ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Activyl Tick Plus 75 mg + 240 mg spot-on solution for very small dogs
Activyl Tick Plus 150 mg + 480 mg spot-on solution for small dogs
Activyl Tick Plus 300 mg + 960 mg spot-on solution for medium dogs
Activyl Tick Plus 600 mg + 1920 mg spot-on solution for large dogs
Activyl Tick Plus 900 mg + 2880 mg spot-on solution for extra large dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:

One ml contains 150 mg indoxacarb and 480 mg permethrin.
One unit dose pipette delivers:

	Volume of unit dose (ml)	Indoxacarb (mg)	Permethrin (mg)
Very small dogs (1.2 - 5 kg)	0.5	75	240
Small dogs (5.1 - 10 kg)	1	150	480
Medium dogs (10.1 - 20 kg)	2	300	960
Large dogs (20.1 - 40 kg)	4	600	1920
Extra large dogs (40.1 - 60 kg)	6	900	2880

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Spot-on solution.
A clear, colourless to yellow or brown-coloured solution.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

Treatment of flea infestations (*Ctenocephalides felis*); the product has persistent insecticidal efficacy for up to 4 weeks against *Ctenocephalides felis*.

The product has persistent acaricidal efficacy for up to 5 weeks against *Ixodes ricinus* and up to 3 weeks against *Rhipicephalus sanguineus*. If ticks of these species are present when the product is applied, all the ticks may not be killed within the first 48 hours but they may be killed within a week.
Developing stages of fleas in the dog's immediate surroundings are killed following contact with the treated dogs.

One treatment provides repellent (anti-feeding) activity against sand flies (*Phlebotomus perniciosus*) for up to 3 weeks.

4.3 Contraindications

Do not use in cats as adverse reactions and even death can occur (see also section 4.5 Special precautions for use in animals).
Do not use in cases of known hypersensitivity to the active substances or to any of the excipients.

4.4 Special warnings for each target species

The product provides repellent (anti-feeding) activity against sand flies, thus preventing the repelled parasites from taking a blood meal. However, potential transmission of infectious disease by sand flies cannot be excluded if conditions are unfavourable.

After treatment, ticks will generally be killed and fall off the host within 48 hours after infestation without having had a blood meal but an attachment of single ticks after treatment cannot be excluded. For this reason the transmission of infectious diseases by ticks cannot be excluded.

4.5 Special precautions for use

Special precautions for use in animals

The product should not be used in dogs younger than 8 weeks or dogs weighing less than 1.2 kg.

Ensure that the dosage (pipette) corresponds to the weight of the treated dog (see section 4.9).

This product is for external topical application only. Do not administer orally or via any other route. Care should be taken to avoid contact of the veterinary medicinal product with the eyes of the dog.

Apply the product only to the skin surface and on intact skin. It is important to ensure that the product is applied to an area where the dog cannot lick it off, and to ensure that other animals do not lick the treatment sites following application. Keep treated animals separately until the application site is dry.

The veterinary medicinal product remains effective when treated dogs are exposed to sunlight or immersed in water (e.g. swimming, bathing). However, dogs should not be allowed to swim or be shampooed within 48 hours after treatment. In case of frequent shampooing, the duration of activity may be reduced.

All dogs in a household should be treated with a suitable flea product. A proper treatment of the pet´s environment by additional chemical or physical measures is recommended.

Ticks already attached 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.

The veterinary medicinal product is extremely poisonous to cats and can induce potentially fatal convulsions in cats due to the unique physiology of this species which is unable to metabolise certain compounds including permethrin. Signs of poisoning are severe tremors, muscle cramp and ataxia. In case of accidental dermal exposure, wash the cat with shampoo or soap, and seek veterinary advice rapidly. To prevent cats from being accidentally exposed to the product, keep treated dogs away from cats 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. In case of exposure of this type seek veterinary advice immediately.

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

Keep pipettes in the original packaging until ready to use.

Do not eat, drink or smoke while handling the veterinary medicinal product.

