

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{ 1 x 1 ml, 1 x 10 ml }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SEDAN 35 mg/ml oral gel for horses and dogs
(CZ, , BG, CY, , EL, ES, HR, HU, IT, LT, LV, , PL, PT, RO, SK)
PROMASED 35 mg/ml oral gel for horses and dogs
(AT, FR, BE, DE, NL)
PROMASED
(EE, DK, NO, SE)
Acepromazine

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:

Acepromazine 35.0 mg
(equivalent to 47.5 mg acepromazine maleate)

3. PHARMACEUTICAL FORM

Oral gel.

4. PACKAGE SIZE

1 x 1 ml
1 x 10 ml

5. TARGET SPECIES

Horses (non food-producing), dogs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use. Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period:

Horses: Do not use in horses whose meat, offal and milk are intended for human consumption. The treatment must be recorded in the horse's passport.

9. SPECIAL WARNING(S), IF NECESSARY

Accidental ingestion is dangerous.
Read the package leaflet before use.

10. EXPIRY DATE

EXP: {month/year}

Shelf life after first opening the immediate packaging: 3 months.

Once opened use by:

11. SPECIAL STORAGE CONDITIONS

Keep the syringe tightly closed.

Protect from frost.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT 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

Bioveta, a.s.

Komenského 212/12

683 23 Ivanovice na Hané

Czech Republic

Phone: +420 517 318 500

E-mail: registrace@bioveta.cz

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
{1 ml, 10 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SEDAN 35 mg/ml oral gel for horses and dogs
(CZ, , BG, CY, , EL, ES, HR, HU, IT, LT, LV, , PL, PT, RO, SK)
PROMASED 35 mg/ml oral gel for horses and dogs
(AT, FR, BE, DE, NL)
PROMASED
(EE, DK, NO, SE)
Acepromazine

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each ml contains:
Active substance:
Acepromazine 35.0 mg
(equivalent to 47.5 mg acepromazine maleate)

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

1 ml
10 ml

4. ROUTE(S) OF ADMINISTRATION

Oral use.

5. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Horses: Do not use in horses whose meat, offal and milk are intended for human consumption.

6. BATCH NUMBER

Batch: {number}

7. EXPIRY DATE

EXP: {month/year}
Shelf life after first opening the immediate packaging: 3 months.
Once opened use by:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

