ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ataxxa 2000 mg/400 mg spot-on solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each 4.0 ml pipette contains:

permethrin	2000.0 mg
imidacloprid	400.0 mg

3. PACKAGE SIZE

1 x 4.0 ml
3 x 4.0 ml
4 x 4.0 ml
6 x 4.0 ml
10 x 4.0 ml

4. TARGET SPECIES

Dogs

25 - 40 kg

5. INDICATION(S)

For products not subject to veterinary prescription:

- Eliminates ticks and fleas.
- Repels ticks, mosquitoes and sand flies.
- Reduction of the risk of transmission of canine leishmaniosis

 Ixodida

 Ctenocephalides felis

 Ctenocephalides felis larvae

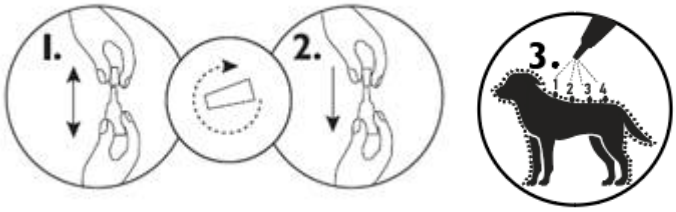
 Phlebotomus perniciosus

 Aedes aegypti


Leishmania infantum

6. ROUTE(S) OF ADMINISTRATION

Spot-on use.



7. WITHDRAWAL PERIOD(S)

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Store in the original packaging in order to protect from light and moisture.

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

KRKA, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

14. MARKETING AUTHORISATION NUMBER(S)

Vm 01656/3037

15. BATCH NUMBER

Lot {number}

Do not use on cats.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bag

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ataxxa

25 – 40 kg

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

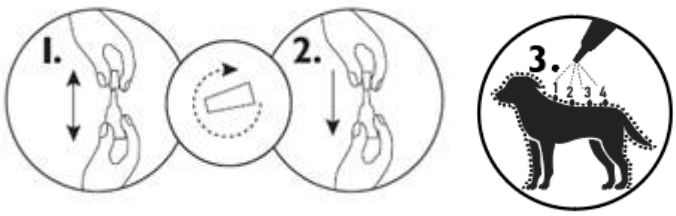
permethrin/imidacloprid
2000 mg/400 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}



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MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

PIPETTE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ataxxa

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

25 – 40 kg

3. BATCH NUMBER

Lot{number}

4. EXPIRY DATE

Exp. {mm/yyyy}

KRKA

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

1. Name of the veterinary medicinal product

Ataxxa 2000 mg/400 mg spot-on solution for dogs over 25 kg

2. Composition

Each 0.4 ml pipette contains:
Active substances:

Permethrin	200.0 mg
Imidacloprid	40.0 mg

Excipients:

Butylhydroxytoluene (E321)	0.4 mg
N-methylpyrrolidone	80.0 mg

Each 1.0 ml pipette contains:
Active substances:

Permethrin	500.0 mg
Imidacloprid	100.0 mg

Excipients:

Butylhydroxytoluene (E321)	1.0 mg
N-methylpyrrolidone	200.0 mg

Each 2.5 ml pipette contains:
Active substances:

Permethrin	1250.0 mg
Imidacloprid	250.0 mg

Excipients:

Butylhydroxytoluene (E321)	2.5 mg
N-methylpyrrolidone	500.0 mg

Each 4.0 ml pipette contains:
Active substances:

Permethrin	2000.0 mg
Imidacloprid	400.0 mg

Excipients:

Butylhydroxytoluene (E321)	4.0 mg
N-methylpyrrolidone	800.0 mg

Clear yellowish to brownish spot on solution.

3. Target species

Dogs.

4. Indications for use

For the treatment and prevention of flea (*Ctenocephalides felis*) infestation.

Fleas on dogs are killed within one day following treatment. One treatment prevents further flea infestation for four weeks. The veterinary medicinal product can be used as part of a treatment strategy for flea allergy dermatitis (FAD).

The veterinary medicinal product has persistent acaricidal efficacy against tick infestations (*Rhipicephalus sanguineus* and *Ixodes ricinus* for four weeks, and *Dermacentor reticulatus* for three weeks) and persistent repellent efficacy (*Ixodes ricinus*) for three weeks. 

Ticks already on the dog may not be killed within two days after treatment and may remain attached and visible. Therefore the removal of ticks already on the dog at the time of treatment is recommended, in order to prevent them from attaching and having a blood meal.

One treatment:
- provides repellent (anti-feeding) activity against the sand fly *Phlebotomus perniciosus* for three weeks, 
- provides repellent (anti-feeding) activity against the mosquito *Aedes aegypti* from 7 days up to 14 days after treatment. 

