**ANNEX I**

**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Activyl 100 mg spot-on solution for very small dogs
Activyl 150 mg spot-on solution for small dogs
Activyl 300 mg spot-on solution for medium dogs
Activyl 600 mg spot-on solution for large dogs
Activyl 900 mg spot-on solution for extra large dogs

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

**Active substance:**

One ml contains 195 mg indoxacarb.
One unit-dose pipette delivers:

| | Unit dose (ml) | Indoxacarb (mg) |
|---|---|---|
| Activyl for very small dogs (1.5 – 6.5 kg) | 0.51 | 100 |
| Activyl for small dogs (6.6 – 10 kg) | 0.77 | 150 |
| Activyl for medium dogs (10.1 – 20 kg) | 1.54 | 300 |
| Activyl for large dogs (20.1 – 40 kg) | 3.08 | 600 |
| Activyl for extra large dogs (40.1 – 60 kg) | 4.62 | 900 |

**Excipients:**

Isopropyl alcohol 354 mg/ml.

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Spot-on solution.
A clear, colourless to yellow solution.

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Dogs.

### 4.2 Indications for use, specifying the target species

Treatment and prevention of flea infestation (*Ctenocephalides felis*). Efficacy against new infestations with fleas persists for 4 weeks following a single application.

Developing stages of fleas in the pet's immediate surroundings are killed following contact with Activyl treated pets.

### 4.3 Contraindications

None.

### 4.4 Special warnings for each target species

None.

## 4.5 Special precautions for use

Special precautions for use in animals

The product should not be used in dogs younger than 8 weeks of age as the safety of the product has not been established in these dogs.

The product should not be used in dogs weighing less than 1.5 kg as the safety of the product has not been established in these dogs.

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

Apply the product only to the skin surface and on intact skin. Apply the dose to an area where the dog cannot lick it off, as described in section 4.9. Ensure that animals do not groom each other immediately following treatment. Keep treated animals separately until the application site is dry.

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

The product remains effective following shampoo treatment, water immersion (swimming, bathing) and exposure to sunlight. However, animals should not be allowed to swim or treated with shampoo within 48 hours after treatment.

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.

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. Used pipettes should be disposed of immediately.

People with known hypersensitivity to indoxacarb should avoid contact with this product.

Local and/or systemic reactions have been observed in some people after exposure. To avoid adverse reactions:

- administer the product in a well-ventilated area;
- do not handle recently 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;
- avoid contact with eyes, as the product may cause moderate eye irritation. If it occurs, the eyes should be rinsed 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)

In very rare cases, a brief period of hypersalivation may occur if the animal licks the application site immediately after treatment. This is not a sign of intoxication and disappears within some minutes without treatment. Correct application (see section 4.9) will minimise licking of the application site. In very rare cases, application site reactions such as transitory scratching, erythema, alopecia or dermatitis at the application site may occur. These effects will usually resolve without treatment.

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 product.

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

## 4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Pregnancy:
Do not use during pregnancy.

Lactation:
Do not use during lactation.

Fertility:
Do not use in breeding animals.

## 4.8 Interaction with other medicinal products and other forms of interaction

None known.

In clinical studies, Activyl was co-administered with deltamethrin collars impregnated with up to 4% deltamethrin without evidence of associated adverse reactions.

## 4.9 Amounts to be administered and administration route

Dosage schedule:

The recommended dose is 15 mg indoxacarb/kg body weight, equivalent to 0.077 ml/kg body weight. 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) |
|---|---|---|---|
| 1.5 – 6.5 | Very small dogs | 0.51 | Minimum of 15 |
| 6.6 – 10 | Small dogs | 0.77 | 15 – 23 |
| 10.1 – 20 | Medium dogs | 1.54 | 15 – 30 |
| 20.1 – 40 | Large dogs | 3.08 | 15 – 30 |
| 40.1 – 60 | Extra large dogs | 4.62 | 15 – 23 |
| > 60 | The appropriate combination of pipettes should be used | | |

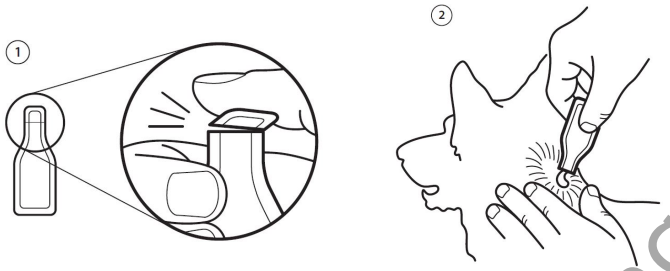
Method of administration:

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

Open one sachet and remove the pipette.

