

Protecting the foetus

Once PIs have been identified and removed, it is crucial to try and prevent the BVD virus working its way back into the breeding herd. In a country with high cattle movements and generally sub-optimal levels of biosecurity, vaccination has an important role to play.

Since PIs result from infection of the foetus in early gestation, the aim of vaccination is to have maximum levels of immunity at this vital stage in order to protect the foetus against transplacental infection.

Bovilis BVD is licensed to protect the foetus against transplacental infection with BVD virus.

Foetal protection can be expected if the primary course of vaccine is completed 4 weeks before the start of gestation.



Product Information

Bovilis BVD is an inactivated vaccine containing 50 ELISA units (EU) and inducing at least 4.6 log² VN units per dose of cytopathogenic BVD virus strain C-86.

Uses: For active immunisation of cows and heifers from eight months of age onwards to protect the foetus against transplacental infection with BVDV.

Dosage and administration: Before using the vaccine allow it to reach ambient temperature (15-25°C).

Suspension for injection: Red to pink-coloured turbid suspension.

Shake well before use: Use sterile syringes and needles. Intramuscular injection.

Individual vaccination: Basic immunisation: Two vaccinations with an interval of 4 weeks. The second vaccination should be given not later than 4 weeks before the start of the gestation. Revaccination: One vaccination 4 weeks before start of the next gestation.

Herd vaccination: Basic immunisation: Two vaccinations with an interval of 4 weeks. For use in cattle from eight months of age, all animals should be vaccinated.

Revaccination: One vaccination 6 months after basic vaccination with next re-vaccinations at an interval no greater than 12 months.

Contra-indications, warnings, etc: Vaccinate only healthy animals. In the case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. In very rare cases a slight swelling may be observed for 14 days at the site of injection. Also in very rare cases transient mild pyrexia may occur. In isolated cases, allergic reactions including anaphylactic shock may occur. In case of anaphylactic reactions, appropriate treatment such as with antihistamine, corticosteroid or adrenaline is recommended. Product can be used during pregnancy. Foetal protection can be expected if the primary immunisation has been finalised 4 weeks before start of the gestation. Animals which are vaccinated later than 4 weeks before gestation or during the early gestation will not be protected against foetal infection. Safety and efficacy data are available which demonstrate that for re-vaccination - in cattle from 15 months of age onwards (i.e. those that have previously been vaccinated separately with Bovilis BVD and Bovilis IBR marker live) - this vaccine can be mixed and administered with Bovilis IBR marker live (in Member States where this veterinary medicinal product is authorised). The product literature of Bovilis IBR marker live should be consulted before administration of the mixed products. The adverse effects observed after administration of one dose or an overdose of the mixed vaccines are not different from those described for the vaccines administered separately. 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. Do not mix with any other veterinary medicinal product, except with Bovilis IBR marker live. Shelf life of the veterinary medicinal product as packaged for sale: 18 months. Shelf life after first opening the immediate packaging: 10 hours. Shelf life after mixing with Bovilis IBR marker live: 3 hours (at room temperature). Store in a refrigerator (2 to 8°C). Do not freeze.



