B. PACKAGE LEAFLET

PACKAGE LEAFLET:

FIXR IBR marker live

lyophilisate and solvent for suspension for injection

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

Marketing authorisation holder and manufacturer responsible for batch release:
Bioveta, a.s., Komenského 212/12, Ivanovice na Hané, 683 23, Czech Republic

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIXR IBR marker live
lyophilisate and solvent for suspension for injection

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

1 dose (2 ml) contains:
Active substance:
Lyophilisate:
Live attenuated Bovine herpesvirus type 1 (BHV-1), strain Bio-27: IBR gE - negative
$10^{5.7}$- $10^{7.5}$ $TCID_{50}$

$TCID_{50}$ - Tissue culture infectious dose – 50%

Lyophilisate and solvent for suspension for injection.
The lyophilisate is a porous plug with a cream to yellowish colour.
The solvent is clear, colourless solution.

4. INDICATION

For active immunisation of cattle to reduce the severity and duration of clinical symptoms of viral infection caused by BHV-1 (IBR - infectious bovine rhinotracheitis) and to reduce the excretion of field virus.

Onset of immunity:

The onset of immunity was demonstrated 7 days after intranasal vaccination and 14 days after intramuscular vaccination of animals without maternally derived antibodies.

Duration of immunity:

6 months after primary vaccination.

The duration of immunity after intranasal administration from 2 weeks of age was demonstrated to be 10 weeks in animals without maternally derived antibodies (demonstrated by challenge), until the intramuscular administration of the second dose from 3 months of age.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

No adverse reactions were observed during safety studies.

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dosage:

2 ml of reconstituted vaccine per animal.

Method of administration:

- *Intranasal*: from 2 weeks up to 3 months of age
- *Intramuscular:* from 3 months of age

Administer one dose (2 ml) of the reconstituted vaccine intranasally to calves from 14 days of age using an intranasal applicator. It is recommended to use a new applicator for each animal to prevent the transmission of infection.

Vaccination schedule:

Primary vaccination:

Calves from 2 weeks of age without maternal antibodies up to 3 months of age

The first administration (intranasal) from 2 weeks of age, the second administration (intramuscular) from the age of 3 months.

Cattle from 3 months of age

One intramuscular administration of one dose per animal from 3 months of age.

Revaccination:

Revaccination is always intramuscular with one dose every 6 months after completion of primary vaccination.

Sterile equipment free of disinfectants should be used for vaccination as disinfectants could reduce the efficacy of vaccination.

9. ADVICE ON CORRECT ADMINISTRATION

Reconstitute vaccine immediately before use by aseptically mixing lyophilisate with the solvent in 2 steps:
1. Inject suitable volume of solvent on the lyophilised plug in the lyophilisate vial.
2. Shake well and extract the resuspended lyophilisate from the lyophilisate vial and mix with the rest of solvent in the solvent vial.
Shake well before use.
After reconstitution, the formed slightly opalescent liquid has a pink-and-red or yellowish colour.

In case of intranasal administration suck the required volume of reconstituted vaccine (1 ml of the reconstituted vaccine for each nostril) with a syringe needle from the vial, then replace the needle with an applicator and administer the vaccine. The applicator is used to apply the desired amount of the vaccine in aerosol form from the syringe into the nostrils of a vaccinated calf. The applicator used should spray the vaccine in the form of 30 µm to 100 µm droplets.

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).
Protect from light.

Store the reconstituted vaccine below 25°C (for 8 hours).

Do not use this veterinary medicinal product after the expiry date which is stated on the label.
Shelf life after reconstitution according to directions: 8 hours

12. SPECIAL WARNING(S)

Special precautions for use in animals:
Due to the nature of the vaccine (live vaccine) the possibility of transmission of the virus from animals vaccinated intranasally to unvaccinated animals (for max. 5 days after vaccination) that are in contact with them cannot be ruled out completely. For this reason, it is recommended to either vaccinate all animals in the herd or isolate the cattle to be absolutely free of antibodies to BHV-1 from the animals vaccinated intranasally.

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

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or label to the physician.

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 veterinary medicinal product except solvent supplied for use with the veterinary medicinal product.

Pregnancy and, lactation:
Can be used during pregnancy and lactation. No information is available on the use of this vaccine in breeding bulls.

Special warnings for each target species
Maternal antibodies may have a negative impact on the efficacy of vaccination. Therefore, it is recommended to verify the immune status of calves prior to vaccination.
Vaccinate healthy animals only.

Overdose (symptoms, emergency procedures, antidotes, if necessary)
Administration of a 10-fold recommended dose of the vaccine did not cause any adverse effects.

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

15. OTHER INFORMATION

Package size:
5 x 5 doses (5x 5 doses of lyophilised vaccine + 5x10 ml of solvent
1 x 25 doses (1x 25 doses of lyophilised vaccine + 1x50 ml of solvent)

Applicators are distributed together with the vaccine and packaged separately.

Not all pack sizes may be marketed

For animals treatment only.

Veterinary medicinal product subject to prescription.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.