

## **Labelling and Package leaflet**

**A. Labelling**

<b>PARTICULARS TO APPEAR ON THE OUTER PACKAGE (Cardboard box for glass vials and bottles)</b>
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## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

### **Rotacur**

Emulsion for injection for cattle.

## 2. STATEMENT OF ACTIVE SUBSTANCES

One dose of the vaccine (3 ml) contains:

### **Active substance:**

Bovine rotavirus strain TM-91, serotype G6P1 (inactivated)  $\geq 6.0 \log_2$  (VNT)\*

Bovine coronavirus strain C-197 (inactivated)  $\geq 5.0 \log_2$  (HIT)\*\*

*Escherichia coli* strain EC/17 (inactivated)  
expressing F5 (K99) and F41 Adhesin  $\geq 44.8$  % of inhibition (ELISA F5)\*\*\*

\*VNT – virus neutralisation test (rabbit serology induced by 2/3 dose of vaccine)

\*\*HIT - haemagglutination inhibition test (rabbit serology induced by 2/3 dose of vaccine)

\*\*\*ELISA –Enzyme-linked immunosorbent assay (rabbit serology induced by 2/3 dose of vaccine)

## 3. PHARMACEUTICAL FORM

Emulsion for injection.

## 4. PACKAGE SIZE

15 ml (5 doses)

90 ml (30 doses)

450 ml (150 doses)

## 5. TARGET SPECIES

Cattle (pregnant cows and heifers).

## 6. INDICATION(S)

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular use. Read the package leaflet before use.

## 8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.  
Accidental self-injection is dangerous.

**10. EXPIRY DATE**

EXP {DD.MM.YYYY}  
Once broached use within 10 days.

**11. SPECIAL STORAGE CONDITIONS**

Store in a refrigerator. Protect from light. Do not freeze.

**12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Disposal: read package leaflet.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

For animal treatment only. To be supplied only on veterinary prescription.

**14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Forte Healthcare Limited  
Cougar Lane  
Naul  
Co Dublin  
K32 FH74  
Ireland

**16. MARKETING AUTHORISATION NUMBER**

Vm 27819/5001

**17. MANUFACTURER’S BATCH NUMBER**

Batch {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**  
**(Glass vials of 15 ml)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

**Rotacur**

Emulsion for injection for cattle.

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

One dose of the vaccine (3 ml) contains:

**Active substance:**

Bovine rotavirus strain TM-91, serotype G6P1 (inactivated)  $\geq 6.0 \log_2$  (VNT)

Bovine coronavirus strain C-197 (inactivated)  $\geq 5.0 \log_2$  (HIT)

*Escherichia coli* strain EC/17 (inactivated)  
expressing F5 (K99) and F41 Adhesin  $\geq 44.8$  % of inhibition (ELISA F5)

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

15 ml (5 doses)

**4. ROUTE(S) OF ADMINISTRATION**

For intramuscular use.

**5. WITHDRAWAL PERIOD**

Withdrawal period: Zero days.

**6. BATCH NUMBER**

Batch {number}

**7. EXPIRY DATE**

EXP {DD.MM.YYYY}

Once broached use within 10 days.

**8. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**  
**(Glass vials of 90 ml and glass bottles of 450 ml)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

**Rotacur**

Emulsion for injection for cattle.

**2. STATEMENT OF ACTIVE SUBSTANCES**

One dose of the vaccine (3 ml) contains:

**Active substance:**

Bovine rotavirus strain TM-91, serotype G6P1 (inactivated)	≥ 6.0 log <sub>2</sub> (VNT)
Bovine coronavirus strain C-197 (inactivated)	≥ 5.0 log <sub>2</sub> (HIT)
<i>Escherichia coli</i> strain EC/17 (inactivated) expressing F5 (K99) and F41 Adhesin (ELISA F5)	≥ 44.8 % of inhibition

**3. PHARMACEUTICAL FORM**

Emulsion for injection.

**4. PACKAGE SIZE**

90 ml (30 doses)  
450 ml (150 doses)

**5. TARGET SPECIES**

Cattle (pregnant cows and heifers).

**6. INDICATION(S)**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

For intramuscular use. Read the package leaflet before use.