Use Medicines Responsibly

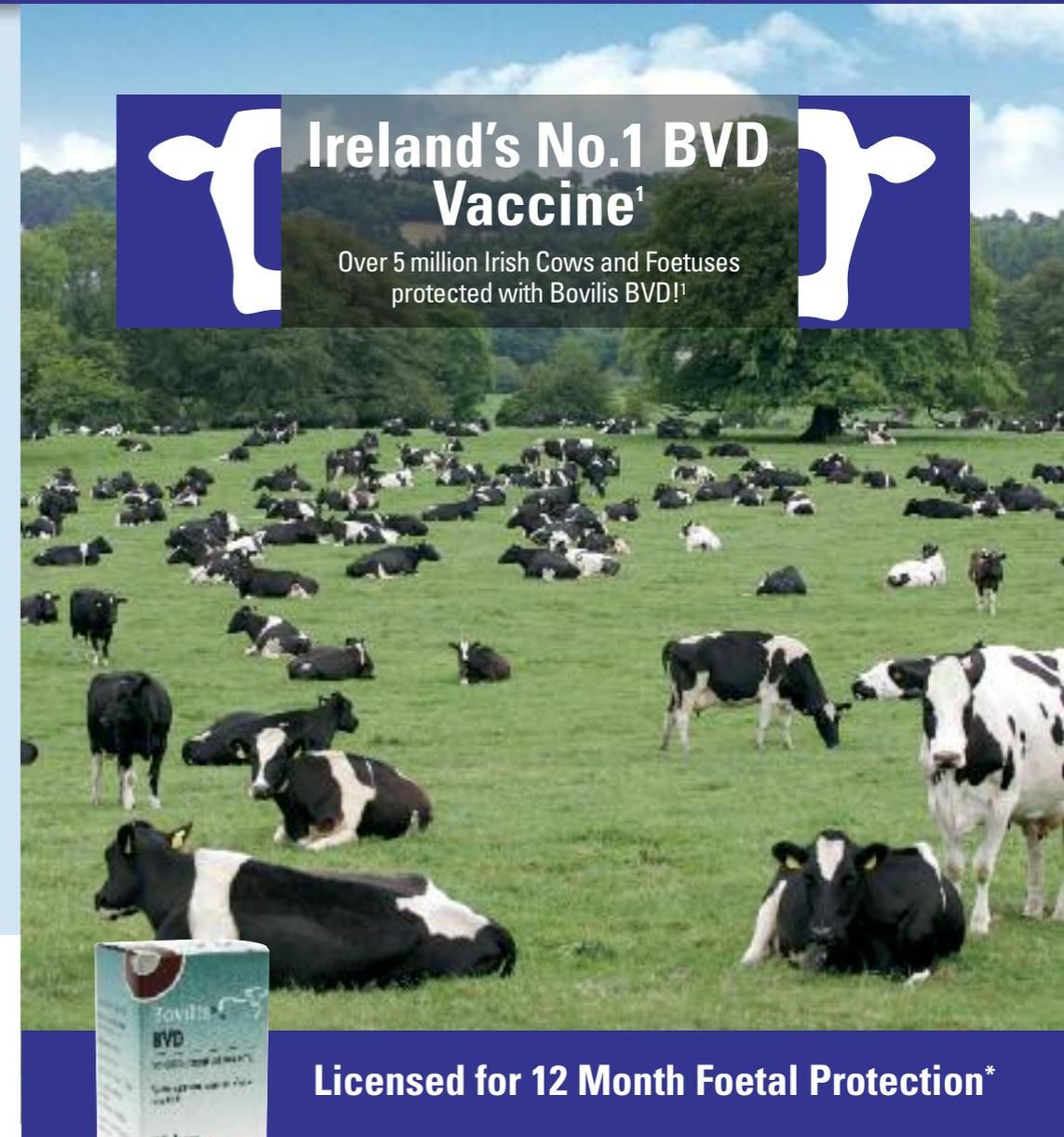
Bovilis BVD Suspension for injection for cattle vaccine contains inactivated antigen of cytopathogenic BVD virus strain C-86.

Legal categories: ROI: **POM (E)** NI: **POM-V**. Withdrawal period: zero days.

For further information see SPC, contact prescriber or MSD Animal Health, Red Oak North, South County Business Park, Leopardstown, Dublin 18, Ireland. Tel: +353(0)1 2970220. E-Mail: vet-support.ie@merck.com Web: www.msd-animal-health.ie

¹Based on 2006 - 2016 sales figures, Kynetec

*One vaccination 6 months after basic vaccination course with next re-vaccination at an interval no greater than 12 months.



Ireland's No.1 BVD Vaccine¹
Over 5 million Irish Cows and Foetuses protected with Bovilis BVD!¹



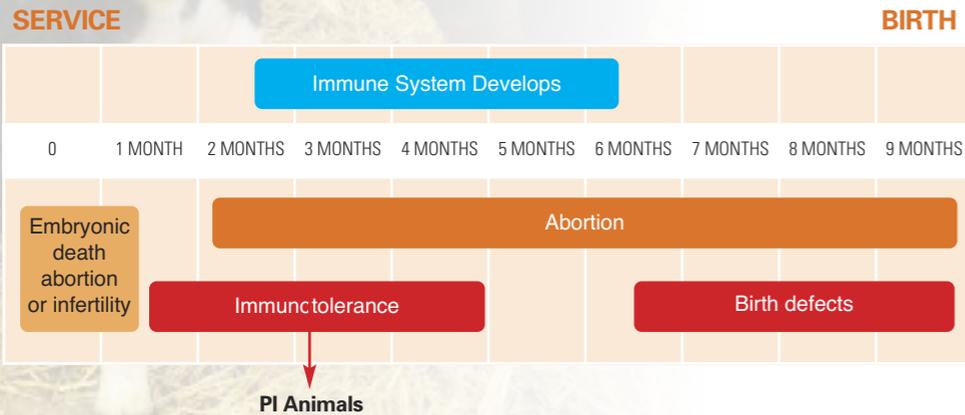
Licensed for 12 Month Foetal Protection*

BVD - a hidden enemy

Bovine viral diarrhoea (BVD) is one of the most costly infectious diseases in the modern cattle industry.

