SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ROTAGAL emulsion for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose of the vaccine (3 ml) contains:
Active substance:
Rotavirus bovinum inactivatum, strain TM-91
2/3 dose of vaccine stimulates (in rabbits) the increase of ELISA antibody titre $\geq 32,1^{*}$
Coronavirus bovinum inactivatum, strain C-197
2/3 dose of vaccine stimulates (in rabbits) the increase of ELISA antibody titre $\geq 44,8^{*}$
Escherichia coli Adhesin F5 (K99)
2/3 dose of vaccine stimulates (in rabbits) the increase of ELISA antibody titre $\geq 39,7^{*}$
*expressed as a percentage of inhibition

Adjuvant:
Oil emulsion (mineral oil) 1,5 ml

Excipients:
Formaldehyde max. 5,4 mg
Thiomersal max. 0,36 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection.
White liquid emulsion. During storage the easily shakable sediment may form.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle (pregnant cows and heifers)

4.2 Indications for use, specifying the target species

For active immunization of pregnant cows and heifers to provide calves with passive immunity targeted at reduction of mortality, incidence and severity of diarrhoea caused by bovine rotavirus, coronavirus and enteropathogenic E. coli F5 (K99) and reduction of rotavirus and coronavirus shedding by infected calves.
Onset of immunity: Passive immunity starts with colostrum feeding.
Duration of immunity: Calves fed with collected colostrum are protected until the end of colostral nutrition. It has been shown that in sucking calves the protection against rotavirus and coronavirus lasts for minimum 7 days after birth. Over the next 7 days the gradual degradation of the antibodies occures.

4.3 Contraindications

Do not vaccinate animals ill or suspected from any disease.

4.4 Special warnings

None.

4.5 Special precautions for use

i) Special precautions for use in animals

None.

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

To the user:
This 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 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."

4.6 Adverse reactions (frequency and seriousness)

Occasionally a slight sweling up to 2 cm in diameter may be observed at the site of injection. It is resorbed during 14 days after injection.

4.7 Use during pregnancy, lactation

The medicinal product is designated for the use in cows and heifers in the last trimester of pregnancy.

4.8 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.

4.9 Amounts to be administered and administration route

3 ml, Intramuscularly in accordance with the following schema:

Non-vaccinated cows the first injection in the week 6 – 5 before calving is expected
the second injection in the week 3 – 2 before calving is expected

Vaccinated cows: One injection in the course of each pregnancy between the week 6 – 3 before calving is expected.

Colostral feed
Protection of calves depends on the presence of colostral antibodies (obtained from vaccinated cows) in the gut during the first weeks of life until the individual immune status of the calves is formed. For the maximum efficacy of vaccination the adequate intake of colostrum throughout first 2-3 weeks of life is required. All calves must be supplied with sufficient amount of colostrum up to six hours after

calving. The highest content of antibodies in the colostrum is reached 72 hours after parturition. In the herds with unfavourable epizootological situation to collect the colostrums of vaccinated mothers from the first 6 – 8 milkings is recommended. During the first two weeks of life the calves must be fed with 2,5 – 3,5 liters of colostrum/milk per one day .
To reach the maximum decrease of morbidity and reduction of intensity of diarrhoea it is necessary to assure that the whole herd of cows undergoes the vaccination treatment and all newborn calves must be fed with the prime-quality colostrum.

Common aseptic procedures should be used during vaccination.
Only sterile syringes and needles should be used.
Put the vaccine to the tepmerature 18 to 22° C before use.
Shake well before and occasionally during administration.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Administration of double dose can occasionally slightly extend a swelling size.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

ATCvet code: QI02AL01

Inactivated oil vaccine prepared from chemically inactivated virus antigens: bovine rotavirus strain TM-91, bovine coronavirus strain C-197 propagated on the established cell cultures and from adhesin F5 (K99) of Escherichia coli propagated on the liquid growth medium.
The vaccine is designed for stimulation of the active immunity of pregnant cows to induce passive immunity in calves fed with the colostrum / milk of vaccinated cows.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mineral oil emulsion (Montanide ISA)
Formaldehyde
Thiomersal

6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 24 months
Shelf-life after first opening the immediate packaging: 10 hours .

6.4. Special precautions for storage

Store and transport refrigerated (2 - 8°C). Protect from light. Do not freeze.

