

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{ALU bag for a tube 2.68 ml; paper box 1 x 2.68 ml, 3 x 2.68 ml, 25 x 2.68 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIPRON 268 mg spot-on solution for dogs L
Fipronil

2. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

1 tube (2.68 ml) contains:

Active substance: Fipronil 268 mg

Excipients:

Butylated hydroxyanisole (E 320) 0.536 mg

Butylated hydroxytoluene (E 321) 0.268 mg

3. PHARMACEUTICAL FORM

Spot-on solution.

4. PACK SIZE

1 single-dose tube
3 single-dose tubes
25 single-dose tubes

5. TARGET SPECIES

Dogs.

6. INDICATIONS

Treatment and prevention of flea infestation (*Ctenocephalides* spp.) and (*Rhipicephalus* spp., *Dermatocentor* spp., *Ixodes* spp.) in dogs.

Treatment and prevention related flea allergy dermatitis (FAD) in dogs.

Prevention and treatment of infestation by lice (*Trichodectes canis*) in dogs.

7. METHOD AND ROUTE OF ADMINISTRATION

Spot-on use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: {month/year}

Use immediately after opening the bag.

11. SPECIAL STORAGE CONDITIONS

Store in the original container in order to protect from light.

Store in a dry place.

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.

Veterinary medicinal product of 25 tubes to be supplied only on prescription.

Veterinary medicinal product of 1 and 3 tubes belongs in restricted veterinary medicinal products and is to be supplied without 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

683 23 Ivanovice na Hané

Czech Republic

16. MARKETING AUTHORISATION NUMBER

17. MANUFACTURER’S BATCH NUMBER

Batch no.: {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{tube 2.68 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIPRON 268 mg spot-on solution for dogs L
Fipronil

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Bioveta, a.s.

3. EXPIRY DATE

EXP: {month/year}

4. BATCH NUMBER

Batch no.: {number}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only