

IRISH MEDICINES BOARD ACT 1995, as amended

European Communities (Animal Remedies) (No. 2) Regulations 2007

VPA: **10857/044/001**
Case No: 7008127

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Merial Animal Health Limited

Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex CM19 5TG, United Kingdom

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Geskypur

The particulars of which are set out in the attached Schedule. The authorisation is also subject to any special conditions as may be specified in the Schedule.

The authorisation, unless revoked, shall continue in force from **08/07/2010**.

Signed on behalf of the Irish Medicines Board

A person authorised in that behalf by the said Board.

(NOTE: This authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

GESKYPUR

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2-ml dose of vaccine contains:

Active substance

Aujeszky's disease virus glycoproteins ≥1.1 ΔG7.U*

* 1 ΔG7.U: q.s. to obtain a ΔG7 of 1.0 during protection against challenge, according to Ph. Eur.

Adjuvant

Light paraffin oil, q.s. 2ml

Excipient

Benzyl alcohol, maximum 10.56 mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Emulsion for injection

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs.

4.2 Indications for use, specifying the target species

For breeder pigs and fattening pigs:

Active immunisation of fattening pigs to reduce weight loss caused by Aujeszky's disease. Active immunisation of gilts and sows to reduce the number of stillborn piglets caused by Aujeszky's disease.

Passive immunisation of piglets to reduce mortality caused by Aujeszky's disease, by vaccination of pregnant sows.

The duration of immunity in fattening pigs is extended from the primary vaccination to the end of the fattening period. In gilts and sows, the onset of immunity starts 3 weeks after the second injection of primary vaccination and persists up to 4 months. In piglets, passive immunity persists up to 15 days of age.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate only healthy animals.

Apply usual procedures for the handling of animals.

Apply the usual aseptic precautions.

Vaccination of the entire herd is recommended to reduce virus spread.

4.5 Special precautions for use

Special precautions for use in animals

None.

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

In the case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

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 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.

4.6 Adverse reactions (frequency and seriousness)

Vaccination can induce at the site of injection a small (about 1 cm) local reaction (granuloma) disappearing generally two or three months later, without any effect on the health and the reproductive performance of the animal.

The vaccination can cause a slight rise in body temperature ($< 0.2^{\circ}\text{C}$) that returns to normal values from 1 to 2 days after vaccination without any consequence to the health or the production parameters of the animal.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the compatibility of this vaccine with any other.

Therefore the safety and efficacy of this product when used with any other (either when used on the same day or at different times) has not been demonstrated.

4.9 Amounts to be administered and administration route

Shake well prior to use.

Deep intramuscular route into the neck muscles behind the ear.

Inject one 2-ml dose according to the following schedule:

Sows and gilts from 6 months of age

Basic vaccination scheme:

2 doses with a 21- to 28-day interval.

The second dose should be given at least 8 days before service mating.

Re-vaccination scheme:

1 dose every 6 months (in sows this should be 3 to 4 weeks before farrowing).

Boars from 10 weeks of age:

Basic vaccination scheme:

2 doses with a 21- to 28-day interval.

Re-vaccination scheme:

Half-yearly boosters.

Fattening pigs from 10 weeks of age:

2 doses at the ages of 10 and 14 weeks.

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

No undesirable effects except those mentioned in Section 4.6 were observed after the administration of a double dose of vaccine.

4.11 Withdrawal Period(s)

Zero Days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC Vet Code: Q109AA01

The vaccine induces an active immune status against Aujeszky's disease virus, shown by challenge, and passive immunity by the presence of seroneutralizing antibodies, transmissible by colostral route.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Light Paraffin oil

Benzyl alcohol

6.2 Incompatibilities

Do not mix with any other medicinal product

6.3 Shelf-life

Shelf-life : 24 months.

Use immediately after opening the bottle

6.4 Special precautions for storage

Store between +2°C and +8°C, protected from light.

6.5 Nature and composition of immediate packaging

Nature of primary packaging elements:

Type I glass or polypropylene bottle, Nitrile elastomer closure, Aluminium cap.

Authorised Packaging Presentations (Not all pack sizes may be marketed):

2 ml (1-dose) bottle, box of 1 bottle.

2 ml (1-dose) bottle, box of 5 bottles.

2 ml (1-dose) bottle, box of 10 bottles.

20 ml (10-dose) bottle, box of 1 bottle.

100 ml (50-dose) bottle, box of 1 bottle.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Merial Animal Health Limited

Sandringham House

Harlow Business Park

Harlow

Essex CM19 5TG

England

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10857/044/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st May 2008

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

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

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