

Medicinal product no longer authorised

**ANNEX I**  
**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Gripovac 3 suspension for injection for pigs

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 2 ml contains:

### Active substances:

Strains of inactivated Influenza A virus/swine/

Bakum/IDT1769/2003 (H3N2)	$\geq 10.53 \log_2 \text{GMNU}^1$
Haselünne/IDT2617/2003 (H1N1)	$\geq 10.22 \log_2 \text{GMNU}^1$
Bakum/1832/2000 (H1N2)	$\geq 12.34 \log_2 \text{GMNU}^1$

<sup>1</sup>GMNU = Geometric mean of neutralizing units induced in Guinea pigs after twice immunisation with 0.5 ml of this vaccine

### Adjuvant:

Carbomer 971 P NF 2.0 mg

### Excipient:

Thiomersal 0.21 mg

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Clear, yellowish orange to pink colored suspension for injection.

## 4. CLINICAL PARTICULARS

### 4.1. Target species

Pigs

### 4.2. Indication for use, specifying the target species

Active immunisation of pigs from the age of 56 days onwards including pregnant sows against swine influenza caused by subtypes H1N1, H3N2 and H1N2 to reduce clinical signs and viral lung load after infection.

Onset of immunity:	7 days after primary vaccination
Duration of immunity:	4 months in pigs vaccinated between the age of 56 and 96 days and 6 months in pigs vaccinated for the first time at 96 days and above.

Active immunisation of pregnant sows after finished primary immunisation by administration of a single dose 14 days prior to farrowing to develop high colostral immunity which provides clinical protection of piglets for at least 33 days after birth.

#### **4.3. Contraindications**

None.

#### **4.4. Special warnings for the target species**

None.

#### **4.5. Special precautions for use**

Special precautions for use in animals

Not applicable.

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

In case of accidental self-injection only a minor injection site reaction is expected.

#### **4.6. Adverse reactions (frequency and seriousness)**

A transient slight swelling may occur on very rare occasions after vaccination at the site of injection, regressing within 2 days. On very rare occasions, a slight transient rectal temperature increase might occur after vaccination.

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

- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals )
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports)

#### **4.7. Use during pregnancy, lactation or lay**

Can be used during pregnancy and lactation.

#### **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**

For intramuscular use.

Piglets:

Primary vaccination: 2 injections of one dose (2 ml)

- From the age of 96 days, with an interval of 3 weeks between injections to achieve duration of immunity over 6 months.

or

- Between the age of 56 and 96 days, with an interval of 3 weeks between injections to achieve duration of immunity over 4 months.

Gilts and sows:

Primary vaccination: see above

A booster is possible at each stage of pregnancy and lactation. When vaccination is performed 14 days prior to farrowing with one dose (2 ml), it provides maternally-derived immunity to the piglets which protects them from clinical signs of influenza at least until day 33 after birth.

Maternally-derived immunity in the piglets interacts with antibody induction. Generally, maternally-derived antibodies induced by vaccination last for approx. 5-8 weeks after birth. In particular cases of multiple contacts of the sows with antigens (field infections + vaccination) the antibodies transmitted to the piglets may last until week 12 of life. In the latter case piglets should be vaccinated after the age of 96 days.

#### **4.10. Overdose (symptoms, emergency procedures, antidotes), if necessary**

After administration of a double dose (4 ml), no adverse reactions other than those described in section 4.6 were observed.

#### **4.11. Withdrawal period**

Zero days

### **5. IMMUNOLOGICAL PROPERTIES**

Pharmacotherapeutic group: Immunologicals, Inactivated viral vaccines

ATC vet code: QI09AA03

The vaccine stimulates an active immunity against Swine Influenza A virus subtypes H1N1, H3N2 and H1N2. It induces neutralizing and haemagglutination inhibiting antibodies against each of the three subtypes. When a single dose of the vaccine is administered 14 days prior to farrowing as a booster to previously vaccinated sows, the vaccine stimulates active immunity in order to provide maternally-derived immunity to the progeny against Swine Influenza A virus subtypes H1N1, H3N2 and H1N2.

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1. List of excipients**

Carbomer 971 P NF

Thiomersal

Sodium chloride solution (0.9 %)

#### **6.2. Incompatibilities**

Do not mix with any other veterinary medicinal product.

#### **6.3. Shelf-life**

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

Shelf life after first opening the vial: 10 hours.

#### **6.4. Special precautions for storage**

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

Keep the vial in the outer carton in order to protect from light.

## **6.5. Nature and composition of immediate packaging**

Glass vials: 20 ml vials, glass type I  
50 ml vials, glass type II  
100 ml vials, glass type II

PET vials: 20 ml Polyethylene terephthalate (PET) vials, clear  
50 ml PET vials, clear  
100 ml PET vials, clear

Stoppers: Bromobutyl rubber stoppers

Caps: Flanged caps

Package sizes:

Cardboard box with 1 glass vial of 10 doses (20 ml), 25 doses (50 ml) or 50 doses (100 ml) with a rubber stopper and flanged cap.

