

Medicinal product no longer authorised

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac FluFend H5N3 RG emulsion for injection for chickens and ducks

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose of 0.5 ml contains:

Active substance:

Inactivated recombinant avian influenza virus
of H5N3 subtype (strain rg-A/ck/VN/C58/04) > 1:40 HI units per dose

Adjuvants:

White Oil
Sorbitan sesquioleate
Polysorbate 80

Excipients:

Thiomersal
Phosphate Buffer Saline

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens and ducks.

4.2 Indications for use, specifying the target species

For active immunisation of chickens and ducks against avian influenza virus type A, subtype H5.

Chickens: Reduction of mortality and virus excretion after challenge.

Onset of immunity: 3 weeks after the second injection.

Duration of immunity in chickens has not been established yet.

Ducks: Reduction of clinical signs and virus excretion after challenge.

Onset of immunity: 3 weeks after the second injection.

Duration of immunity in ducks : 14 weeks after the second injection.

4.3 Contraindications

None

4.4 Special warnings for each target species

The level of efficacy attained may vary depending on the degree of antigenic homology between the vaccine strain and circulating field strains.

No information is available on the interference of maternally derived antibodies on vaccination for both target species.

4.5 Special precautions for use

Special precautions for use in animals

Avoid stress in the birds around the time of vaccination.

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

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)

A transient local site reaction (swelling) may occasionally occur as is normal with oil adjuvanted vaccines.

4.7 Use during pregnancy, lactation or lay

No information is available on the safety of this vaccine for birds in lay.

4.8 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.

4.9 Amounts to be administered and administration route

Chickens

3 weeks of age or older: 0.5 ml intramuscularly in the breast muscle. Revaccinate after 3 weeks. The vaccination schedule should be completed at least 4 weeks before the start of laying.

Ducks

At one day old: 0.2 ml subcutaneously in the neck.

Revaccinate after 3 weeks: 0.5 ml subcutaneously in the neck

The vaccination schedule should be completed at least 4 weeks before the start of laying.

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

Following the administration of a double dose in chickens and ducks, no adverse reactions other than those described in section 4.6 have been observed.

4.11 Withdrawal period

Zero days

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Inactivated recombinant vaccine, ATC vet code: QI01AA23

To stimulate active immunity in chickens and ducks against avian influenza virus, H5 subtype.
To induce serological response against N3 neuraminidase which can act as a marker to Differentiate Infected from Vaccinated Animals (DIVA strategy).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

White Oil
Sorbitan sesquioleate
Polysorbate 80
Thiomersal
Sodium chloride
Sodium phosphate dibasic
Potassium phosphate monobasic

6.2. Incompatibilities

Do not mix with any other medicinal product.

6.3 Shelf life

1 year.
The entire content of the bottle should be used within 2 hours after broaching the container.

6.4 Special precautions for storage

Store and transport refrigerated (2° to 8°C).
Store in the original container in order to protect from light.
Do not freeze.

6.5 Nature and composition of immediate packaging

500 ml of vaccine in high-density polyethylene bottles, closed with a nitrile rubber stopper and aluminium cap.

The vaccine is presented in boxes of 1 or 10 bottles of 500 ml.

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

Pfizer Limited
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom

8. MARKETING AUTHORISATION NUMBER

EU/2/06/060/001-002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

01/09/2006

10. DATE OF REVISION OF THE TEXT

13/12/2010

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

The import, sale, supply and/or use of Poulvac FluFend H5N3 RG is or may be prohibited in certain Member States on the whole or part of their territory pursuant to national animal health policy. Any person intending to import, sell, supply and/or use Poulvac FluFend H5N3 RG must consult the relevant Member States competent authority on the current vaccination policies prior to the import, sale, supply and/or use.

