PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ataxxa 1250 mg/250 mg mg spot-on solution for dogs over 10 kg up to 25 kg
Permethrin/Imidacloprid

2. STATEMENT OF ACTIVE SUBSTANCES

Each 2.5 ml pipette contains:
Active substances:

Permethrin	1250.0 mg
Imidacloprid	250.0 mg

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZE

1 unit-dose pipette of 2.5 ml
4 unit-dose pipette of 2.5 ml
6 unit-dose pipette of 2.5 ml
10 unit-dose pipette of 2.5 ml

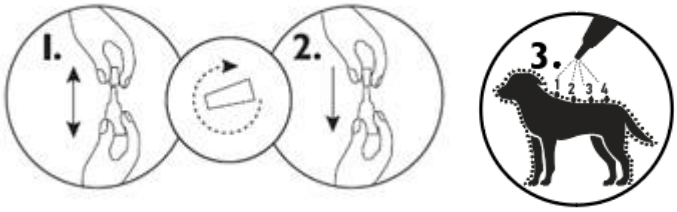
5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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



8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
Do not use on cats.

10. EXPIRY DATE

EXP

11. SPECIAL STORAGE CONDITIONS

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

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

The product should not enter water courses as this may be dangerous for fish and other aquatic organisms.
After use, replace cap on tube. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

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

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

16. MARKETING AUTHORISATION NUMBER

Vm 01656/4093

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ataxxa 1250 mg/250 mg mg spot-on solution for dogs over 10 kg up to 25 kg
Permethrin/Imidacloprid

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each 2.5 ml pipette contains:
Active substances:

Permethrin	1250.0 mg
Imidacloprid	250.0 mg

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

1 unit-dose pipette of 2.5 ml

4. ROUTE(S) OF ADMINISTRATION

Spot-on use.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.
Do not use on cats.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

PIPETTE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ataxxa
Permethrin/Imidacloprid

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

2.5 ml

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Ataxxa 200 mg/40 mg spot-on solution for dogs up to 4 kg
Ataxxa 500 mg/100 mg spot-on solution for dogs over 4 kg up to 10 kg
Ataxxa 1250 mg/250 mg spot-on solution for dogs over 10 kg up to 25 kg
Ataxxa 2000 mg/400 mg spot-on solution for dogs over 25 kg

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
KRKA, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ataxxa 200 mg/40 mg spot-on solution for dogs up to 4 kg
Ataxxa 500 mg/100 mg spot-on solution for dogs over 4 kg up to 10 kg
Ataxxa 1250 mg/250 mgspot-on solution for dogs over 10 kg up to 25 kg
Ataxxa 2000 mg/400 mg spot-on solution for dogs over 25 kg
Permethrin/Imidacloprid

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each 0.4 ml pipette contains:
Active substances:
Permethrin 200.0 mg
Imidacloprid 40.0 mg

Excipients:
Butylhydroxytoluene (E321) 0.4 mg

Each 1.0 ml pipette contains:
Active substances:
Permethrin 500.0 mg
Imidacloprid 100.0 mg

Excipients:
Butylhydroxytoluene (E321) 1.0 mg

Each 2.5 ml pipette contains:
Active substances:

Permethrin	1250.0 mg
Imidacloprid	250.0 mg

Excipients:

Butylhydroxytoluene (E321)	2.5 mg

Each 4.0 ml pipette contains:
Active substances:

Permethrin	2000.0 mg
Imidacloprid	400.0 mg

Excipients:

Butylhydroxytoluene (E321)	4.0 mg

Clear yellowish to brownish solution.

4. INDICATION(S)

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 product can be used as part of a treatment strategy for flea allergy dermatitis (FAD).

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

5. CONTRAINDICATIONS

In the absence of available data do not use the 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 12. – Special warnings).

6. ADVERSE REACTIONS

In very rare cases pruritus, hair loss, erythema, oedema and erosions at the application site may occur. These are generally self-resolving.

In very rare cases dogs may show behaviour changes (agitation, restlessness, whining or rolling), gastro-intestinal symptoms (vomiting, diarrhoea, hypersalivation, diminished appetite) and neurological signs such as unsteady movement and twitching, or lethargy in dogs susceptible to the ingredient permethrin. These signs are generally transient and self-resolving.

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

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any serious effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

Alternatively you can report via your national reporting system https://www.vmd.defra.gov.uk/adversereactionreporting/

7. TARGET SPECIES

Dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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

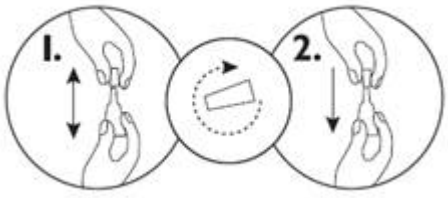
For dogs > 40 kg the appropriate combination of pipettes should be used.

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 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.

10. WITHDRAWAL PERIOD(S)

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 moisture and light.

Do not use this veterinary medicinal product after the expiry date which is stated on the labels and carton after EXP.

12. SPECIAL WARNING(S)

Special warnings for each target species:
There may be an attachment of single ticks. For this reason, a transmission of infectious diseases cannot be excluded if conditions are unfavourable. The 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 product or at least 2 weeks after application, to optimise efficacy of the product.
The effectiveness of the product against ticks following swimming or shampooing has not been investigated.

Special precautions for use in animals:
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 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 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 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 product. Seek veterinary advice immediately if this occurs.

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

The 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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Avoid contact between the 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 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 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 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.

The solvent in the 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 during pregnancy and lactation. In these animals, 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 (symptoms, emergency procedures, antidotes):
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.

Incompatibilities:
None known.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

The product should not enter water courses as this may be dangerous for fish and other aquatic organisms.
After use, replace cap on tube. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2020

15. OTHER INFORMATION

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
Box containing 1, 4, 6, 10 pipettes.

Not all pack sizes may be marketed.

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

To be supplied only on veterinary prescription.

Vm No: 01656/4091
Vm No: 01656/4092
Vm No: 01656/4093
Vm No: 01656/4094

Local representative:
KRKA UK Ltd
United Kingdom
Tel: 02071 646 156
pharmacovigilance.uk@krka.biz

Approved: 07/01/21