



London, 13 November 2009
Doc. Ref.: EMEA/CVMP/661084/2009

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE
SUMMARY OF OPINION*
GRIPOVAC 3

Inactivated vaccine against swine influenza in pigs

On 11 November 2009, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the veterinary medicinal product Gripovac 3, a suspension for injection intended for the 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.

The Applicant for this veterinary medicinal product is Merial SAS.

The active substance of Gripovac 3 contains 3 different inactivated influenza A virus/ swine strains:

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)	$\geq 12.34 \log_2 \text{GMNU}^1$

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

The benefits of Gripovac 3 are the 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 and the 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.

The most common side effects are a transient slight swelling after vaccination at the site of injection in a small number of pigs, regressing within 2 days. On occasions, a slight transient rectal temperature increase might occur after vaccination.

The approved indication is:

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.

* Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the Opinion.

** Applicants may appeal any CVMP opinion, provided they notify the EMEA in writing of their intention to appeal within 15 days of receipt of the opinion.

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.

Detailed conditions for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Gripovac 3 and therefore recommends the granting of the marketing authorisation.

Medicinal product no longer authorised