6.5 Nature and composition of immediate packaging

Paper carton containing one glass vial, type I (15 ml, 90 ml) closed with chlorobutyl rubber stopper or one glass bottle, type I (450 ml) closed with bromobutyl rubber stopper sealed with aluminium cap.
Plastic bottles (240 ml, 450 ml) closed with chlorobutyl rubber stopper and sealed with aluminium cap without outer package.
Commercial sizes: 15 ml (5doses), 90 ml (30 doses), 240 ml (80 doses), 450 ml (150 doses).

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accodrance with local requirements.

7. MARKETING AUTHORISATION HOLDER

PHARMAGAL BIO, s. r. o.,
Murgašova 5, 949 01 Nitra
Slovak Republic
tel.: +421-37-6533171
fax: +421-37-6533171
email: bio@pharmagalbio. sk

8. MARKETING AUTHORISATION NUMBER

97/072/07-S

9. DATE OF FIRST AUTHORISATION OR RENEWAL OF THE AUTHORISATION

Date of authorisation: 18.12.2007

10. DATE OF REVISION OF THE TEXT

28.12.2012

PROHIBITION OF SALE, SUPPLY AND/OR USE
Not applicable.

PACKAGE LEAFLET

ROTAGAL emulsion for injection

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

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ROTAGAL emulsion for injection

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

One dose of the vaccine (3 ml) contains:
Active substance:
Rotavirus bovinum inactivatum, strain TM-91
2/3 dose of vaccine stimulates (in rabbits) the increase of ELISA antibody titre $\geq 32,1^{*}$
Coronavirus bovinum inactivatum, strain C-197
2/3 dose of vaccine stimulates (in rabbits) the increase of ELISA antibody titre $\geq 44,8^{*}$
Escherichia coli Adhesin F5 (K99)
2/3 dose of vaccine stimulates (in rabbits) the increase of ELISA antibody titre $\geq 39,7^{*}$
*expressed as a percentage of inhibition

Adjuvant:
Oil emulsion (mineral oil)

Excipients:
Thiomersal, Formaldehyde

4. INDICATION

For active immunization of pregnant cows and heifers to provide calves with passive immunity targeted at reduction of mortality, incidence and severity of diarrhoea caused by bovine rotavirus, coronavirus and enteropathogenic E. coli F5 (K99) and reduction of rotavirus and coronavirus shedding by infected calves.
Onset of immunity: Passive immunity starts with colostrum feeding.
Duration of immunity: Calves fed with collected colostrum are protected until the end of colostral nutrition. It has been shown that in sucking calves the protection against rotavirus and coronavirus lasts for minimum 7 days after birth. Over the next 7 days the gradual degradation of the antibodies occures.

5. CONTRAINDICATIONS

Do not vaccinate animals ill or suspected from any disease.

6. ADVERSE REACTIONS

Occasionally a slight sweling up to 2 cm in diameter may be observed at the site of injection. It is resorbed during 14 days after injection.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle (pregnant cows and heifers)

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

3 ml, Intramuscularly in accordance with the following schema:

Non-vaccinated cows the first injection in the week 6 – 5 before calving is expected
the second injection in the week 3 – 2 before calving is expected

Vaccinated cows: One injection in the course of each pregnancy between the week 6 – 3 before calving is expected.

Colostral feed
Protection of calves depends on the presence of colostral antibodies (obtained from vaccinated cows) in the gut during the first weeks of life until the individual immune status of the calves is formed. For the maximum efficacy of vaccination the adequate intake of colostrums throughout first 2-3 weeks of life is required. All calves must be supplied with sufficient amount of colostrum up to six hours after calving. The highest content of antibodies in the colostrum is reached 72 hours after parturition. In the herds with unfavourable epizootological situation to collect the colostrum of vaccinated mothers from the first 6 – 8 milkings is recommended. During the first two weeks of life the calves must be fed with 2,5 – 3,5 liters of colostrum/milk per one day .
To reach the maximum decrease of morbidity and reduction of intensity of diarrhoea it is necessary to assure that the whole herd of cows undergoes the vaccination treatment and all newborn calves must be fed with the prime-quality colostrum.

9. ADVICE ON CORRECT ADMINISTRATION

Common aseptic procedures should be used during vaccination.
Only sterile syringes and needles should be used.
Put the vaccine to the tepmerature 18 to 22° C before use.
Shake well before and occasionally during administration.
Do not mix with any other vaccine or immunological product.

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL PRECAUTIONS FOR STORAGE

Store and transport refrigerated (2 - 8°C). Protect from light. Do not freeze.
Once broached use within 10 hours .
Keep out of the reach and sight of children.
Do not use after the expiry date stated on the label.

12. SPECIAL WARNING(S)

Special precautions for use in animals

The medicinal product is designated for the use in cows and heifers in the last trimester of pregnancy.