**Step 1**: The dog should be standing for easy application. 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:** Part the hair until the skin is visible.Place the pipette tip against the skin between the shoulder blades for dogs.
Squeeze pipette firmly and apply the entire contents directly to the skin.




In larger dogs, the entire contents of the pipette(s) should be applied evenly to 2-4 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.

Treatment schedule:
Following a single administration, the veterinary medicinal product will prevent further flea infestation for 4 weeks.

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

No adverse effects were observed in dogs aged 8 weeks or older when administered 5 times the recommended dose on 8 occasions at 4 weeks intervals or administered 5 times the recommended dose on 6 occasions at 2 weeks intervals.

### 4.11 Withdrawal period

Not applicable.

## 5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides for topical use, incl. insecticides: indoxacarb.
ATCvet code: QP53AX27.

### 5.1 Pharmacodynamic properties

Indoxacarb is an ectoparasiticide belonging to the oxadiazine chemical family. After being converted into a metabolite, indoxacarb is active against adult, larval and egg stages of insects. In fleas, in addition to its adulticidal activity, indoxacarb activity on the developing larval stages in the immediate surroundings of the treated pet has been demonstrated.

Indoxacarb is a pro-drug that requires bioactivation by the insect enzymes 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.

### 5.2 Pharmacokinetic particulars

Following a single spot-on application of the product, indoxacarb 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 is extensively metabolised by the liver to a variety of metabolites. The major route of excretion is in faeces.

**Environmental properties**

See section 6.6.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Triacetin
Ethyl acetoacetate
Isopropyl alcohol.

### 6.2 Incompatibilities

None known.

### 6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 4 years.

### 6.4 Special precautions for storage

This veterinary medicinal product does not require any special temperature storage conditions.
Store the pipettes in the original package in order to protect from moisture.

### 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 0.51 ml, 0.77 ml, 1.54 ml, 3.08 ml or 4.62 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 sachets.

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 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/2/10/118/001-010
EU/2/10/118/015-019

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18/02/2011.
Date of latest renewal: 07/01/2016.

## 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.

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Activyl 100 mg spot-on solution for small cats
Activyl 200 mg spot-on solution for large cats

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

**Active substance:**

One ml contains 195 mg indoxacarb.
One unit-dose pipette delivers:

| | Unit dose (ml) | Indoxacarb (mg) |
|---|---|---|
| Activyl for small cats (≤ 4 kg) | 0.51 | 100 |
| Activyl for large cats (> 4 kg) | 1.03 | 200 |

**Excipients:**

Isopropyl alcohol 354 mg/ml.

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Spot-on solution.
A clear, colourless to yellow solution.

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Cats.

### 4.2 Indications for use, specifying the target species

Treatment and prevention of flea infestation (*Ctenocephalides felis*). Efficacy against new infestations with fleas persists for 4 weeks following a single application.

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

Developing stages of fleas in the pet's immediate surroundings are killed following contact with Activyl treated pets.

### 4.3 Contraindications

None.

### 4.4 Special warnings for each target species

The safety of the product has not been established in cats younger than 8 weeks of age.
The safety of the product has not been established in cats weighing less than 0.6 kg.

## 4.5 Special precautions for use

Special precautions for use in animals

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

Apply the product only to the skin surface and on intact skin. Apply the dose to an area where the cat cannot lick it off, as described in section 4.9. Ensure that animals do not groom each other immediately following treatment. Keep treated animals separately until the application site is dry.

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

The product remains effective following shampoo treatment, water immersion (swimming, bathing) and exposure to sunlight. However, animals should not be allowed to swim or treated with shampoo within 48 hours after treatment.

All cats 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.

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. Used pipettes should be disposed of immediately.

People with known hypersensitivity to indoxacarb should avoid contact with this product.

