins F5 and F41), strain EC/17, Inactivated

45.20 enzyme-linked immunosorbent assay unit / 1.00 Dose

Bovine coronavirus, strain C-197, Inactivated

Bovine rotavirus A, type G6P1, strain TM-91, Inactivated 6.00 log2 virus neutralising unit(s) / 1.00 Dose

#### **Pharmaceutical form:**

Emulsion for injection

# Withdrawal period by route of administration: Intramuscular use:

Cattle

# Anatomical therapeutic chemical veterinary (ATCvet) codes:

**OI02AL01** 

# Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

#### **Authorisation status:**

Valid

#### **Authorised in:**

Bulgaria

# Package description:

Available only in Bulgarian

Available only in Bulgarian

Available only in Bulgarian

# Additional information

# **Entitlement type:**

Marketing Authorisation

# Legal basis of product authorisation:

Informed consent application (Article 13c of Directive No 2001/82/EC)

# Marketing authorisation holder:

Vet Pro Komers OOD

# Marketing authorisation date:

1/04/2015

# Manufacturing sites for batch release:

Pharmagal Bio spol. s r.o.

# **Responsible authority:**

**Bulgarian Food Safety Authority** 

#### **Authorisation number:**

0022-2511

# **Date of authorisation status change:**

1/04/2015

To consult adverse reactions on veterinary medicinal products please go to <a href="https://www.adrreports.eu/vet">www.adrreports.eu/vet</a>

# **Documents**

Summary of Product Characteristics

This document does not exist in this language (English). You can find it in another language below.

Package Leaflet

This document does not exist in this language (English). You can find it in another language below.

Labelling

This document does not exist in this language (English). You can find it in another language below.