1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rokopig, emulsion for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose (2 ml) of the vaccine contains:

Active substances:

Rotavirus suis inact.	OSU 6	RP ≥ 1*
Escherichia coli inact.	O101:K99 (F5)	RP ≥ 1*
Escherichia coli inact.	O147:K88 ab (F4); O149:K88 ac (F4)	RP ≥ 1*
Escherichia coli inact.	K85:987P (F6)	RP ≥ 1*
Escherichia coli inact.	O101:K99:F41 (F5, F41)	RP ≥ 1*

* Relative potency determined by serological method on mice in comparison with reference vaccine, which satisfied in potency testing on target species.

Adjuvant: Montanide ISA 25 VG 0.5 ml

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Thiomersal	0.2 mg
Sodium chloride	
Water for injection	

White or slightly pinkish oily liquid with easy resuspendable deposit.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (pregnant sows and gilts)

3.2 Indications for use for each target species

For the active immunisation of pregnant sows and gilts to provide passive immunity in suckling piglets against rotavirus and *E. coli* strains expressing fimbrial adhesion factors F4, F5, F6 and F41.

Onset of immunity: passive immunity commences with suckling of piglets and is dependent on piglets receiving sufficient colostrum after birth.

Duration of immunity: the duration of passive immunity has not been established.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.
The passive protection of piglets is achieved by colostrum intake. Thus, it is important to ensure that each piglet ingests a sufficient quantity of colostrum within the first hours of life

3.5 Special precautions for use

Special precautions for safe use in the target species:
Not applicable.

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 ischaemic 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.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Target species: Pigs (pregnant sows and gilts)

Very common (>1 animal / 10 animals treated):	Injection site swelling*
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction**

* with a diameter of less than 5 cm, which may be accompanied by warmth and/or erythema (diameter of less than 2 cm) during the first 2 days and resolves spontaneously within 17 days after the vaccination

** symptomatic treatment should be applied

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation

holder or its local representative or the national competent authority via the national reporting system. See also the last section of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Can be used during pregnancy.

3.8 Interactions 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.

3.9 Administration routes and dosage

For intramuscular use (neck muscles, behind the ear).
Dose: 2 ml.
Shake the content of the vial before use.

Basic vaccination:
Sows and gilts: administer 2 doses separated by an interval of 2 to 4 weeks. The 2nd dose should be administered at the latest 2 weeks prior to expected parturition.

Revaccination:
For each subsequent pregnancy, administer 1 dose 4 to 2 weeks prior to expected parturition.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No adverse reactions were observed after an overdose administration (2 doses) of the veterinary medicinal product other than those mentioned in section 3.6

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI 09AL02.

The vaccine contains selected serotypes of *E. coli* (O147:K88 ab, O149:K88 ac, O101:K99, 987P and O101:K99:F41) and an inactivated porcine rotavirus type A. Vaccination of pregnant sows and gilts induces the production of protective antibodies which are transferred via colostrum to suckling piglets, to provide passive protection against enterotoxigenic *E. coli* (ETEC) and pathogenic rotavirus.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after first opening of the immediate packaging: 10 hours

5.3 Special precautions for storage

Store and transport refrigerated (2°C – 8°C).
Protect from light.
Store in a dry place.

5.4 Nature and composition of immediate packaging

High density polyethylene bottle of 60 ml, 120 ml or 250 ml volume, glass vial (hydrolytic glass class I) of 10 ml or glass vial (hydrolytic glass class II) of 50 ml and 100 ml sealed with rubber stopper (chlorobutyl material) and aluminium or flip-off cap, in a cardboard or plastic box.

Package sizes:

Cardboard box:
1 × 10 ml (1 x 5 doses) in 10 ml glass vial hydrolytic class I
1 × 50 ml (1 x 25 doses) in 50 ml glass vial hydrolytic class II
1 × 50 ml (1 x 25 doses) in 60 ml HDPE plastic vial
1 × 100 ml (1 x 50 doses) in 100 ml glass vial hydrolytic class II
1 × 100 ml (1 x 50 doses) in 120 ml HDPE plastic vial
1 × 250 ml (1 x 125 doses) in 250 ml HDPE plastic bottle

Plastic box:
10 × 10 ml (10 x 5 doses) in 10 ml glass vial hydrolytic class I

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste material derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Animal Health Distributors Limited
Tullow Industrial Estate, Bunclody Road
R93WOD8 Tullow - Carlow
Ireland

7. MARKETING AUTHORISATION NUMBER(S)

VPA 22715/005/001

8. DATE OF FIRST AUTHORISATION

DD/MM/YYYY

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database.