Local and/or systemic reactions have been observed in some people after exposure. To avoid adverse reactions:

- administer the product in a well-ventilated area;
- do not handle recently 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;
- avoid contact with eyes, as the product may cause moderate eye irritation. If it occurs, the eyes should be rinsed 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)

In rare cases, neurological signs (e.g. incoordination, tremor, ataxia, convulsions, mydriasis and impaired vision) have been observed. Other signs observed include emesis in rare cases or anorexia, lethargy, hyperactivity and vocalisation in very rare cases. All signs are generally reversible following supportive treatment.

In very rare cases, a brief period of hypersalivation may occur if the animal licks the application site immediately after treatment. This is not a sign of intoxication and disappears within some minutes without treatment. Correct application (see section 4.9) will minimise licking of the application site. In rare cases, application site reactions such as transitory scratching, erythema, alopecia or dermatitis at the application site may occur. These effects will usually resolve without treatment.

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 product.

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

## 4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Pregnancy:
Do not use during pregnancy.

Lactation:
Do not use during lactation.

Fertility:
Do not use in breeding animals.

## 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 dose is 25 mg indoxacarb/kg body weight, equivalent to 0.128 ml/kg body weight. The following table defines the size of pipette to be used according to the weight of the cat:

| Weight of cat (kg) | Pipette size to be used | Volume (ml) | Indoxacarb (mg/kg) |
|---|---|---|---|
| ≤ 4 | Small cats | 0.51 | Minimum of 25 |
| > 4 | Large cats | 1.03 | Maximum of 50 |

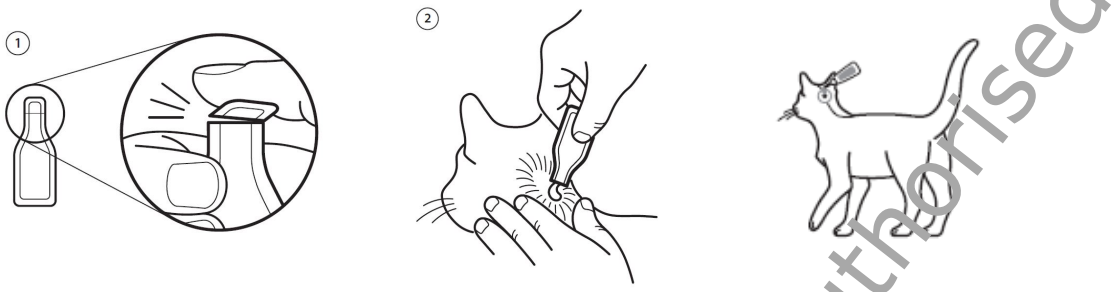
Method of administration:

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

Open one sachet and remove the pipette.

**Step 1**: The cat should be standing for easy application. 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:** Part the hair until the skin is visible.Place the pipette tip against the skin at the base of the skull, where the cat cannot lick it off.
Squeeze pipette firmly and apply the entire contents directly to the skin.




Treatment schedule:
Following a single administration, the veterinary medicinal product will prevent further flea infestation for 4 weeks.

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

No adverse effects were observed in cats aged 8 weeks or older when administered 5 times the recommended dose on 8 occasions at 4 weeks intervals or administered 5 times the recommended dose on 6 occasions at 2 weeks intervals.

### 4.11 Withdrawal period

Not applicable.

## 5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides for topical use, incl. insecticides: indoxacarb.
ATCvet code: QP53AX27.

### 5.1 Pharmacodynamic properties

Indoxacarb is an ectoparasiticide belonging to the oxadiazine chemical family. After being converted into a metabolite, indoxacarb is active against adult, larval and egg stages of insects. In fleas, in addition to its adulticidal activity, indoxacarb activity on the developing larval stages in the immediate surroundings of the treated pet has been demonstrated.

Indoxacarb is a pro-drug that requires bioactivation by the insect enzymes 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.

## 5.2 Pharmacokinetic particulars

Following a single spot-on application of the product, indoxacarb 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 is extensively metabolised by the liver to a variety of metabolites. The major route of excretion is in faeces.

**Environmental properties**

See section 6.6.

# 6. PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Triacetin
Ethyl acetoacetate
Isopropyl alcohol.

## 6.2 Incompatibilities

None known.

