

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GRIPORK emulsion for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (2 ml) contains:

Active ingredients:

Inactivated swine influenza A (H1/N1) virus, OLL strain $\geq 1/50$ HI*

Inactivated swine influenza A (H3/N2) strain, G strain $\geq 1/50$ HI*

* Hemoagglutination Inhibition Titer.

Adjuvants:

Light mineral oil 424.00 mg

Aluminium hydroxide gel 48.00 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Polysorbate 80	
Sorbitan oleate	
Simulsol 5100	
Sodium methyl parahydroxybenzoate	2.00 mg
Sodium propyl parahydroxybenzoate	0.40 mg
Disodium phosphate dodecahydrate	
Potassium dihydrogen phosphate	
Sodium chloride	
Potassium chloride	
Water for injections	

White homogeneous emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Pigs.

3.2 Indications for use for each of the target species

For active immunization of healthy pigs (sows, boars, weaned piglets, and fattening pigs) to prevent swine influenza.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special Precautions for use

Special precautions for safe use in target species:

In the event of accidental injection into the animal into subcutaneous tissue, local reactions may appear and subside within a few days.

Specific 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 veterinary medicinal 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 veterinary medicinal 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

Pigs (sows, boars, weaned piglets and fattening pigs):

Uncommon (1 to 10 animals / 1 000 animals treated):	Injection site reaction ¹
Very rare: (<1 animal / 10 000 animals treated, including isolated reports):	Hypersensitivity reactions ²

¹Local reactions at the inoculation site that disappear after a few days.

²If such reactions occur, appropriate treatment, e.g. antihistamine treatment, is recommended.

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 the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used during pregnancy and lactation.

3.8 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.

3.9 Administration routes and dosage

A single dose is 2 ml.
Administer to pigs from 1 month of age.
For intramuscular use.

The method of administration is deep intramuscular injection in the neck muscles, behind the base of the ear.

Dosage:

Sows:

Primary vaccination: administer a dose of 2 ml to all sows (including pregnant and lactating animals) followed by a second dose of 2 ml 21 days later.

Revaccination: administer a single dose of 2 ml in subsequent pregnancies, approximately 1 month before parturition, or administer a single dose 6 months after completion of primary vaccination and thereafter a single dose every 6 months.

Adult boars:

Primary vaccination: administer a dose of 2 ml to all adult boars followed by a second dose of 2 ml 21 days later.

Revaccination: administer a single dose of 2 ml 6 months after completion of primary vaccination and thereafter a single dose every 6 months.

Weaned piglets:

Primary vaccination: administer half a single dose (1 ml) at 30 – 40 days of age followed by a single dose (2 ml) at 60 – 65 days of age.

Fattening pigs

Primary vaccination: administer half a single dose (1 ml) to all pigs upon arrival at the farm followed by a single dose (2 ml) 3 weeks later.

Disinfect the site of injection prior to vaccination and use sterile equipment for vaccination.

Allow the vaccine to warm to a temperature of approximately 15 to 25 °C prior to using and shake the vial before use.

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

It does not cause any adverse reaction when administered twice the recommended dose other than those observed in section “Adverse events”.

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

PROHIBITION OF SALE, SUPPLY AND/OR USE

The import, sale, supply and/or use of Gripork is restricted or prohibited in Ireland pursuant to national animal health policy.

Any person intending to import, sell, supply and/or use Gripork must consult the Department of Agriculture on the current vaccination policies prior to import, sale, supply and/or use.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet Code: QI09AA03

To stimulate active immunity against swine influenza viruses (H1N1 and H3N2 strains).

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 the immediate packaging: use immediately.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).

Do not freeze.

Protect from light.

5.4 Nature and composition of immediate packaging

Type I 20 ml topaz-coloured glass vials (10 doses) and Type II 100 ml (50 doses) topaz-coloured glass vials, with their corresponding Type I-classified rubber stoppers, and anodised aluminium closure capsules.

Formats:

Box with 10 vials of 10 doses (20 ml).

Box with 1 vial of 50 doses (100 ml).

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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 materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10846/021/001

8. DATE OF FIRST AUTHORISATION

14/11/2025

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

06/11/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product can be found in the Union Medicinal Products Database (<https://medicines.health.europa.eu/veterinary>)