The negative effects of BVDV infections on reproduction depends on the timing of the infection relative to the stage of gestation. Other clinical manifestations of BVD include diarrhoea, haemorrhagic syndrome and Mucosal Disease. Because the virus causes immunosuppression, the infected animals are highly susceptible to other secondary infections.

BVD infection during pregnancy

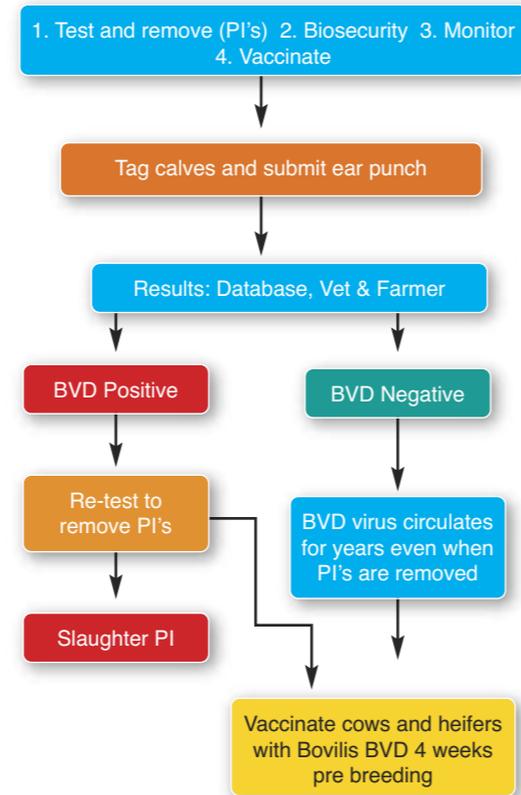


The PI animal is the main source of BVDV infection in a herd

Eradicating BVD

Progress has been made towards eradicating BVD with the implementation of a compulsory eradication programme in Ireland. Results of ear notch testing for 2016 indicate that 99.2% of calves tested for BVD virus were negative. However, 4,510 BVD persistently infected (PI) calves were born in this timeframe in 2016, in over 2,500 herds, and are scattered geographically all over the country.

BVD Eradication



CRITICAL POINTS RELATING TO BVD ERADICATION

- Take tissue tag samples from all calves incl. still births within 7 days of birth and submit to a designated lab within 7 days of sampling
- Carry out all necessary follow up testing once a PI is identified e.g. test dam of PI. If the dam is also positive, all her other offspring must be tested
- A PI animal should not be sold but should be isolated and culled at the earliest opportunity
- Vaccinate all breeding animals with Bovilis BVD before service each year to protect against infection
- Maintain high level biosecurity and continue monitoring to ensure freedom from disease

Long Term BVD Eradication

Long Term BVD Eradication

BVD is proven to circulate for 5 years even in the absence of PI's³. Herds with circulating BVD are high risk for the development of PI's³.

Solid BVD control is based on 4 pillars

- Remove PI's from herd
- Maintain a high level of biosecurity
- Monitor your herd to ensure it stays clear of circulating virus
- Vaccinate with Bovilis BVD

Bovilis® BVD

- Bovilis BVD is licensed to provide foetal protection
- Bovilis BVD and Leptavoid-H are licensed for concurrent use
- Bovilis IBR Marker Live can be mixed and given in one syringe* with Bovilis BVD
- Conveniently delivered via intra-muscular (I/M) injection
- Licensed for the active immunisation of cows and heifers from 8 months of age, when MDA is likely to have waned
 - Boost 4 weeks prior to service every year
- Flexible range of vial sizes: 5, 10, 25 and 50 dose (25 and 50 dose bottles are PET)



³ Indication of transmission of BVDV in the absence of persistently infected (PI) animals. Moen et al, Preventive Veterinary Medicine 72 (2005) 93-98.

*For use as a booster dose in cattle from 15 months of age previously vaccinated separately with Bovilis IBR Marker Live and Bovilis BVD.