## 6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 4 years.

## 6.4 Special precautions for storage

This veterinary medicinal product does not require any special temperature storage conditions.
Store the pipettes in the original package in order to protect from moisture.

## 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 0.51 ml or 1.03 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 sachets.

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 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/2/10/118/011-014
EU/2/10/118/020-021

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18/02/2011.
Date of latest renewal: 07/01/2016.

## 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 S.A.
Rue de Lyons
27460 Igoville
France

## B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

For dogs: Veterinary medicinal product not subject to prescription.
For cats: Veterinary medicinal product 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 100 mg spot-on solution for very small dogs (1.5 - 6.5 kg)
Activyl 150 mg spot-on solution for small dogs (6.6 - 10 kg)
Activyl 300 mg spot-on solution for medium dogs (10.1 - 20 kg)
Activyl 600 mg spot-on solution for large dogs (20.1 - 40 kg)
Activyl 900 mg spot-on solution for extra large dogs (40.1 - 60 kg)

indoxacarb

## 2. STATEMENT OF ACTIVE SUBSTANCES

Indoxacarb 100 mg
Indoxacarb 150 mg
Indoxacarb 300 mg
Indoxacarb 600 mg
Indoxacarb 900 mg

## 3. PHARMACEUTICAL FORM

Spot-on solution

## 4. PACKAGE SIZE

1 pipette
4 pipettes
6 pipettes

## 5. TARGET SPECIES

Dogs 1.5 - 6.5 kg
Dogs 6.6 – 10 kg
Dogs 10.1 – 20 kg
Dogs 20.1 – 40 kg
Dogs 40.1 – 60 kg

## 6. INDICATION(S)

Treatment and prevention of flea infestations.

## 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 pipettes in the original packaging until ready to use.

## 10. EXPIRY DATE

EXP {month/year}

## 11. SPECIAL STORAGE CONDITIONS

Store in the original package in order to protect from moisture.

## 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/02/10/118/001
EU/02/10/118/002

EU/02/10/118/003
EU/02/10/118/004
EU/02/10/118/005
EU/02/10/118/006
EU/02/10/118/007
EU/02/10/118/008
EU/02/10/118/009
EU/02/10/118/010
EU/02/10/118/015
EU/02/10/118/016
EU/02/10/118/017
EU/02/10/118/018
EU/02/10/118/019

## 17. MANUFACTURER'S BATCH NUMBER

Batch {number}

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**CARTON BOX**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Activyl 100 mg spot-on solution for small cats (≤ 4 kg)
Activyl 200 mg spot-on solution for large cats (> 4 kg)

indoxacarb

## 2. STATEMENT OF ACTIVE SUBSTANCES

Indoxacarb 100 mg
Indoxacarb 200 mg

## 3. PHARMACEUTICAL FORM

Spot-on solution

## 4. PACKAGE SIZE

1 pipette
4 pipettes
6 pipettes

## 5. TARGET SPECIES

Cats ≤ 4 kg
Cats > 4 kg

## 6. INDICATION(S)

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

For spot-on use.

Apply to the skin only, at the base of the skull.
Read the package leaflet before use.

## 8. WITHDRAWAL PERIOD(S)

## 9. SPECIAL WARNING(S), IF NECESSARY

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

## 10. EXPIRY DATE

EXP {month/year}

## 11. SPECIAL STORAGE CONDITIONS

Store in the original package in order to protect from moisture.

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

Disposal: read package leaflet.
The veterinary product should not be allowed to enter surface waters.

## 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

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

## 16. MARKETING AUTHORISATION NUMBER(S)

EU/02/10/118/011
EU/02/10/118/012
EU/02/10/118/013
EU/02/10/118/014
EU/02/10/118/020
EU/02/10/118/021

## 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 100 mg spot-on for very small dogs
Activyl 150 mg spot-on for small dogs
Activyl 300 mg spot-on for medium dogs
Activyl 600 mg spot-on for large dogs
Activyl 900 mg spot-on for extra large dogs

indoxacarb

## 2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

100 mg
150 mg
300 mg
600 mg
900 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.

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**SACHET**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Activyl 100 mg spot-on for small cats
Activyl 200 mg spot-on for large cats

indoxacarb

## 2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

100 mg
200 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.

