

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE**Carton****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

BelaZin 20 mg/ml Solution for injection for cattle, horses, dogs and cats
Xalyzin 20 mg/ml Solution for injection for cattle, horses, dogs and cats
Xylazine

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:

Xylazine 20.0 mg
(equivalent to 23.3 mg xylazine hydrochloride)

Excipients:

Methyl parahydroxybenzoate (E218) 1.0 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

1 x 25 ml
10 x 25 ml
12 x 25 ml
1 x 50 ml
12 x 50 ml

5. TARGET SPECIES

Cattle, horses, dogs and cats

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

IV (cattle, horse, dog), IM (cattle, dog, cat), SC (cat)

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):

Cattle:

Meat and offal: 1 day

Milk: zero hours

Horses:

Meat and offal: 1 day

Not authorised for use in mares producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Shelf life after first opening the immediate packaging: 28 days

11. SPECIAL STORAGE CONDITIONS

Do not freeze.

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

Disposal: read package leaflet.

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

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

bela-pharm GmbH & Co. KG
Lohner Str. 19
49377 Vechta
Germany

16. MARKETING AUTHORISATION NUMBER(S)**17. MANUFACTURER’S BATCH NUMBER**

<Batch><Lot> {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**Vials of 25 and 50 ml****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

BelaZin 20 mg/ml Solution for injection for cattle, horses, dogs and cats

Xalyzin 20 mg/ml Solution for injection for cattle, horses, dogs and cats

Xylazine

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

20 mg xylazine /ml

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

25 ml

50 ml

4. ROUTE(S) OF ADMINISTRATION

IV (cattle, horse, dog), IM (cattle, dog, cat), SC (cat)

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s):

Cattle:

Meat and offal: 1 day

Milk: zero hours

Horses:

Meat and offal: 1 day

Not authorised for use in mares producing milk for human consumption.

6. BATCH NUMBER

<Batch><Lot> {number}

7. EXPIRY DATE

EXP {month/year}

Once opened use by...

Shelf life after first opening the immediate packaging: 28 days

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