Cardboard box with 1 PET vial of 10 doses (20 ml), 25 doses (50 ml) or 50 doses (100 ml) with a rubber stopper and flanged cap.

Not all pack sizes may be marketed.

## **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 accordance with the local requirements.

## **7. MARKETING AUTHORISATION HOLDER**

MERIAL  
29, avenue Tony Garnier  
69007 Lyon  
FRANCE

## **8. MARKETING AUTHORISATION NUMBER**

EU/2/09/102/001-006

## **9. DATE OF FIRST AUTHORISATION**

Date of first authorisation: 14/01/2010

Date of last renewal : DD/MM/YYYY

## **10. DATE OF REVISION OF THE TEXT**

DD/MM/YYYY

Detailed information on this product is available on the website of the European Medicines Agency  
<http://www.ema.europa.eu/>

**PROHIBITION OF SALE; SUPPLY AND/OR USE**

Not applicable.

Medicinal product no longer authorised

**ANNEX II**

- A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE**
- B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**
- C. STATEMENT OF THE MRLs**

**A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND  
MANUFACTURER RESPONSIBLE FOR BATCH RELEASE**

Name and address of the manufacturer of the biological active substance

IDT Biologika GmbH  
Am Pharmapark  
06861 Dessau-Rosslau  
Germany

Name and address of the manufacturer(s) responsible for batch release

IDT Biologika GmbH  
Am Pharmapark  
06861 Dessau-Rosslau  
Germany

**B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION  
REGARDING SUPPLY AND USE**

Veterinary medicinal product subject to prescription

**C. STATEMENT OF THE MRLs**

The active substance being a principle of biological origin intended to produce active immunity is not within the scope of Regulation (EC) No 470/2009.

The excipients (including adjuvants) listed in section 6.1 of the SPC are either allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.



Medicinal product no longer authorised

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

Medicinal product no longer authorised

#### **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

Cardboard box for 20ml, 50 ml, 100 ml

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

Gripovac 3 suspension for injection for pigs

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Each dose of 2 ml contains:

Strains of inactivated Influenza A virus/swine/

Bakum/IDT1769/2003 (H3N2)  $\geq 10.53 \log_2$  GMNU,

Haselünne/IDT2617/2003(H1N1)  $\geq 10.22 \log_2$  GMNU,

Bakum/1832/2000 (H1N2)  $\geq 12.34 \log_2$  GMNU

**3. PHARMACEUTICAL FORM**

Suspension for injection

**4. PACKAGE SIZE**

20 ml (10 doses),

50 ml (25 doses),

100 ml (50 doses)

**5. TARGET SPECIES**

Pigs

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

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.

**10. EXPIRY DATE**

EXP {month/year}

Once opened, use within 10 hours.

**11. SPECIAL STORAGE CONDITIONS**

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

**12. SPECIFIC 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**

MERIAL  
29, avenue Tony Garnier  
69007 Lyon  
FRANCE

**16. MARKETING AUTHORISATION NUMBER(S)**

EU/2/09/102/001-006

**17. MANUFACTURER'S BATCH NUMBER**

Lot:

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

Vial of 100 ml

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

Gripovac 3 suspension for injection for pigs

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each dose of 2 ml contains:

Strains of inactivated Influenza A virus/swine/

Bakum/IDT1769/2003 (H3N2)  $\geq 10.53 \log_2$  GMNU,

Haselünne/IDT2617/2003(H1N1)  $\geq 10.22 \log_2$  GMNU,

Bakum/1832/2000 (H1N2)  $\geq 12.34 \log_2$  GMNU

**3. PHARMACEUTICAL FORM**

Suspension for injection

**4. PACKAGE SIZE**

100 ml (50 doses)

**5. TARGET SPECIES**

Pigs

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

IM

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.

**10. EXPIRY DATE**

EXP {month/year}

Once opened, use within 10 hours.

**11. SPECIAL STORAGE CONDITIONS**

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

**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**

MERIAL  
29, avenue Tony Garnier  
69007 Lyon  
FRANCE

**16. MARKETING AUTHORISATION NUMBER(S)**

EU/2/09/102/003  
EU/2/09/102/006

**17. MANUFACTURER'S BATCH NUMBER**

Lot:

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

Vial of 20 ml and 50 ml

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

Gripovac 3 suspension for injection for pigs

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

Strains of inactivated Influenza A virus/swine  
(H3N2)  $\geq 10.53 \log_2$  GMNU, (H1N1)  $\geq 10.22 \log_2$  GMNU, (H1N2)  $\geq 12.34 \log_2$  GMNU

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

20 ml (10 doses),  
50 ml (25 doses)

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

IM

**5. WITHDRAWAL PERIOD**

Withdrawal period: zero days

**6. BATCH NUMBER**

Lot:

**7. EXPIRY DATE**

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

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

For animal treatment only.