**8. WITHDRAWAL PERIOD**

Withdrawal period: Zero days.

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.  
Accidental self-injection is dangerous.

**10. EXPIRY DATE**

EXP {DD.MM.YYYY}

Once broached use within 10 days.

**11. SPECIAL STORAGE CONDITIONS**

Store in a refrigerator. Protect from light. Do not freeze.

**12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Disposal: read package leaflet.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

For animal treatment only. To be supplied only on veterinary prescription.

**14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Forte Healthcare Limited  
Cougar Lane  
Naul  
Co Dublin  
K32 FH74  
Ireland

**16. MARKETING AUTHORISATION NUMBER**

Vm 27819/5001

**17. MANUFACTURER’S BATCH NUMBER**

Batch {number}

<b>PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE ( Plastic bottles of 450 ml)</b>
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## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

### **Rotacur**

Emulsion for injection for cattle.

## 2. STATEMENT OF ACTIVE SUBSTANCES

One dose of the vaccine (3 ml) contains:

### **Active substance:**

Bovine rotavirus strain TM-91, serotype G6P1 (inactivated)	≥ 6.0 log <sub>2</sub> (VNT)*
Bovine coronavirus strain C-197 (inactivated)	≥ 5.0 log <sub>2</sub> (HIT)**
<i>Escherichia coli</i> strain EC/17 (inactivated) expressing F5 (K99) and F41 Adhesin (ELISA F5)***	≥ 44.8 % of inhibition

\*VNT – virus neutralisation test (rabbit serology induced by 2/3 dose of vaccine)

\*\*HIT - haemagglutination inhibition test (rabbit serology induced by 2/3 dose of vaccine)

\*\*\*ELISA - Enzyme-linked immunosorbent assay (rabbit serology induced by 2/3 dose of vaccine)

## 3. PHARMACEUTICAL FORM

Emulsion for injection.

## 4. PACKAGE SIZE

450 ml (150 doses)

## 5. TARGET SPECIES

Cattle (pregnant cows and heifers).

## 6. INDICATION(S)

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular use. Read the package leaflet before use.

## 8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.  
Accidental self-injection is dangerous.

**10. EXPIRY DATE**

EXP {DD.MM.YYYY}  
Once broached use within 10 days.

**11. SPECIAL STORAGE CONDITIONS**

Store in a refrigerator. Protect from light. Do not freeze.

**12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Disposal: read package leaflet.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

For animal treatment only. To be supplied only on veterinary prescription.

**14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Forte Healthcare Limited  
Cougar Lane  
Naul  
Co Dublin  
K32 FH74  
Ireland

**16. MARKETING AUTHORISATION NUMBER**

Vm 27819/5001

**17. MANUFACTURER’S BATCH NUMBER**

Batch {number}

**B. Package leaflet**

## PACKAGE LEAFLET

**Rotacur**  
Emulsion for injection for cattle.

### 1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

Forte Healthcare Limited  
Cougar Lane  
Hazardstown  
Naul  
Co Dublin  
K32 FH74  
Ireland

Manufacturer responsible for batch release:

PHARMAGAL BIO, s. r. o.  
Murgašova 5  
949 01 Nitra  
Slovak Republic.

### 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

**Rotacur**  
Emulsion for injection for cattle.

### 3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

One dose of the vaccine (3 ml) contains:

**Active substance:**

Bovine rotavirus strain TM-91serotype G6P1 (inactivated)	≥ 6.0 log <sub>2</sub> (VNT)*
Bovine coronavirus strain C-197 (inactivated)	≥ 5.0 log <sub>2</sub> (HIT)**
<i>Escherichia coli</i> strain EC/17 (inactivated) expressing F5 (K99) and F41 Adhesin	≥ 44.8 % of inhibition (ELISA F5)***

\*VNT - virus neutralisation test (rabbit serology induced by 2/3 dose of vaccine)

\*\*HIT - haemagglutination inhibition test (rabbit serology induced by 2/3 dose of vaccine)

\*\*\*ELISA - Enzyme-linked immunosorbent assay (rabbit serology induced by 2/3 dose of vaccine)

**Adjuvant:**

Montanide ISA 206 VG                      1.6 ml

**Excipients:**

Formaldehyde                                      max. 1.5 mg

Thiomersal max. 0.36 mg

White liquid emulsion which may form a sediment during storage.