ANNEX II

- A. MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE**
- B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE**
- C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO SAFE AND EFFECTIVE USE**
- D. STATEMENT OF THE MRLs**
- E. SPECIFIC OBLIGATIONS TO BE FULFILLED BY THE MARKETING AUTHORISATION HOLDER**

A. MANUFACTURERS OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer of the biological active substance(s)

Pfizer Global Manufacturing Weesp
CJ van Houtenlaan 36
1381 CP Weesp
The Netherlands

Pfizer Animal Health
2000 Rockford Road
Charles City, Iowa 50616
USA

Name and address of the manufacturer responsible for batch release

Pfizer Global Manufacturing Weesp
CJ van Houtenlaan 36
1381 CP Weesp
The Netherlands

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

To be supplied only on veterinary prescription.

According to Article 71 of Directive 2001/82/EC of the European Parliament and of the Council as amended, Member States prohibit or may prohibit the import, sale, supply and/or use of the veterinary medicinal product on the whole or part of their territory if it is established that:

- a) the administration of the veterinary medicinal product to animals will interfere with the implementation of national programmes for the diagnosis, control and eradication of animal diseases, or will cause difficulties in certifying the absence of contamination in live animals or in foodstuffs or other products obtained from treated animals
- b) the disease to which the veterinary medicinal product is intended to confer immunity is largely absent from the territory.

The use of this veterinary medicinal product is only allowed under the particular conditions established by European Community legislation on the control of Avian Influenza.

The holder of this marketing authorisation must inform the European Commission about the marketing plans for the medicinal product authorised by this decision.

C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO SAFE AND EFFECTIVE USE

Not applicable.

D. 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 following constituents of Poulvac FluFend H5N3 RG are included in Table 1 (Allowed substances) of the annex to Commission Regulation (EU) No 37/2010 as follows:

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Sodium chloride	Not applicable	All food producing species	No MRL required	Not applicable	No Entry	No entry
Thiomersal	Not applicable	All food producing species	No MRL required	Not applicable	For use only as a preservative in multidose vaccines at a concentration not exceeding 0,02 %.	No entry

White oil is a mineral hydrocarbon, Arlacel 83V is sorbitan sesquioleate, Tween 80 is polyoxyethylene sorbitan monooleate, sodium phosphate dibasic (E339) and potassium phosphate monobasic (E340) are substances with E numbers. These constituents of Poulvac FluFend H5N3 RG are included in Table 1 (Allowed substances) of the annex to Commission Regulation (EU) No 37/2010 as follows:

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Mineral hydrocarbons, low to high viscosity including microcrystalline waxes, approximately C10-C60, aliphatic, branched aliphatic and alicyclic compounds	Not applicable	All food producing species	No MRL required	Not applicable	Excludes aromatic and unsaturated compounds	No entry
Sorbitan sesquioleate	Not applicable	All food producing species	No MRL required	Not applicable	No entry	No entry
Polyoxyethylene sorbitan monooleate and trioleate	Not applicable	All food producing species	No MRL required	Not applicable	No entry	No entry
Food additives (substances with a valid E number approved as additives in	Not applicable	All food producing species	No MRL required	Not applicable	Only substances approved as additives in foodstuffs for human	No entry

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
foodstuffs for human consumption)					consumption, with the exception of preservatives listed in part C of Annex III to European Parliament and Council Directive 95/2/EC	

E. SPECIFIC OBLIGATIONS TO BE FULFILLED BY THE MARKETING AUTHORISATION HOLDER

The Marketing Authorisation Holder shall complete the following programme of studies, the results of which shall form the basis of the annual reassessment of the benefit/risk profile. More detailed information on the specific obligations is set out in the CVMP assessment report.

QUALITY ASPECTS

- 1) There are important outstanding issues regarding the differences of production and control between the manufacturing sites (including the nature of the eggs used) and the lack of a validation study for the potency test on finished product (it appears that final product tests are only done at Weesp but in-process tests such as titration and HA quantification need to be equivalent too). With regard to the differences in production and control, harmonization of the production process and the controls between both manufacturing site is strongly suggested. An alternative solution could be to retain only one production site. In particular, a rationalization of the nature of eggs used (taking into consideration the problem of the possible presence of extraneous agents in conventional eggs and the possibility to inactivate them during the inactivation process of the Influenza virus, supported by a corresponding validation study). The Applicant is asked to commit to take appropriate measures to harmonise the productions and/or to provide the adequate demonstrations/data to solve the issues.