Reduction of the risk of infection with *Leishmania infantum* via transmission by sandflies (*Phlebotomus perniciosus*) for up to 3 weeks. The effect is indirect due to the veterinary medicinal product's activity against the vector. 

5. Contraindications

In the absence of available data do not use the veterinary medicinal product on puppies of less than 7 weeks of age, or 1.5 kg of weight (product for dogs up to 4 kg), 4 kg of weight (product for dogs over 4 kg up to 10 kg), 10 kg of weight (product for dogs over 10 kg up to 25 kg), 25 kg of weight (product for dogs over 25 kg).
Do not use in known cases of hypersensitivity to the active substances or to any of the excipients.
Do not use on cats. (Refer to section 6. – Special warnings).

6. Special warnings

Special warnings:
There may be an attachment of single ticks or bites by single sand flies or *Aedes aegypti* mosquitoes. For this reason, a transmission of infectious diseases cannot be excluded if conditions are unfavourable.
As the veterinary medicinal product exerts a repellent (anti-feeding) activity against *Aedes aegypti* mosquitoes 7 days after treatment, the veterinary medicinal product should preferably be applied 1 week before animals are likely to become exposed to these mosquitoes.
The veterinary medicinal product remains effective against fleas if the animal becomes wet. After weekly immersions in water for one minute the period of persistent insecticidal efficacy against fleas was not reduced. However, prolonged, intense exposure to water should be avoided. In cases of frequent and/or prolonged water exposure the persistent efficacy may be reduced. In these cases do not retreat more frequently than once weekly. If a dog requires a shampoo, it should be administered before applying the veterinary medicinal product or at least 2 weeks after application, to optimise efficacy of the veterinary medicinal product.
The effectiveness of the veterinary medicinal product against ticks following swimming or shampooing has not been investigated.
Immediate protection against sandflies bites is not documented. Treated dogs for the reduction of the risk of infection with *Leishmania infantum* via transmission by sandflies *P. perniciosus* should be kept in a protected environment during the first 24 hours after the initial treatment application.

Special precautions for safe use in the target species:
Care should be taken to avoid the content of the pipette coming into contact with the eyes or mouth of the recipient dogs.

Care should be taken to administer the veterinary medicinal product correctly as described under section 8. In particular oral uptake due to the licking of the application site by treated or in-contact animals should be avoided.

Do not use on cats.

This veterinary medicinal product is extremely poisonous to cats and could be fatal due to the unique physiology of cats which is unable to metabolise certain compounds including permethrin. To prevent cats from being accidentally exposed to the veterinary medicinal product, keep treated dogs away from cats after treatment until the application site is dry. It is important to ensure that cats do not groom the site of application on a dog, which has been treated with this veterinary medicinal product. Seek veterinary advice immediately if this occurs.

Consult your veterinary surgeon before using the veterinary medicinal product on sick and debilitated dogs.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Avoid contact between the veterinary medicinal product and skin, eyes or mouth.

Do not eat, drink or smoke during application.
Wash hands thoroughly after use.

In case of accidental spillage onto skin, wash off immediately with soap and water.

People with known skin sensitivity may be particularly sensitive to this veterinary medicinal product.

The predominant clinical symptoms that in extremely rare case may be shown are transient sensory irritations of the skin like tingling, burning sensation or numbness.

If the veterinary medicinal product gets accidentally into the eyes, they should be thoroughly flushed with water. If skin or if eye irritation persists, seek medical advice immediately and show the package leaflet or the label to the physician.

Do not ingest. In case of accidental ingestion seek medical advice immediately and show the package leaflet or the label to the physician.
Treated dogs should not be handled especially by children until the application site is dry. This may be ensured by treating the dogs e.g. in the evening. Recently treated dogs should not be allowed to sleep together with their owner, especially children.

In order to prevent children from getting access to pipettes keep the pipette in the original packaging until ready for use and dispose of used pipettes immediately.

Ataxxa 2000 mg/400 mg spot-on solution for dogs over 25 kg: Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant. Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product by women of childbearing age.

Special precautions for the protection of the environment:
The veterinary medicinal product is toxic for aquatic organisms. Treated dogs should not be allowed to enter surface water for 48 hours after treatment, to avoid adverse effects on aquatic organisms.

Other precautions:
The solvent in the veterinary medicinal product may stain certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established in dogs during pregnancy, lactation or in animals intended for breeding. Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian

Interaction with other medicinal products and other forms of interaction:
None known.

Overdose:
No adverse clinical signs were noted in healthy puppies or adult dogs exposed to 5x overdosage or for puppies whose mothers were treated with 3x overdosage of the combination of imidacloprid and permethrin. The severity of skin erythema, which sometimes occurs at the application site, increases with overdose.

Major incompatibilities:
None known.

7. Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Application site disorders (application site pruritus, application site hair loss, application site erythema, application site oedema, and application site lesions)[1] Behavioural disorders (agitation, restlessness, whining or rolling)[2] Digestive tract disorders (vomiting, diarrhoea, hypersalivation, decreased appetite)[2] Neurological disorders (e.g. unsteady gait, twitching, lethargy)[2,3]

[1] generally self-resolving
[2] generally transient and self-resolving
[3] in dogs susceptible to the ingredient permethrin

Accidental oral uptake may result in transient vomiting and neurological disorders such as tremor and incoordination. Treatment should be symptomatic. There is no known specific antidote.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has

not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

Route of administration and dosage:
Spot-on use only. Apply only to undamaged skin.

The recommended minimum dose is:
10 mg/kg body weight (bw) imidacloprid and 50 mg/kg body weight (bw) permethrin.

Administer by topical application to the skin according to the bodyweight as follows:

Dogs (kg body weight)	**Trade name**	**Volume (ml)**	**Imidacloprid (mg/kg body weight)**	**Permethrin (mg/kg body weight)**
≤ 4 kg	Ataxxa 200 mg/40 mg spot-on solution for dogs up to 4 kg	0.4 ml	minimum of 10	minimum of 50
>4 kg ≤ 10 kg	Ataxxa 500 mg/100 mg spot-on solution for dogs over 4 kg up to 10 kg	1.0 ml	10 - 25	50 - 125
>10 kg ≤ 25 kg	Ataxxa 1250 mg/250 mg spot-on solution for dogs over 10 kg up to 25 kg	2.5 ml	10 - 25	50 - 125
>25 kg ≤ 40 kg	Ataxxa 2000 mg/400 mg spot-on solution for dogs over 25 kg	4.0 ml	10 - 16	50 - 80

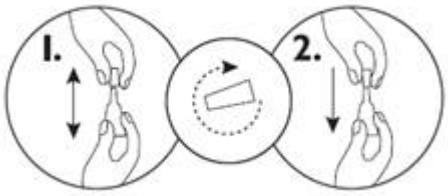
For dogs > 40 kg the appropriate combination of pipettes should be used.

To ensure correct dosage, body weight should be determined as accurately as possible.

Transient cosmetic changes (e.g. skin scaling, white deposits and spiking of the hair) may be observed at application sites.

Method of administration:

Remove one pipette from the package. Hold applicator pipette in an upright position. Tap the narrow part of pipette to ensure the contents are within the main body of the pipette, twist and pull cap off. Turn the cap around and place the other end of cap back on pipette. Push and twist the cap to break seal, and then remove the cap from the pipette.



For dogs 10 kg body weight or less:

With the dog standing still, part the coat between the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze firmly several times to empty the contents directly onto the skin.

For dogs of more than 10 kg body weight:

With the dog standing still, the entire contents of the pipette should be applied evenly to four spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the pipette on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog.

9. Advice on correct administration

To reduce re-infestation from emergence of new fleas, it is recommended to treat all dogs in a household. Other animals living in the same household should also be treated with a suitable veterinary medicinal product. To aid further in reducing environmental challenge, the additional use of a suitable environmental treatment against adult fleas and their developmental stages is recommended.

Depending on the ectoparasite challenge, it may be necessary to repeat the treatment. The interval between two treatments should be 4 weeks. However, in cases of frequent and/or prolonged water exposure the persistent efficacy

may be reduced. In these cases do not retreat more frequently than once weekly.

To protect a dog over the whole sand fly season, treatment should be compliantly continued throughout.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Store in the original packaging in order to protect from light and moisture.

Do not use this veterinary medicinal product after the expiry date which is stated on the labels and carton after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as permethrin/imidacloprid may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription. (BE, IE, UK(NI))
Veterinary medicinal product not subject to prescription. (AT, BG, CZ, DE, EE, ES, FR, HR, HU, IT, LT, LV, NL, PL, PT, RO, SI, SK)

14. Marketing authorisation number and pack sizes

Vm 01656/3037

White polypropylene pipette closed with either a polyethylene or polyoxymethylene cap. Each pipette is packed in a polyethylene terephthalate/aluminium/low density polyethylene triplex bag.

1 ml pipette containing 0.4 ml of solution
3 ml pipette containing 1.0 ml of solution
6 ml pipette containing 2.5 ml and 4.0 ml of solution

Pack sizes:
Box containing 1, 3, 4, 6, 10 pipettes.
Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
KRKA, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia
Tel: *Telephone number*

Manufacturer responsible for batch release:
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia
TAD Pharma GmbH, Heinz-Lohmann-Straße 5, 27472 Cuxhaven, Germany

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

<17. Other information>

Gavin Hall
Approved: 14 May 2025