#### **4. INDICATION(S)**

For the active immunisation of pregnant cows and heifers to raise antibodies against *E coli* adhesion F5 (K99) and F41 antigen, rotavirus and coronavirus. When calves are fed colostrum from vaccinated cows during the first week of life, these antibodies have been demonstrated to reduce the severity of diarrhoea caused by bovine rotavirus, bovine coronavirus and enteropathogenic *E. coli* F5 (K99) and F41, and to reduce the shedding of virus by calves infected with bovine rotavirus or bovine coronavirus.

Onset of immunity: Passive immunity commences with colostrum feeding and is dependent on calves receiving colostrum after birth.

#### **5. Contraindications**

None.

#### **6. Adverse reactions**

A slight swelling of 5-7 cm in diameter at the site of injection is common and may in some cases be accompanied initially by increased local temperature. Typically, such swelling resolves within 15 days.

Slight, transient increases in temperature (up to 0.8 °C) may be observed within 24 hours of vaccination, resolving within 4 days after vaccination.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

#### **7. Target species**

Cattle (pregnant cows and heifers)

#### **8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION**

For intramuscular use.

One dose: 3 ml

One dose in the course of each pregnancy, given in the 12 – 3 week period before calving is expected.

### Feeding of colostrum

The protection of calves depends on adequate ingestion of colostrum from vaccinated cows. Measures should be taken to ensure that calves receive sufficient amounts of colostrum within the first few days of life. If calves do not get enough antibodies through the colostrum soon after they are born, they will have failure of passive transfer of antibodies. It is important that all calves receive as much colostrum as possible from the first milking within the first six hours after calving. It is recommended that at least 3 litres of colostrum are fed within the first 24 hours and this amount is equivalent to approximately 10% of the weight of a calf.

To achieve optimum results and to reduce infection pressure on the farm, a whole herd cow vaccination policy should be adopted.

## **9. ADVICE ON CORRECT ADMINISTRATION**

Common aseptic procedures should be used during vaccination.

Only sterile syringes and needles should be used.

Allow the vaccine to reach room temperature before use.

Shake well before and occasionally during use to ensure that the sediment is dissolved prior to administration.

For the 90 ml and 450 ml pack sizes, it is recommended to use automated dosing equipment to protect the stopper against damage from multiple piercing.

## **10. WITHDRAWAL PERIOD**

Zero days.

## **11. Special STORAGE precautions**

Keep out of the sight and reach of children.

Store in a refrigerator (2 °C – 8 °C). Protect from light. Do not freeze.

Once broached use within 10 days.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.

After broaching and first use, store upright and refrigerated (2 °C – 8 °C) until the next use.

## **12. SPECIAL WARNING(S)**

Special precautions for use in animals:

Vaccinate healthy animals only.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

To the user:

This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this product, seek prompt

medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:

This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

Pregnancy:

This veterinary medicinal product is intended for use in the last trimester of pregnancy.

Interaction with other medicinal products and other forms of interaction:

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product.

A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

Overdose (symptoms, emergency procedures, antidotes):

Following the administration of an overdose, no adverse reactions other than those mentioned in section 6 occur.

Incompatibilities

Do not mix with any other veterinary medicinal product.

### **13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

Medicines should not be disposed of via wastewater or household waste.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

### **14. PID LINK (Do not print heading)**

*[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]*

Find more product information by searching for the 'Product Information Database' on [www.gov.uk](http://www.gov.uk).

### **15. OTHER INFORMATION**

*E. coli* vaccine strain has been qualitatively confirmed to produce F5 and F41 adhesins. The presence of F41 adhesin has not been quantified.

Not all pack sizes may be marketed.

Package sizes:

Cardboard box with 1 vial of 15 ml (5 doses)

Cardboard box with 1 vial of 90 ml (30 doses)

Cardboard box with 1 glass bottle of 450 ml (150 doses)

Plastic bottle with 450 ml (150 doses)

*Expiry:* 3 years.

FOR ANIMAL TREATMENT ONLY

AVAILABLE ON PRESCRIPTION ONLY