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Rovac -rotavirus bydłęcy, szczep TM-91, serotyp G6P1 (inaktywowany): 2/3 dawki szczepionki indukuje  $\geq 6,0 \log_2$  (VNT)\*;-koronawirus bydłęcy, szczep C-197 (inaktywowany): 2/3 dawki szczepionki indukuje  $\geq 5,0 \log_2$  (HIT)\*\*;-adhezyna E.coli F5 (K99): 2/3 dawki indukuje  $\geq 40\%$  hamowania (ELISA)\*\*;\* VNT-Test neutralizacji wirusa,\*\*HIT- Test hamowania hemaglutynacji,\*\*ELISA-enzymatyczny test immunosorpcyjny. Emulsja do wstrzykiwań

- Bovine rotavirus A, type G6P1, strain TM-91, Inactivated
- Bovine coronavirus, strain C-197, Inactivated
- Escherichia coli, fimbrial adhesin F5

## Product identification

### Medicine name:

Rovac -rotavirus bydłęcy, szczep TM-91, serotyp G6P1 (inaktywowany): 2/3 dawki szczepionki indukuje  $\geq 6,0 \log_2$  (VNT)\*;-koronawirus bydłęcy, szczep C-197 (inaktywowany): 2/3 dawki szczepionki indukuje  $\geq 5,0 \log_2$  (HIT)\*\*;-adhezyna E.coli F5 (K99): 2/3 dawki indukuje  $\geq 40\%$  hamowania (ELISA)\*\*;\* VNT-Test neutralizacji wirusa,\*\*HIT- Test hamowania hemaglutynacji,\*\*ELISA- enzymatyczny test immunosorpcyjny. Emulsja do wstrzykiwań

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### Active substance:

Bovine rotavirus A, type G6P1, strain TM-91, Inactivated  
Bovine coronavirus, strain C-197, Inactivated  
Escherichia coli, fimbrial adhesin F5

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### Target species:

Cattle

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### Route of administration:

Intramuscular use

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## Product details

### Active substance and strength:

Bovine rotavirus A, type G6P1, strain TM-91, Inactivated  
2.58 unknown / 2.00 millilitre(s)

Bovine coronavirus, strain C-197, Inactivated

Escherichia coli, fimbrial adhesin F5

40.00 enzyme-linked immunosorbent assay unit / 2.00 millilitre(s)

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### Pharmaceutical form:

Emulsion for injection/infusion

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### Withdrawal period by route of administration:

Intramuscular use:

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## **Cattle**

- Meat and offal. 0 day

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### **Anatomical therapeutic chemical veterinary (ATCvet) codes:**

QI02AL01

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### **Legal status of supply:**

Veterinary medicinal product subject to veterinary prescription

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### **Authorisation status:**

Valid

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### **Authorised in:**

Poland

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### **Package description:**

Available only in [Polish](#)

Available only in [Polish](#)

Available only in [Polish](#)

Available only in [Polish](#)

Available only in [Polish](#)

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## **Additional information**

### **Entitlement type:**

Marketing Authorisation

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### **Legal basis of product authorisation:**

Full application (Article 12(3) of Directive No 2001/82/EC)

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### **Marketing authorisation holder:**

Pharmagal spol. s r.o.

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### **Marketing authorisation date:**

5/12/2016

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### **Manufacturing sites for batch release:**

Pharmagal Bio spol. s r.o.

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**Responsible authority:**

Office For Registration Of Medicinal Products Medical Devices And Biocidal Products

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**Authorisation number:**

2607

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**Date of authorisation status change:**

5/12/2016

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To consult adverse reactions on veterinary medicinal products please go to  
[www.adrreports.eu/vet](http://www.adrreports.eu/vet)

## Documents

### Labelling

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### 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.

Package Leaflet and Labelling

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