

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{ALU sachet for pipette 0.25 ml, 0.5 ml, 1.0 ml, 2.0 ml, 3.0 ml, paper box 3 x 0.25 ml, 3 x 0.5 ml, 3 x 1.0 ml, 3 x 2.0 ml, 3 x 3.0 ml, 6 x 0.25 ml, 6 x 0.5 ml, 6 x 1.0 ml, 6 x 2.0 ml, 6 x 3.0 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SELIVERM 30 mg spot-on solution for dogs S
SELIVERM 60 mg spot-on solution for dogs M
SELIVERM 120 mg spot-on solution for dogs L
SELIVERM 240 mg spot-on solution for dogs XL
SELIVERM 360 mg spot-on solution for dogs XXL

2. STATEMENT OF ACTIVE SUBSTANCES

Selamectin 30 mg/pipette
Selamectin 60 mg/pipette
Selamectin 120 mg/pipette
Selamectin 240 mg/pipette
Selamectin 360 mg/pipette

3. PACKAGE SIZE

3 x 0.25 ml
6 x 0.25 ml
3 x 0.5 ml
6 x 0.5 ml
3 x 1.0 ml
6 x 1.0 ml
3 x 2.0 ml
6 x 2.0 ml
3 x 3.0 ml
6 x 3.0 ml

4. TARGET SPECIES

Dogs.

5. INDICATIONS

For products not subject to veterinary prescription:

Treatment and prevention of flea infestations caused by *Ctenocephalides spp.*. Prevention of heartworm disease caused by *Dirofilaria immitis*. Treatment of ear mites (*Otodectes cynotis*). Treatment of biting lice infestations (*Trichodectes canis*). Treatment of sarcoptic mange (caused by *Sarcoptes scabiei*). Treatment of adult intestinal roundworms (*Toxocara canis*).

6. ROUTES OF ADMINISTRATION

Spot-on use.
Read the package leaflet before use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C. Store in the original package in a dry place.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Bioveta, a.s.

Logo:

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{pipette 0.25 ml, 0.5 ml, 0.5 ml, 1.0 ml, 2.0 ml, 3.0 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SELIVERM 30 mg spot-on solution for dogs S
SELIVERM 60 mg spot-on solution for dogs M
SELIVERM 120 mg spot-on solution for dogs L
SELIVERM 240 mg spot-on solution for dogs XL
SELIVERM 360 mg spot-on solution for dogs XXL

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Selamectin	30 mg
Selamectin	60 mg
Selamectin	120 mg
Selamectin	240 mg
Selamectin	360 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}