The sachet is child-resistant. Keep the product in the sachet until use, in order to prevent children from getting direct access to the product. Keep the used pipette out of sight and reach of children.
Used pipettes should be disposed of immediately.

People with known hypersensitivity to indoxacarb and/or permethrin should avoid contact with this product.

Local and/or systemic reactions have been observed in some people after exposure to the product such as: local skin reactions; nasal or throat/mouth irritation; neurological signs; respiratory signs; gastrointestinal signs or other systemic signs.

To avoid adverse reactions:

- wear protective gloves when handling or applying the product;
- administer the product in a well-ventilated area;
- do not handle treated animals until the application site is dry;
- on the day of treatment, children must not handle treated animals and the animals should not be permitted to sleep with their owners, especially children;
- wash hands immediately after use and wash off any product in contact with the skin immediately with soap and water;
- as the veterinary medicinal product may cause moderate eye irritation, avoid contact with eyes. If this occurs, rinse slowly and gently with water.

If symptoms occur, seek medical advice and show the package leaflet to the physician.

This product is highly flammable. Keep away from heat, sparks, open flame or other sources of ignition.

4.6 Adverse reactions (frequency and seriousness)

Transitory erythema, hair loss or itching at the application site were commonly observed in clinical studies. These effects will usually resolve without treatment.

Gastrointestinal signs (e.g. emesis, diarrhoea or anorexia), reversible neurological signs (e.g. tremor or ataxia) or lethargy have been observed in very rare cases. These signs are usually transient and generally resolve within 24 - 48 hours.

If adverse reactions occur, bathe the animal with mild soap and rinse with large amounts of water.

The application of the veterinary medicinal product may produce a local, temporary oily appearance or hair clumping at the application site. A dry white residue may be also observed. This is normal and will generally resolve within a couple of days after administration. These changes do not affect the safety or efficacy of the veterinary medicinal product.

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).

4.7 Use during pregnancy, lactation or lay

Pregnancy:

Do not use in pregnant dogs.

Laboratory studies in rats, mice and rabbits with indoxacarb and permethrin have not produced any evidence of teratogenic, foetotoxic or materno toxic effects. However, a reproductive toxicity study conducted in the dog at three times the recommended therapeutic dose did reveal a significant reduction in the live pup ratio; the clinical significance of this latter finding is unknown as no studies were carried out in dogs using the recommended therapeutic dose.

Lactation:
Do not use in lactating dogs.

Fertility:
Do not use in breeding dogs.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Dosage schedule:

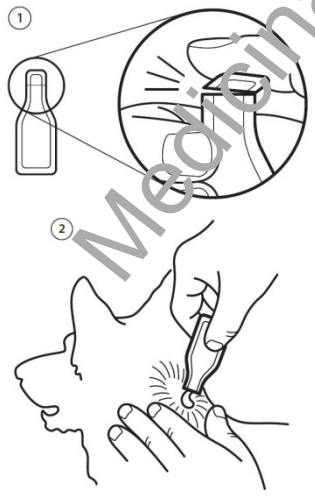
The recommended minimum dose is 15 mg indoxacarb/kg bodyweight and 48 mg/kg permethrin, equivalent to 0.1 ml spot-on solution per kg bodyweight.
The following table defines the size of pipette to be used according to the weight of the dog:

Weight of dog (kg)	Pipette size to be used	Volume (ml)	Indoxacarb (mg/kg)	Permethrin (mg/kg)
1.2 - 5	Very small dogs	0.5	Minimum of 15	Minimum of 48
5.1 - 10	Small dogs	1	15 - 30	48 - 96
10.1 - 20	Medium dogs	2	15 - 30	48 - 96
20.1 - 40	Large dogs	4	15 - 30	48 - 96
40.1 - 60	Extra large dogs	6	15 - 22.5	48 - 72
> 60	The appropriate combination of pipettes should be used			

Method of administration:

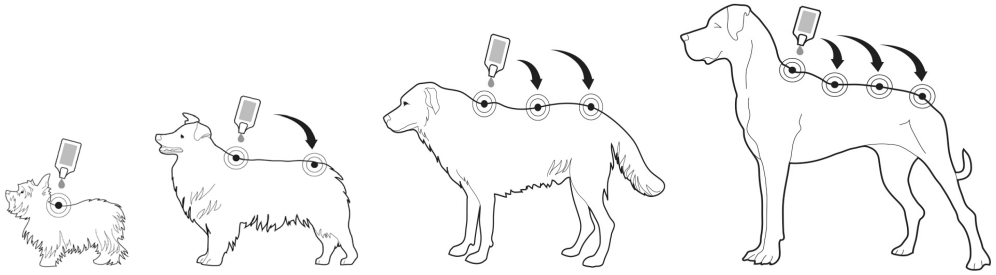
Spot-on use.
Care should be taken to apply the product to intact skin.

Open one sachet and remove the pipette.



Step 1: Hold the pipette in an upright position away from your face. Snap the tip open by bending it and folding it back on itself.

Step 2: The dog should be standing for easy application. Part the hair until the skin is visible and place the pipette tip against the skin between the shoulder blades.



Step 3: For very small and small dogs, squeeze the pipette firmly and apply the entire contents directly to the skin in one spot between the shoulder blades.

For larger dogs, apply the contents of the pipette evenly to 2 (medium dogs) or 3 (large dogs) or 4 (very large dogs) spots along the backline from the shoulder to the base of the tail.

Do not apply an excessive amount of solution at any one spot in order to prevent run-off. Should run-off occur, re-application is not necessary.

Treatment schedule
Following a single administration, the veterinary medicinal product will prevent further flea infestation for 4 weeks and prevent tick re-infestation (through an acaricidal effect) with *I. ricinus* and *R. sanguineus* for 5 and 3 weeks, respectively; repellent (anti-feeding) activity against sand flies will last for 3 weeks.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No adverse reactions were observed in dogs aged 8 weeks and older, treated 8 times at 4 week intervals or 6 times at 2 week intervals, with 5 times the recommended dose.

In case of accidental exposure of cats:
Intravenous infusion of electrolytes should be provided to stabilize vital functions if clinical signs of poisoning occur (e.g. hypersalivation, tremor, muscle cramp). Signs related to the nervous system can be treated with e.g. atropine (salivation) and diazepam (muscle tremors/fasciculation/cramp). Pentobarbital, phenobarbital or propofol might be indicated if repeated occasions of cramp/tremors occur. Recovery occurs normally within 24-36 hours after treatment.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides for topical use, incl. insecticides; permethrin, combinations.
ATCvet code: QP53AC54.

5.1 Pharmacodynamic properties

Indoxacarb is an ectoparasiticide belonging to the oxadiazine chemical family. Indoxacarb is a pro- drug that requires bioactivation by enzymes in susceptible insects to exert its pharmacodynamic effects. It enters the insect primarily through ingestion but is also absorbed, to a lesser degree, through the insect cuticle. In the mid-gut of susceptible insect species, the insect's enzymes remove the carbomethoxy group from parent indoxacarb, and convert it into its biologically active form. The bioactivated metabolite acts as a voltage-dependent sodium channel antagonist in insects, by blocking the sodium channels that regulate the flow of sodium ions in the insect's nervous system. This results in a rapid cessation of feeding within 0 to 4 hours after treatment followed by cessation of egg laying (oviposition), paralysis and death occurring

within 4 to 48 hours. In addition to its adulticidal activity against fleas, indoxacarb has activity against the developing stages of fleas in the immediate surroundings of the treated dog.

Permethrin belongs to the Type I class of pyrethroids, which are acaricides and insecticides with repellent activity. Pyrethroids affect the voltage-gated sodium channels in vertebrates and non- vertebrates. Pyrethroids are so-called "open channel blockers" affecting the sodium channel by slowing both the activation and the inactivation properties, thus leading to hyper-excitability and death of the parasite.