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**BLISTER (pipette label)**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Activyl 100 mg spot-on for dogs 1.5 - 6.5 kg
Activyl 150 mg spot-on for dogs 6.6 – 10 kg
Activyl 300 mg spot-on for dogs 10.1 – 20 kg
Activyl 600 mg spot-on for dogs 20.1 – 40 kg
Activyl 900 mg spot-on for dogs 40.1 – 60 kg

indoxacarb

## 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.

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**BLISTER (pipette label)**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Activyl 100 mg spot-on for cats ≤ 4 kg
Activyl 200 mg spot-on for cats > 4 kg

indoxacarb

## 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.

**B. PACKAGE LEAFLET**

**PACKAGE LEAFLET**
**Activyl 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 S.A.
Rue de Lyons
27460 Igoville
France

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Activyl 100 mg spot-on solution for very small dogs
Activyl 150 mg spot-on solution for small dogs
Activyl 300 mg spot-on solution for medium dogs
Activyl 600 mg spot-on solution for large dogs
Activyl 900 mg spot-on solution for extra large dogs
indoxacarb

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

**Active substance:**
One ml contains 195 mg indoxacarb.
One pipette of Activyl delivers:

| | Volume (ml) | Indoxacarb (mg) |
|---|---|---|
| Activyl for very small dogs (1.5 - 6.5 kg) | 0.51 | 100 |
| Activyl for small dogs (6.6 – 10 kg) | 0.77 | 150 |
| Activyl for medium dogs (10.1 – 20 kg) | 1.54 | 300 |
| Activyl for large dogs (20.1 – 40 kg) | 3.08 | 600 |
| Activyl for extra large dogs (40.1 – 60 kg) | 4.62 | 900 |

Also contains isopropyl alcohol 354 mg/ml.

A clear, colourless to yellow solution.

## 4. INDICATION(S)

Treatment and prevention of flea infestation (*Ctenocephalides felis*). Efficacy against new infestations with fleas persists for 4 weeks following a single application.
Developing stages of fleas in the pet's immediate surroundings are killed following contact with Activyl treated pets.

## 5. CONTRAINDICATIONS

None.

## 6. ADVERSE REACTIONS

In very rare cases, a brief period of hypersalivation (drooling) may occur if the animal licks the application site immediately after treatment. This is not a sign of intoxication and disappears within some minutes without treatment. Correct application (see section 9) will minimise licking of the application site.

In very rare cases, application site reactions such as transitory scratching, erythema (redness of skin), alopecia (loss of hair) or dermatitis (inflammation of the skin) at the application site may occur. These effects will usually resolve without treatment.

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 product.

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

If you notice any serious effects or other effects not mentioned in this package leaflet, 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 is 15 mg indoxacarb/kg body weight, equivalent to 0.077 ml/kg body weight. The following table defines the pipette to be used according to the weight of the dog:

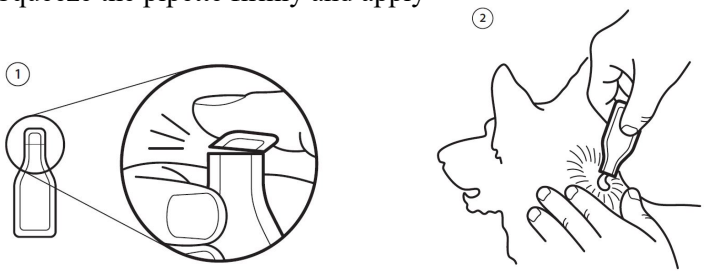
| Weight of dog (kg) | Pipette size to be used |
|---|---|
| 1.5 – 6.5 | Activyl 100 mg for very small dogs |
| 6.6 – 10 | Activyl 150 mg for small dogs |
| 10.1 – 20 | Activyl 300 mg for medium dogs |
| 20.1 – 40 | Activyl 600 mg for large dogs |
| 40.1 – 60 | Activyl 900 mg for extra large dogs |
| > 60 | The appropriate combination of pipettes should be used |