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.
Administration of double dose can occasionally slightly extend a swelling size.
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
To the user:
This 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 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."

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accodrance with local requirements.

14. DATE OF LAST REVISION OF THE TEXT

28.12.2012

OTHER INFORMATION

Appearance:
White liquid emulsion. During storage the easily shakable sediment may form.

Commercial sizes:
15 ml (5 doses), 90 ml (30 doses), 240 ml (80 doses), 450 ml (150 doses).
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

For animal treatment only!

Available on prescription only !

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Paper box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ROTAGAL emulsion for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One dose of the vaccine (3 ml) contains:
Active substance:
Bovine rotavirus strain TM-91 (inactivated)
2/3 dose of vaccine stimulates (in rabbits) the increase of ELISA antibody titre $\geq 32,1^{*}$
Bovine coronavirus strain C-197 (inactivated)
2/3 dose of vaccine stimulates (in rabbits) the increase of ELISA antibody titre $\geq 44,8^{*}$
Escherichia coli Adhesin F5 (K99)
2/3 dose of vaccine stimulates (in rabbits) the increase of ELISA antibody titre $\geq 39,7^{*}$
*expressed as a percentage of inhibition

Adjuvant:
Oil emulsion (Mineral oil)
Excipients:
Thiomersal, Formaldehyde

3. PHARMACEUTICAL FORM

Emulsion for injection.

4. PACKAGE SIZE

15 ml (5 doses), 90 ml (30 doses), 240 ml (80 doses), 450 ml (150 doses).

5. TARGET SPECIES

Cattle (pregnant cows and heifers).

6. INDICATION(S)

For active immunization of pregnant cows and heifers to provide calves with passive immunity targeted at reduction of mortality, incidence and severity of diarrhoea caused by bovine rotavirus, coronavirus and enteropathogenic E. coli F5 (K99) and reduction of rotavirus and coronavirus shedding by infected calves.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

3 ml, Intramuscular injection.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated (2 - 8°C). Protect from light. Do not freeze.

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

For 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. Available on prescription only.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

97/072/07-S

17. MANUFACTURER'S BATCH NUMBER

Batch number

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

{NATURE/TYPE: Label on the plastic bottle = leaflet

ROTAGAL emulsion for injection

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

Marketing authorisation holder and manufacturer responsible for batch release:

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

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

One dose of the vaccine (3 ml) contains:
Active substance:
Rotavirus bovinum inactivatum, strain TM-91
2/3 dose of vaccine stimulates (in rabbits) the increase of ELISA antibody titre $\geq 32{,}1^{*}$
Coronavirus bovinum inactivatum, strain C-197
2/3 dose of vaccine stimulates (in rabbits) the increase of ELISA antibody titre $\geq 44{,}8^{*}$
Escherichia coli Adhesin F5 (K99)
2/3 dose of vaccine stimulates (in rabbits) the increase of ELISA antibody titre $\geq 39{,}7^{*}$
*expressed as a percentage of inhibition

Adjuvant:
Oil emulsion (mineral oil)

Excipients:
Thiomersal, Formaldehyde

3. TYPE AND PACKAGE SIZE

450 ml

4. INDICATION

For active immunization of pregnant cows and heifers to provide calves with passive immunity targeted at reduction of mortality, incidence and severity of diarrhoea caused by bovine rotavirus, coronavirus and enteropathogenic E. coli F5 (K99) and reduction of rotavirus and coronavirus shedding by infected calves.
Onset of immunity: Passive immunity starts with colostrum feeding.
Duration of immunity: Calves fed with collected colostrum are protected until the end of colostral nutrition. It has been shown that in sucking calves the protection against rotavirus and coronavirus lasts for minimum 7 days after birth. Over the next 7 days the gradual degradation of the antibodies occures.

5. CONTRAINDICATIONS

Do not vaccinate animals ill or suspected from any disease.

6. ADVERSE REACTIONS

Occasionally a slight sweling up to 2 cm in diameter may be observed at the site of injection. It is resorbed during 14 days after injection.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle (pregnant cows and heifers)

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

3 ml, Intramuscularly in accordance with the following schema:

Non-vaccinated cows the first injection in the week 6 – 5 before calving is expected
the second injection in the week 3 – 2 before calving is expected

Vaccinated cows: One injection in the course of each pregnancy between the week 6 – 3 before calving is expected.