Medicinal product no longer authorised

#### **B. PACKAGE LEAFLET**



## PACKAGE LEAFLET FOR:

### Gripovac 3 Suspension for injection for pigs

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

Marketing authorisation holder:

MERIAL  
29 avenue Tony Garnier  
69007 Lyon,  
France

Manufacturer responsible for batch release:

IDT Biologika GmbH  
Am Pharmapark  
06861 Dessau-Rosslau  
Germany

#### 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Gripovac 3 suspension for injection for pigs

#### 3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Clear, yellowish orange to pink colored suspension for injection.

Each dose of 2 ml contains:

**Active substances:**

Strains of inactivated Influenza A virus/swine/  
Bakum/IDT1769/2003 (H3N2)  
Haselünne/IDT2617/2003 (H1N1)  
Bakum/1832/2000 (H1N<sub>2</sub>)

$\geq 10.53 \log_2$  GMNU<sup>1</sup>  
 $\geq 10.22 \log_2$  GMNU<sup>1</sup>  
 $\geq 12.34 \log_2$  GMNU<sup>1</sup>

<sup>1</sup> GMNU = Geometric mean of neutralizing units induced in Guinea pigs after twice immunisation with 0.5 ml of this vaccine.

**Adjuvant:**

Carbomer 971 P NF 2.0 mg

**Excipient:**

Thiomersal 0.21 mg

#### 4. INDICATION(S)

Active immunisation of pigs from the age of 56 days onwards including pregnant sows against swine influenza caused by subtypes H1N1, H3N2 and H1N2 to reduce clinical signs and viral lung load after infection.

Onset of immunity: 7 days after primary vaccination

Duration of immunity: 4 months in pigs vaccinated between the age of 56 and 96 days and 6 months in pigs vaccinated for the first time at 96 days and above.

Active immunisation of pregnant sows after finished primary immunisation by administration of a single dose 14 days prior to farrowing to develop high colostral immunity which provides clinical protection of piglets for at least 33 days after birth.

## **5. CONTRAINDICATIONS**

None.

## **6. ADVERSE REACTIONS**

A transient slight swelling may occur on very rare occasions after vaccination at the site of injection, regressing within 2 days. On very rare occasions, a slight transient rectal temperature increase might occur after vaccination ("very rare" corresponds to a frequency of adverse reactions less than 1 animal in 10,000 animals, including isolated reports).

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

## **7. TARGET SPECIES**

Pigs

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

For intramuscular use.

Piglets:

Primary vaccination: 2 injections of one dose (2 ml)

- From the age of 96 days, with an interval of 3 weeks between injections to achieve duration of immunity over 6 months.

or

- Between the age of 56 and 96 days, with an interval of 3 weeks between injections to achieve duration of immunity over 4 months.

Gilts and sows:

Primary vaccination: see above

A booster is possible at each stage of pregnancy and lactation. When vaccination is performed 14 days prior to farrowing with one dose (2 ml), it provides maternally-derived immunity to the piglets which protects them from clinical signs of influenza at least until day 33 after birth.

Maternally-derived immunity in the piglets interacts with antibody induction. Generally, maternally-derived antibodies induced by vaccination last for approx. 5-8 weeks after birth. In particular cases of multiple contacts of the sows with antigens (field infections + vaccination) the antibodies transmitted to the piglets may last until week 12 of life. In the latter case piglets should be vaccinated after the age of 96 days.

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

None.

## **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). Do not freeze.

Keep the vial in the outer carton in order to protect from light.

Shelf-life after first opening the container: 10 hours.

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

## **12. SPECIAL WARNINGS**

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

In case of accidental self-injection only a minor injection site reaction is expected.

Pregnancy and lactation:

The vaccine can be used during pregnancy and lactation.

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.

Incompatibilities:

Do not mix with any other 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 or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

## **14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

Detailed information on this product is available on the website of the European Medicines Agency <http://www.ema.europa.eu/>.

## 15. OTHER INFORMATION

The vaccine stimulates an active immunity against Swine Influenza A virus subtypes H1N1, H3N2 and H1N2. It induces neutralizing and haemagglutination inhibiting antibodies against each of the three subtypes. When a single dose of the vaccine is administered 14 days prior to farrowing as a booster to previously vaccinated sows, the vaccine stimulates active immunity in order to provide maternally-derived immunity to the progeny against Swine Influenza A virus subtypes H1N1, H3N2 and H1N2.

Package sizes:

Cardboard box with 1 glass or PET vial of 10 doses (20 ml), 25 doses (50 ml) or 50 doses (100 ml) with a rubber stopper and flanged cap.

Not all pack sizes may be marketed.

Medicinal product no longer authorised