5.2 Pharmacokinetic particulars

Following a single spot-on application of the product, indoxacarb and permethrin can still be detected in both skin and hair coat after 4 weeks post-treatment. Absorption through the skin also occurs, but this systemic absorption is partial and not relevant for the clinical efficacy. The absorbed indoxacarb and permethrin are extensively metabolised by the liver to a variety of metabolites. The major route of excretion is in faeces for indoxacarb and both in urine and faeces for permethrin.

Environmental properties

Indoxacarb and permethrin may have harmful effects on aquatic organisms.
See section 6.6

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propyl gallate (E310)
Propylene glycol monomethyl ether (Dowanol PM)

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Cardboard box with 1, 4 or 6 sachets; each sachet contains one unit-dose pipette. One unit-dose pipette holds 0.5 ml, 1 ml, 2 ml, 4 ml, or 6 ml spot-on solution. One size of unit-dose pipette only per box.
The pipette consists of a blister film (polypropylene/cyclic-olefin- copolymer/polypropylene) and a foil lidstock (aluminium/polypropylene co-extruded) sealed into aluminium child-resistant sachet.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Activyl Tick Plus should not enter water courses as this may be dangerous for fish and other aquatic organisms.

7. MARKETING AUTHORISATION HOLDER

Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/11/137/001-015

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 09/01/2012.
Date of latest renewal: 14/12/2016.

10 DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu/.

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Intervet Productions SA
Rue de Lyons
27460 Igoville
France

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product not subject to prescription.

C. STATEMENT OF THE MRLs

Not applicable.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Activyl Tick Plus 75 mg + 240 mg spot-on solution for very small dogs (1.2 – 5 kg)
Activyl Tick Plus 150 mg + 480 mg spot-on solution for small dogs (5.1 – 10 kg)
Activyl Tick Plus 300 mg + 960 mg spot-on solution for medium dogs (10.1 – 20 kg)
Activyl Tick Plus 600 mg + 1920 mg spot-on solution for large dogs (20.1 – 40 kg)
Activyl Tick Plus 900 mg + 2880 mg spot-on solution for extra large dogs (40.1 – 60 kg)

Indoxacarb + permethrin

2. STATEMENT OF ACTIVE SUBSTANCES

Indoxacarb 75 mg + permethrin 240 mg
Indoxacarb 150 mg + permethrin 480 mg
Indoxacarb 300 mg + permethrin 960 mg
Indoxacarb 600 mg + permethrin 1920 mg
Indoxacarb 900 mg + permethrin 2880 mg

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZE

1 pipette
4 pipettes
6 pipettes

5. TARGET SPECIES

Dogs 1.2 – 5 kg
Dogs 5.1 – 10 kg
Dogs 10.1 – 20 kg
Dogs 20.1 – 40 kg
Dogs 40.1 – 60 kg

6. INDICATION(S)

Read the package leaflet before use.

Fleas 

Ticks 

Sand flies 

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For spot-on use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
Keep the pipettes in the original packaging until ready to use.

DANGER – Do not use in cats

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

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

Disposal: read package leaflet.
The veterinary product should not enter water courses.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

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

Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The NETHERLANDS

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/11/137/001
EU/2/11/137/002
EU/2/11/137/003
EU/2/11/137/004
EU/2/11/137/005
EU/2/11/137/006
EU/2/11/137/007
EU/2/11/137/008
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EU/2/11/137/010
EU/2/11/137/011
EU/2/11/137/012
EU/2/11/137/013
EU/2/11/137/014
EU/2/11/137/015

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

SACHET

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Activyl Tick Plus 75 mg + 240 mg spot-on solution for very small dogs
Activyl Tick Plus 150 mg + 480 mg spot-on solution for small dogs
Activyl Tick Plus 300 mg + 960 mg spot-on solution for medium dogs
Activyl Tick Plus 600 mg + 1920 mg spot-on solution for large dogs
Activyl Tick Plus 900 mg + 2880 mg spot-on solution for extra large dogs