## 9. ADVICE ON CORRECT ADMINISTRATION

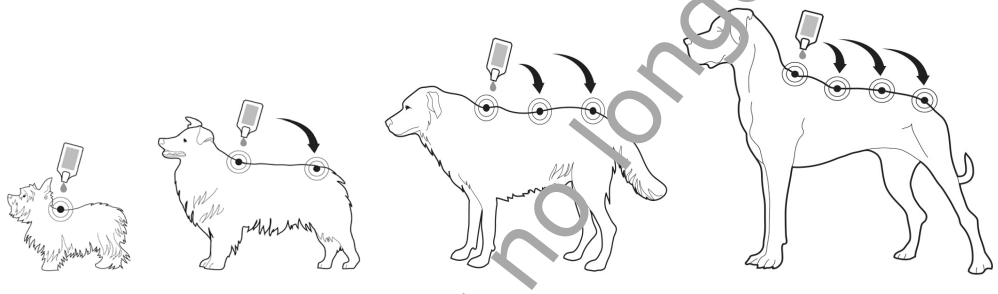
Open one sachet and remove the pipette.

**Step 1**: The dog should be standing for easy application. 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:** Part the hair until the skin is visible. Place the pipette tip against the skin between the shoulder blades. Squeeze the pipette firmly and apply the entire contents directly to the skin.




In larger dogs, the entire contents of the pipette(s) should be applied evenly to 2-4 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.



## 10. WITHDRAWAL PERIOD

Not applicable.

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special temperature storage conditions.
Store the pipettes in the original package in order to protect from moisture.
Do not use after the expiry date 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:
None.

Special precautions for use in animals:
The product should not be used in dogs younger than 8 weeks of age as the safety of the product has not been established in these dogs.

The product should not be used in dogs weighing less than 1.5 kg as the safety of the product has not been established in these dogs.

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

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

This product is for skin application on dogs only. Do not give the product by mouth or any other route. Care should be taken to avoid the product coming into contact with the dog's eyes.

The product remains effective following shampoo treatment, water immersion (swimming, bathing) and exposure to sunlight. However, dogs should not be allowed to swim or treated with shampoo within 48 hours after treatment.

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.

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. Used pipettes should be disposed of immediately.

People with known hypersensitivity to indoxacarb should avoid contact with this product.
Local and/or systemic reactions have been observed in some people after exposure. To avoid adverse reactions:

- administer the product in a well-ventilated area;
- do not handle recently 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;
- avoid contact with eyes, as the product may cause moderate eye irritation. If it occurs, the eyes should be rinsed slowly and gently with water.

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

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

Pregnancy and Fertility:
Do not use on pregnant dogs and breeding dogs.

Lactation:
Do not use on lactating dogs.

Interaction with other medicinal products and other forms of interaction:
In clinical studies, Activyl was co-administered with deltamethrin collars impregnated with up to 4% deltamethrin without evidence of associated adverse reactions.

Consult a veterinarian if you intend to use the product on dogs with other products or medication.

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

Medicines should not be disposed of via wastewater or household waste.
Activyl should not enter water courses as this may be dangerous for fish and other aquatic organisms.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

## 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 with 1, 4 or 6 sachets; each sachet contains one unit-dose pipette.

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.

**België/Belgique/Belgien:**
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**Sverige:**
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FR-06516 Carros,
Frankrike,
Tel: + 33 (0) 4 92 08 73 00

**United Kingdom:**
VIRBAC Ltd,
Suffolk IP30 9 UP – UK,
Tel: + 44 (0) 1359 243243

**PACKAGE LEAFLET**
**Activyl spot-on solution for cats**

## 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 S.A.
Rue de Lyons
27460 Igoville
France

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Activyl 100 mg spot-on solution for small cats
Activyl 200 mg spot-on solution for large cats
indoxacarb

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

**Active substance:**
One ml contains 195 mg indoxacarb.
One pipette of Activyl delivers:

| | **Volume (ml)** | **Indoxacarb (mg)** |
|---|---|---|
| Activyl for small cats (≤ 4 kg) | 0.51 | 100 |
| Activyl for large cats (> 4 kg) | 1.03 | 200 |

Also contains isopropyl alcohol 354 mg/ml.

A clear, colourless to yellow solution.

## 4. INDICATION(S)

Treatment and prevention of flea infestation (*Ctenocephalides felis*). Efficacy against new infestations with fleas persists for 4 weeks following a single application.
The veterinary medicinal product can be used as part of a treatment strategy for flea allergy dermatitis (FAD).
Developing stages of fleas in the pet's immediate surroundings are killed following contact with Activyl treated pets.

