SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac IBMM

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative composition
Avian infectious bronchitis vaccine (live), freeze-dried

Quantitative composition per dose
Active Ingredients

Infectious Bronchitis virus Strain 1263 (Massachusetts serotype)	$10^{3.3}$ – $10^{5.3}$ EID_{50}/dose

Excipients

Stabilising excipients	qs 1 dose

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate for suspension.

4. CLINICAL PARTICULARS

4.1. Target species

Chickens of one day of age or older.

4.2. Indications for use, specifying the target species

For the vaccination of broilers and growing chicks for the prevention of respiratory signs caused by the Massachusetts serotype of Infectious Bronchitis. The onset of immunity is from 2 weeks after vaccination. A duration of immunity of at least 6 weeks has been established, from a vaccination and challenge experiment, but experience from use in the field suggests that the actual duration of immunity may be 3 – 4 months.

4.3. Contraindications

Do not use in unhealthy chickens.

4.4. Special warnings

Maternally derived antibody (MDA) can interfere with the development of active immunity. Where it is likely that recent field infection or vaccination of the parent flock has stimulated a high antibody titre and consequently a high level of MDA, the timing of the vaccination programme should be planned accordingly.
It is recommended that all birds on a site be vaccinated simultaneously as the vaccine virus may spread to non-vaccinated birds.

4.5. Special precautions for use

i) Special precautions for use in animals

None.

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

When spraying the vaccine operators should wear respiratory and eye protection conforming to current European Standards. A helmet with filtered air circulation may be used instead.
On completion, operators should wash and disinfect hands with an approved disinfectant.

4.6. Adverse reactions (frequency and seriousness)

Mild and transitory reactions are commonly seen after administration and include gasping, snicking and raling lasting up to 3 days and sneezing or coughing lasting 10 days.

Reddened eyes or nasal discharge may very occasionally be seen following intra-ocular or intranasal administration.

4.7. Use during pregnancy, lactation or lay

Do not use in birds in lay

If the vaccine were to be used in laying birds in an emergency, this may result in a transient drop in egg production.

4.8. Interaction with other medicinal products and other forms of interaction

Safety and/or efficacy data are available which demonstrate that this vaccine can be mixed with Poulvac NDW, where this vaccine is authorised.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the product mentioned above. 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

One dose of vaccine to be administered to each bird from one day of age by intranasal, intraocular or spray routes or to birds from 2 weeks of age in drinking water.

Use clean vaccination materials.
Protect the reconstituted vaccine from exposure to heat and/or direct sunlight.
Avoid contact with disinfectants as they will render the vaccine ineffective.

Intranasal and intraocular route
A drop dispenser is required for administration by the intranasal and ocular routes and must be obtained separately. 30 ml of sterile diluent (sterile water for injection) for reconstitution are required per 1,000 doses (in which the freeze-dried vaccine must be completely dissolved) and a drop dispenser calibrated to deliver at least 0.03 ml per drop. Reconstitution is to be performed as follows:

The sterile diluent should be at room temperature when used. Remove the seal and rubber stopper from the vaccine vial and add sterile diluent to the vaccine vial to half fill the vial. Replace the stopper and shake gently until contents are dissolved. Pour the reconstituted vaccine into the diluent container, replace the stopper and shake until completely mixed with the remaining diluent. Remove the stopper and replace with the drop-dispensing tip.

For intranasal vaccination, place finger over one nostril of the bird. Allow one drop of the vaccine to fall into the other nostril. Vaccination is complete when the vaccine is inhaled into the nasal cavity. Do not release the bird until this occurs.
For intraocular vaccination, hold the bird so that one eye is pointed upwards and allow one drop of vaccine to fall into the eye and hold the bird until the drop has been absorbed or a swallowing reaction is noted.