Indoxacarb + permethrin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

75 mg + 240 mg
150 mg + 480 mg
300 mg + 960 mg
600 mg + 1920 mg
900 mg + 2880 mg

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

4. ROUTE(S) OF ADMINISTRATION

Spot-on use

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Danger - Do not use in cats.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER (pipette label)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Activyl Tick Plus 75 mg + 240 mg for dogs 1.2 – 5 kg
Activyl Tick Plus 150 mg + 480 mg for dogs 5.1 – 10 kg
Activyl Tick Plus 300 mg + 960 mg for dogs 10.1 – 20 kg
Activyl Tick Plus 600 mg + 1920 mg for dogs 20.1 – 40 kg
Activyl Tick Plus 900 mg + 2880 mg for dogs 40.1 – 60 kg

Indoxacarb + permethrin

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International BV

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Batch {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Do not use in cats.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Activyl Tick Plus spot-on solution for dogs

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

Marketing authorisation holder:
Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Manufacturer responsible for batch release:
Intervet Productions SA
Rue de Lyons
27460 Igoville
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Activyl Tick Plus 75 mg + 240 mg spot-on solution for very small dogs
Activyl Tick Plus 150 mg + 480 mg spot-on solution for small dogs
Activyl Tick Plus 300 mg + 960 mg spot-on solution for medium dogs
Activyl Tick Plus 600 mg + 1920 mg spot-on solution for large dogs
Activyl Tick Plus 900 mg + 2880 mg spot-on solution for extra large dogs

Indoxacarb + permethrin

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

Active substances:
One ml contains 150 mg indoxacarb and 480 mg permethrin.
One pipette delivers:

	Volume (ml)	Indoxacarb (mg)	Permethrin (mg)
For very small dogs (1.2 – 5 kg)	0.5	75	240
For small dogs (5.1 – 10 kg)	1	150	480
For medium dogs (10.1 – 20 kg)	2	300	960
For large dogs (20.1 – 40 kg)	4	600	1920
For extra large dogs (40.1 – 60 kg)	6	900	2880

A clear, colourless to yellow or brown-coloured solution.

4. INDICATION(S)

Treatment of flea infestations (*Ctenocephalides felis*); the product has persistent insecticidal efficacy for up to 4 weeks against *Ctenocephalides felis*.

The product has persistent acaricidal efficacy for up to 5 weeks against *Ixodes ricinus* and up to 3 weeks against *Rhipicephalus sanguineus*. If ticks of these species are present when the product is applied, all the ticks may not be killed within the first 48 hours but they may be killed within a week.
Developing stages of fleas in the dog's immediate surroundings are killed following contact with the

treated dogs.

One treatment provides repellent (anti-feeding) activity against sand flies (*Phlebotomus perniciosus*) for up to 3 weeks.

5. CONTRAINDICATIONS

Do not use on dogs in case of known hypersensitivity to the active substances or any of the excipients.

DANGER – Do not use in cats as adverse reactions and even death can occur (see also section Special precautions for use in animals).

6. ADVERSE REACTIONS

Transitory erythema (redness of skin), hair loss or itching at the application site were commonly (13 of 359 dogs) observed in clinical studies. These effects will usually resolve without treatment.

Gastrointestinal signs (e.g. emesis (vomiting), diarrhoea or anorexia (loss of appetite), reversible neurological signs (e.g. tremor (shakiness) or ataxia (unsteady movement)) or lethargy (drowsiness) have been observed in very rare cases. These signs are usually transient and generally resolve within 24 - 48 hours.

If adverse reactions occur, bathe the animal with mild soap and rinse with large amounts of water.

The application of the veterinary medicinal product may produce a local, temporary oily appearance or hair clumping at the application site. A dry white residue may also be observed. This is normal and will generally resolve within a couple of days after administration. These changes do not affect the safety or efficacy of the veterinary product.

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

7. TARGET SPECIES

Dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Spot-on use. For application to the dog's skin only.