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**ANNEX III
LABELLING AND PACKAGE LEAFLET**

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A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac FluFend H5N3 RG
Emulsion for injection for chickens and ducks

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One dose of 0.5 ml contains:
Inactivated recombinant avian influenza virus
of H5N3 subtype (strain rg-A/ck/VN/C58/04) > 1:40 HI Units
Water in oil adjuvant

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

1 x 500 ml
10 x 500 ml

5. TARGET SPECIES

Chickens and ducks

6. INDICATIONS

For active immunisation of chickens and ducks against avian influenza virus type A, subtype H5.

Chickens:

Reduction of mortality and virus excretion after challenge.
Onset of immunity: 3 weeks after the second injection.
Duration of immunity in chickens has not been established yet.

Ducks:

Reduction of clinical signs and virus excretion after challenge.
Onset of immunity: 3 weeks after the second injection.
Duration of immunity in ducks: 14 weeks after the second injection.

7. METHOD AND ROUTES OF ADMINISTRATION

Chickens

3 weeks of age or older: 0.5 ml intramuscularly in the breast muscle. Revaccinate after 3 weeks.
The vaccination schedule should be completed at least 4 weeks before the start of laying.

Ducks

At one day old: 0.2 ml subcutaneously in the neck.
Revaccinate after 3 weeks: 0.5 ml subcutaneously in the neck
The vaccination schedule should be completed at least 4 weeks before the start of laying.

Read the package leaflet before use

8. WITHDRAWAL PERIOD

Withdrawal period - Zero days

9. SPECIAL WARNINGS, IF NECESSARY

Accidental injection is dangerous.

10. EXPIRY DATE

EXP (month/year)

Once broached, use within 2 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated (2° to 8°C).
Store in the original container in order to protect from light.
Do not freeze.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with the local requirements.

13. THE WORDS 'FOR ANIMAL TREATMENT ONLY' AND CONDITIONS OF RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only

The use of this veterinary medicinal product is only allowed under the particular conditions established by European Community legislation on the control of Avian Influenza.

14. THE WORDS “KEEP OUT OF THE REACH AND SIGHT OF CHILDREN”

Keep out of the reach and sight of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Pfizer Limited
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/06/060/001-002

17. MANUFACTURER'S BATCH NUMBER

Lot (Number)

Medicinal product no longer authorised

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

BOTTLE LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac FluFend H5N3 RG
Emulsion for injection for chickens and ducks

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One dose of 0.5 ml contains:
Inactivated recombinant avian influenza virus
of H5N3 subtype (strain rg-A/ck/VN/C58/04) > 1:40 HI Units

Water in oil adjuvant

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

500 ml

5. TARGET SPECIES

Chickens and ducks

6. INDICATION

For active immunisation of chickens and ducks against avian influenza virus type A, subtype H5.

Chickens:

Reduction of mortality and virus excretion after challenge.
Onset of immunity: 3 weeks after the second injection.
Duration of immunity in chickens has not been established yet.

Ducks:

Reduction of clinical signs and virus excretion after challenge.
Onset of immunity: 3 weeks after the second injection.
Duration of immunity in ducks : 14 weeks after the second injection.

7. METHOD AND ROUTES OF ADMINISTRATION

Chickens

3 weeks of age or older: 0.5 ml intramuscularly in the breast muscle. Revaccinate after 3 weeks. The vaccination schedule should be completed at least 4 weeks before the start of laying.

Ducks

At one day old: 0.2 ml subcutaneously in the neck.