Colostral feed
Protection of calves depends on the presence of colostral antibodies (obtained from vaccinated cows) in the gut during the first weeks of life until the individual immune status of the calves is formed. For the maximum efficacy of vaccination the adequate intake of colostrums throughout first 2-3 weeks of life is required. All calves must be supplied with sufficient amount of colostrum up to six hours after calving. The highest content of antibodies in the colostrum is reached 72 hours after parturition. In the herds with unfavourable epizootological situation to collect the colostrum of vaccinated mothers from the first 6 – 8 milkings is recommended. During the first two weeks of life the calves must be fed with 2,5 – 3,5 liters of colostrum/milk per one day .
To reach the maximum decrease of morbidity and reduction of intensity of diarrhoea it is necessary to assure that the whole herd of cows undergoes the vaccination treatment and all newborn calves must be fed with the prime-quality colostrum.

9. ADVICE ON CORRECT ADMINISTRATION

Common aseptic procedures should be used during vaccination.
Only sterile syringes and needles should be used.
Put the vaccine to the tepmerature 18 to 22° C before use.
Shake well before and occasionally during administration.
Do not mix with any other vaccine or immunological product.

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL PRECAUTIONS FOR STORAGE

Store and transport refrigerated (2 - 8°C). Protect from light. Do not freeze.
Once broached use within 10 hours.
Keep out of the reach and sight of children.
Do not use after the expiry date stated on the label.

12. SPECIAL WARNINGS

Special precautions for use in animals
The medicinal product is designated for the use in cows and heifers in the last trimester of pregnancy.
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.
Administration of double dose can occasionally slightly extend a swelling size.
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
To the user:
This 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 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."

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accodrance with local requirements.

14. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. Available on prescription only.

15. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

16. MARKETING AUTHORISATION NUMBER

97/072/07-S

17. MANUFACTURER'S BATCH NUMBER

Batch number

18. EXPIRY DATE

EXP month/year
Once broached use within 10 hours.

19. DATE OF LAST REVISION OF THE TEXT

28.12.2012

20. OTHER INFORMATION

Appearance: White liquid emulsion. During storage the easily shakable sediment may form.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Label on the vial of more than 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ROTAGAL emulsion for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One dose of the vaccine (3 ml) contains:
Active substance:
Bovine rotavirus strain TM-91 (inactivated)
2/3 dose of vaccine stimulates (in rabbits) the increase of ELISA antibody titre $\geq 32{,}1^{*}$
Bovine coronavirus strain C-197 (inactivated)
2/3 dose of vaccine stimulates (in rabbits) the increase of ELISA antibody titre $\geq 44{,}8^{*}$
Escherichia coli Adhesin F5 (K99)
2/3 dose of vaccine stimulates (in rabbits) the increase of ELISA antibody titre $\geq 39{,}7^{*}$
*expressed as a percentage of inhibition

Adjuvant:
Oil emulsion (mineral oil)
Excipients:
Thiomersal, Formaldehyde

3. PHARMACEUTICAL FORM

Emulsion for injection.

4. PACKAGE SIZE

80 doses, 150 doses

5. TARGET SPECIES

Cattle (pregnant cows and heifers).

6. INDICATION(S)

For active immunization of pregnant cows and heifers to provide calves with passive immunity targeted at reduction of mortality, incidence and severity of diarrhoea caused by bovine rotavirus, coronavirus and enteropathogenic E. coli F5 (K99) and reduction of rotavirus and coronavirus shedding by infected calves.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

3 ml, Intramuscular injection.

8. WITHDRAWAL PERIOD

Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated (2 - 8°C). Protect from light. Do not freeze.

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

For 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. Available on prescription only.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

97/072/07-S

17. MANUFACTURER'S BATCH NUMBER

Batch number

MINIMUM PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING UNITS
Label on the glass vial less than 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ROTAGAL emulsion for injection

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

One dose of the vaccine (3 ml) contains:
Active substance:
Bovine rotavirus strain TM-91 (inactivated)
2/3 dose of vaccine stimulates (in rabbits) the increase of ELISA antibody titre $\geq 32,1^{*}$
Bovine coronavirus strain C-197 (inactivated)
2/3 dose of vaccine stimulates (in rabbits) the increase of ELISA antibody titre $\geq 44,8^{*}$
Escherichia coli Adhesin F5 (K99)
2/3 dose of vaccine stimulates (in rabbits) the increase of ELISA antibody titre $\geq 39,7^{*}$
*expressed as a percentage of inhibition

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

5 doses, 30 doses

4. ROUTE(S) OF ADMINISTRATION

Intramuscular injection.

5. WITHDRAWAL PERIOD

Zero days.

6. BATCH NUMBER

Batch number

7. EXPIRY DATE

EXP {month/year}
Once broached use within 10 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.