The recommended dose for dogs is 15 mg indoxacarb and 48 mg permethrin per kg bodyweight, equivalent to 0.1 ml/kg bodyweight. The following table defines the pipette to be used according to the

weight of the dog:

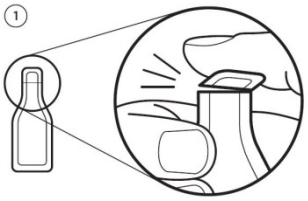
Weight of dog (kg)	Pipette size to be used
1.2 - 5	Activyl Tick Plus for very small dogs
5.1 - 10	Activyl Tick Plus for small dogs
10.1 - 20	Activyl Tick Plus for medium dogs
20.1 - 40	Activyl Tick Plus for large dogs
40.1 - 60	Activyl Tick Plus for extra large dogs
> 60	The appropriate combination of pipettes should be used

Treatment schedule
Following a single administration, the veterinary medicinal product will prevent further flea infestation for 4 weeks and prevent tick re-infestation (through an acaricidal effect) with *I. ricinus* and *R. sanguineus* for 5 and 3 weeks, respectively; repellent (anti-feeding) activity against sand flies will last for 3 weeks.

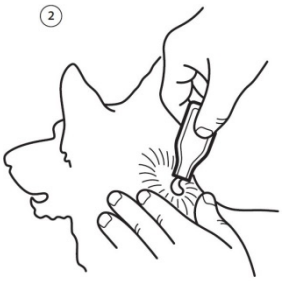
9. ADVICE ON CORRECT ADMINISTRATION

Care should be taken to apply the product to intact skin.

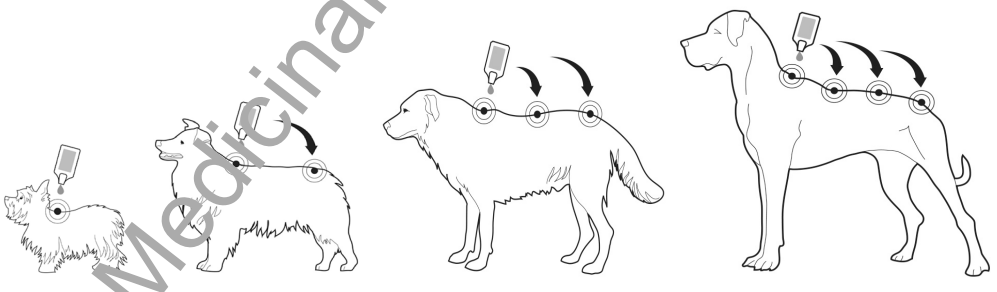
Open one sachet and remove the pipette.



Step 1: Hold the pipette in an upright position away from your face. Snap the tip open by bending it and folding it back on itself.



Step 2: The dog should be standing for easy application. Part the hair until the skin is visible and place the pipette tip against the skin between the shoulder blades.



Step 3: For very small and small dogs, squeeze the pipette firmly and apply the entire contents directly to the skin in one spot between the shoulder blades.

For larger dogs, apply the contents of the pipette evenly to 2 (medium dogs) or 3 (large dogs) or 4 (very large dogs) spots along the backline from the shoulder to the base of the tail.
Do not apply an excessive amount of solution at any one spot in order to prevent run-off. Should run-off occur, re-application is not necessary.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Stored pipettes must be kept in the child-resistant sachet.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the carton, foil and pipette after "EXP". The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for each target species:
The product provides repellent (anti-feeding) activity against sand flies, thus preventing the repelled parasites from taking a blood meal. However, potential transmission of infectious disease by sand flies cannot be excluded if conditions are unfavourable.
After treatment, ticks will generally be killed and fall off the host within 48 hours after infestation without having had a blood meal but an attachment of single ticks after treatment cannot be excluded. For this reason the transmission of infectious diseases by ticks cannot be excluded.

Special precautions for use in animals:
The product should not be used in dogs younger than 8 weeks or dogs weighing less than 1.2 kg.

Ensure that the dosage (pipette) corresponds to the weight of the treated dog (see section 8).

This product is for external topical application only. Do not administer orally or via any other route. Care should be taken to avoid contact of the veterinary medicinal product with the eyes of the dog.

Apply the product only to the skin surface and on intact skin. It is important to ensure that the product is applied to an area where the dog cannot lick it off, and to ensure that other animals do not lick the treatment sites following application. Keep treated animals separately until the application site is dry.