Revaccinate after 3 weeks: 0.5 ml subcutaneously in the neck

The vaccination schedule should be completed at least 4 weeks before the start of laying.

Read the package leaflet before use

8. WITHDRAWAL PERIOD

Withdrawal period - Zero days

9. SPECIAL WARNINGS, IF NECESSARY

Accidental injection is dangerous.

10. EXPIRY DATE

EXP (month/year)

Once broached, use within 2 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated (2°C - 8°C). Keep in the original container in order to protect from light. Do not freeze.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

For disposal read the package leaflet.

13. THE WORDS 'FOR ANIMAL TREATMENT ONLY' AND CONDITIONS OF RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only

14. THE WORDS 'KEEP OUT OF THE REACH AND SIGHT OF CHILDREN'

Keep out of the reach and sight of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Pfizer Limited
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom

16. MARKETING AUTHORISATION NUMBER

EU/2/06/060/001-002

17. MANUFACTURER'S BATCH NUMBER

Lot (Number)

Medicinal product no longer authorised

Medicinal product no longer authorised

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
Poulvac FluFend H5N3 RG
Emulsion for injection for chickens and ducks

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

Marketing Authorisation Holder:

Pfizer Limited
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom

Manufacturer for the batch release:

Pfizer Global Manufacturing Weesp
CJ van Houtenlaan 36
1381 CP Weesp
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac FluFend H5N3 RG
Emulsion for injection for chickens and ducks

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

One dose of 0.5 ml contains:

Active substance:

Inactivated recombinant avian influenza virus
of H5N3 subtype (strain rg-A/ck/VN/C58/04) > 1:40 HI Units

Adjuvants:

White Oil
Sorbitan sesquioleate
Polysorbate 80

Excipients:

Thiomersal
Phosphate Buffer Saline

4. INDICATIONS

For active immunisation of chickens and ducks against avian influenza virus type A, subtype H5.

Chickens:

Reduction of mortality and virus excretion after challenge.
Onset of immunity: 3 weeks after the second injection.
Duration of immunity in chickens has not been established yet.

Ducks:

Reduction of clinical signs and virus excretion after challenge.

Onset of immunity: 3 weeks after the second injection.

Duration of immunity in ducks : 14 weeks after the second injection.

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

A transient local site reaction (swelling) may occasionally occur as is normal with oil adjuvanted vaccines.

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

7. TARGET SPECIES

Chickens and ducks

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION**Chickens**

3 weeks of age or older: 0.5 ml intramuscularly in the breast muscle. Revaccinate after 3 weeks. The vaccination schedule should be completed at least 4 weeks before the start of laying.

Ducks

At one day old: 0.2 ml subcutaneously in the neck.

Revaccinate after 3 weeks: 0.5 ml subcutaneously in the neck

The vaccination schedule should be completed at least 4 weeks before the start of laying.

9. ADVICE ON CORRECT ADMINISTRATION

Do not mix with any other medicinal product.

10. WITHDRAWAL PERIOD

Withdrawal period: Zero days

11. SPECIAL STORAGE CONDITIONS

Keep out of the reach and sight of children.

Store and transport refrigerated (2°C - 8°C). Keep in the original container in order to protect from light. Do not freeze.

The entire content of the bottle should be used within 2 hours after breaching the container.

12. SPECIAL WARNINGS

The level of efficacy attained may vary depending on the degree of antigenic homology between the vaccine strain and circulating field strains.

No information is available on the interference of maternally derived antibodies on vaccination for both target species.

No information is available on the safety of this vaccine for birds in lay.

For animal treatment only

Avoid stress in the birds around the time of vaccination.

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.

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

Following the administration of a double dose in chickens and ducks, no adverse reactions other than those described in section 6 have been observed.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Ask your veterinary surgeon 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

13/12/2010

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 is presented in boxes of 1 or 10 bottles of 500 ml.

The use of this veterinary medicinal product is only allowed under the particular conditions established by European Community legislation on the control of Avian Influenza.

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