Drinking water vaccination

24 hours prior to vaccination, discontinue the use of medications or sanitising agents in the water. Water containing a high level of free chlorine should not be used. A general indication is that if chlorine can be detected in the water by smell or taste it could deactivate the living virus. Ensure there are a sufficient number of waterers; that 2/3 of the birds may drink at one time; and that the waterers are perfectly clean and rust free and free of any potential disinfectant or medication residues. Turn off automatic waterers 1-2 hours prior to vaccinating.

Remove the aluminium seal from the vaccine vial. To dissolve the vaccine pellet, the rubber stopper should then be removed whilst the vial is immersed in a plastic measuring jug containing one litre (approximately 1 quart) of clean cool non-chlorinated water. Half fill the vial with water, replace the stopper and shake to dissolve any remaining vaccine. Using a clean container two-thirds filled with cool, clean, non-chlorinated water; add dried milk at 2.5 g/l (2 ounces per 5 gallons) or skimmed milk at 1 pint per 20 litres of water (1 pint per 5 gallons). Stir the milk/water mixture until the milk is dissolved, then add the rehydrated vaccine from the vial and stir again thoroughly. The vaccine concentrate should then be added to and thoroughly mixed with sufficient drinking water to last for approximately 2 hours.

Distribute the final volume of vaccine evenly in the drinkers.
The vaccine solution is best divided so that the drinkers are charged at least twice with vaccine to ensure a more widespread uptake.
If nipple drinkers are employed, ensure that header tanks are continually refilled with water containing vaccine.
The vaccine may be used in automatic watering equipment. However, the main supply should only be turned on when all the vaccine-treated water has been consumed. NB Check that birds are never left without water after vaccine treatment.

Do not expose prepared drinking water vaccine to sunlight.

Withhold the water 1–2 hours before vaccination to stimulate thirst.
No untreated water should be available until the treated water has been consumed.

The approximate drinking water requirements are:

	Quantity per 1,000 birds	
	Litres	Gallons
Weeks 2-4	8-10	2-2½
Weeks 5-7	12-16	3-4
8 weeks and over	18-20	4½-5

Spray vaccination
Poulvac IBMM has been used in most types of spray equipment, the droplet sizes varying from coarse (Knapsack) to very fine (aerosol).

Remove seal and stopper from vaccine vial(s) and half-fill with cool, clean, non-chlorinated water. Replace stopper and shake to dissolve contents. Pour rehydrated vaccine into a clean container and add approximately 100 ml cool, clean, non-chlorinated water per 1,000 doses. Mix thoroughly.

Apply at the rate of 100 ml rehydrated vaccine per 1,000 birds. Place the appropriate final volume of vaccine into the sprayer and set to discharge. Spray at a rate of 1,000 birds per minute and direct the spray above the heads of the birds.

Revaccination:

Where necessary, revaccination at 3 to 4 month intervals is advisable.

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

Sneezing and snicking are observed in up to 60% of birds administered a 10-fold overdose, starting 2 days after administration of the overdose and lasting up to 18 days.

4.11. Withdrawal period

Zero days.

5. IMMUNOLOGICAL PROPERTIES

To stimulate active immunity against Infectious Bronchitis Disease Virus.

ATCVet code: QI01AD07

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Dehydrated Non-Fat Milk
Pharmatone
Sucrose
Monosodium Glutamate

6.2. Incompatibilities

Do not mix with any other medicinal product except Poulvac NDW, where this vaccine is authorised.

6.3. Shelf life

Shelf-life as packaged for sale: 18 months.
Shelf-life after dilution or reconstitution according to directions: 2 hours

6.4. Special precautions for storage

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

6.5. Nature and composition of immediate packaging

Packs of 1 or 10 Type I Borosilicate Glass bottles containing 1,000, 2,500 or 5,000 doses.
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

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

7. MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
5th Floor, 6 St. Andrew Street
London
EC4A 3AE

8. MARKETING AUTHORISATION NUMBER

Vm: 42058/4105

9. DATE OF FIRST AUTHORISATION

Date: 24 October 2005

10. DATE OF REVISION OF THE TEXT

Date: May 2014

13 May 2014