The veterinary medicinal product remains effective when treated dogs are exposed to sunlight or immersed in water (e.g. swimming, bathing). However, dogs should not be allowed to swim or be shampooed within 48 hours after treatment. In case of frequent shampooing, the duration of activity may be reduced.

All dogs in a household should be treated with a suitable flea product. A proper treatment of the pet´s environment by additional chemical or physical measures is recommended.

Ticks already attached 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.

The veterinary medicinal product is extremely poisonous to cats and can induce potentially fatal convulsions in cats, due to the unique physiology of this species which is unable to metabolise certain compounds, including permethrin. Signs of poisoning are severe tremors, muscle cramp and ataxia. In case of accidental dermal exposure, wash the cat with shampoo or soap, and seek veterinary advice rapidly. To prevent cats from being accidentally exposed to the product, keep treated dogs away from cats 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. In case of exposure of this type seek veterinary advice immediately.

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

Keep pipettes in the original packaging until ready to use.

Do not eat, drink or smoke while handling the veterinary medicinal product.

The sachet is child-resistant. Keep the product in the sachet until use, in order to prevent children from getting direct access to the product. Keep the used pipette out of sight and reach of children. Used pipettes should be disposed of immediately.

People with known hypersensitivity to indoxacarb and/or permethrin should avoid contact with this product.

Local and/or systemic reactions have been observed in some people after exposure to the product such as: local skin reactions; nasal or throat/mouth irritation; neurological signs; respiratory signs; gastrointestinal signs or other systemic signs.

To avoid adverse reactions:

- wear protective gloves when handling or applying the product;
- administer the product in a well-ventilated area;
- do not handle treated animals until the application site is dry;
- on the day of treatment, children must not handle treated animals and the animals should not be permitted to sleep with their owners, especially children;
- wash hands immediately after use and wash off any product in contact with the skin immediately with soap and water;
- as the veterinary medicinal product may cause moderate eye irritation, avoid contact with eyes. If this occurs, rinse slowly and gently with water.

If symptoms occur, seek medical advice and show the package leaflet to the physician.

This product is highly flammable. Keep away from heat, sparks, open flame or other sources of ignition.

Pregnancy:
Do not use in pregnant dogs.
Laboratory studies in rats, mice and rabbits with indoxacarb and permethrin have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects. However, a reproductive toxicity study conducted in the dog at three times the recommended therapeutic dose did reveal a significant reduction in the live pup ratio; the clinical significance of this latter finding is unknown as no studies were carried out in dogs using the recommended therapeutic dose.

Lactation:
Do not use in lactating dogs

Fertility:
Do not use in breeding dogs.

Overdose
No adverse reactions were observed in dogs aged 8 weeks and older, treated 8 times at 4 week intervals or 6 times at 2 week intervals, with 5 times the recommended dose.

In case of accidental exposure of cats:
If clinical signs of poisoning occur, seek veterinary advice immediately and show this package leaflet to your veterinarian.

Advice for the veterinarian: Intravenous infusion of electrolytes should be provided to stabilize vital functions if clinical signs of poisoning occur (e.g. hypersalivation, tremor, muscle cramp). Signs related to

the nervous system can be treated with e.g. atropine (salivation) and diazepam (muscle tremors/fasciculation/cramp). Pentobarbital, phenobarbital or propofol might be indicated if repeated occasions of cramp/tremors occur. Recovery occurs normally within 24-36 hours after treatment.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Activyl Tick Plus should not enter water courses as this may be dangerous for fish and other aquatic organisms.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu/.

15. OTHER INFORMATION

Cardboard box of 1 pipette of 0.5 ml, 1 ml, 2 ml, 4 ml or 6 ml.
Cardboard box of 4 pipettes of 0.5 ml, 1 ml, 2 ml, 4 ml or 6 ml.
Cardboard box of 6 pipettes of 0.5 ml, 1 ml, 2 ml, 4 ml or 6 ml.

Not all pack sizes may be marketed.