

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**a/ Plastic box:**

**5 x 5 doses – (5x5 doses of lyophilised vaccine + 5x10 ml of solvent)**

**b/ Cardboard:**

**1 x 25 doses – (1x25 doses of lyophilised vaccine + 1x50 ml of solvent)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

FIXR IBR marker live

lyophilisate and solvent for suspension for injection

**2. STATEMENT OF ACTIVE SUBSTANCES**

1 dose (2 ml) contains:

**Active substance:**

Live attenuated Bovine herpesvirus type 1 (BHV-1), strain Bio-27: IBR gE – negative,  $10^{5,7}$  -  $10^{7,5}$  TCID<sub>50</sub>

**3. PHARMACEUTICAL FORM**

Pharmaceutical form: Lyophilisate and solvent for suspension for injection.

**4. PACKAGE SIZE**

5 x 5 doses (5x5 doses of lyophilised vaccine + 5x10 ml of solvent)

1 x 25 doses (1x25 doses of lyophilised vaccine + 1x50 ml of solvent)

**5. TARGET SPECIES**

Target species: Cattle.



**6. INDICATION**

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**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Dose 2 ml of reconstituted vaccine per animal.

Intranasal or intramuscular administration

For intranasal administration is recommended to use the intranasal applicator.

Before use, read the package leaflet.

**8. WITHDRAWAL PERIOD**

Withdrawal period: Zero days

**9. SPECIAL WARNING, IF NECESSARY**

Before use, read the package leaflet.

**10. EXPIRY DATE**

EXP:

Shelf life after reconstitution according to directions: 8 hours

**11. SPECIAL STORAGE CONDITIONS**

Store in a refrigerator (2°C-8°C).  
Protect from light.  
Store the reconstituted vaccine below 25°C.

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

Disposal: read the package leaflet.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

For animal treatment only.  
Veterinary medicinal product subject to prescription.

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

Keep out of sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Bioveta, a.s.  
Komenského 212/12  
Ivanovice na Hané  
683 23  
Czech Republic

**16. MARKETING AUTHORISATION NUMBER(S)**

**17. MANUFACTURER’S BATCH NUMBER**

Batch:

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**  
**Lyophilisate**  
**5 doses (3 ml glass vial with 5 doses of lyophilized vaccine)**  
**25 doses (10 ml glass vial with 25 doses of lyophilized vaccine)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

FIXR IBR marker live  
Lyophilisate for suspension

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

1 dose (2 ml) contains:  
Live attenuated Bovine herpesvirus type 1 (BHV-1), strain Bio-27: IBR gE – negative,  $10^{5.7}$  -  $10^{7.5}$  TCID<sub>50</sub>

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

5 doses  
25 doses

**4. ROUTE(S) OF ADMINISTRATION**

i.n./ i.m.

**5. WITHDRAWAL PERIOD**

Withdrawal period: Zero days

**6. BATCH NUMBER**

Batch:

**7. EXPIRY DATE**

EXP:  
Shelf life after reconstitution according to directions: 8 hours

**8. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Solvent**

**5 doses (10 ml glass vial with 10 ml of solvent)**

**25 doses (50 ml glass vial with 50 ml of solvent)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Solvent for lyophilised vaccines for cattle

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

phosphate buffered saline

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

10 ml

50 ml

**4. ROUTE(S) OF ADMINISTRATION**

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**5. WITHDRAWAL PERIOD**

Withdrawal period: Zero days

**6. BATCH NUMBER**

Batch:

**7. EXPIRY DATE**

EXP:

**8. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.