## 5. CONTRAINDICATIONS

None.

## 6. ADVERSE REACTIONS

In rare cases, neurological signs, such as incoordination, tremor (shakiness), ataxia (unsteady movement), convulsions, mydriasis (pupil dilation) and impaired vision, have been observed. Other signs observed include emesis (vomiting) in rare cases or anorexia (loss of appetite), lethargy (drowsiness), hyperactivity and vocalisation in very rare cases. All signs are generally reversible following supportive treatment.
In very rare cases, a brief period of hypersalivation (drooling) may occur if the cat licks the application site immediately after treatment. This is not a sign of intoxication and disappears within some minutes without treatment. Correct application (see section 9) will minimise licking of the application site.

In rare cases, application site reactions such as transitory scratching, erythema (redness of skin), alopecia (loss of hair) or dermatitis (inflammation of the skin) at the application site may occur. These effects will usually resolve without treatment.

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 product.

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

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

## 7. TARGET SPECIES

Cats.

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

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

The recommended dose is 25 mg indoxacarb/kg body weight, equivalent to 0.128 ml/kg body weight.
The following table defines the pipette to be used according to the weight of the cat:

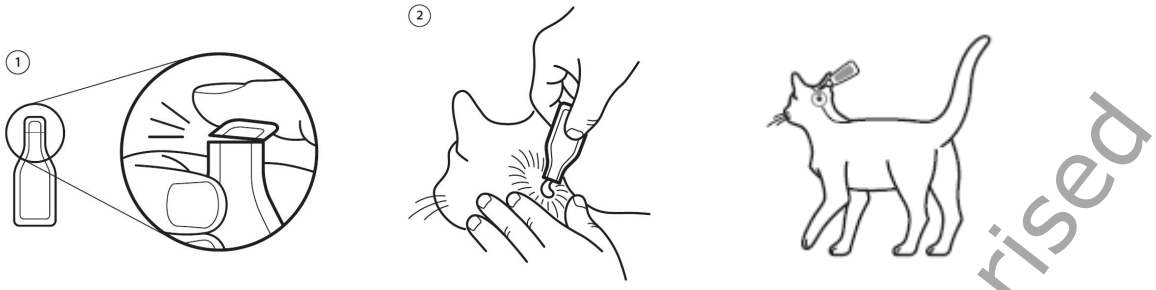
| Weight of cat (kg) | Pipette size to be used |
|---|---|
| ≤ 4 | Activyl 100 mg for small cats |
| > 4 | Activyl 200 mg for large cats |

## 9. ADVICE ON CORRECT ADMINISTRATION

Open one sachet and remove the pipette.

**Step 1**: The cat should be standing for easy application. 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:** Part the hair until the skin is visible. Place the pipette tip against the skin at the base of the skull, where the cat cannot lick it off. Squeeze the pipette firmly and apply the entire contents directly to the skin.




## 10. WITHDRAWAL PERIOD

Not applicable.

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special temperature storage conditions. Store the pipettes in the original package in order to protect from moisture.
Do not use after the expiry date 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 safety of the product has not been established in cats younger than 8 weeks of age.
The safety of the product has not been established in cats weighing less than 0.6 kg.

Special precautions for use in animals:
Ensure that the dosage (pipette) corresponds to the weight of the treated cat (see section 8).

Apply the product only to the skin surface and on intact skin. Apply the dose to an area where the cat cannot lick it off and ensure that animals do not groom each other following treatment. Keep treated animals separately until the application site is dry.

This product is for skin application on cats only. Do not give the product by mouth or any other route. Care should be taken to avoid the product coming into contact with the cat's eyes.

The product remains effective following shampoo treatment, water immersion (swimming, bathing) and exposure to sunlight. However, cats should not be allowed to swim or treated with shampoo within 48 hours after treatment.

All cats 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.

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, to prevent children from getting direct access to the product. Used pipettes should be disposed of immediately.

People with known hypersensitivity to indoxacarb should avoid contact with this product.
Local and/or systemic reactions have been observed in some people after exposure. To avoid adverse reactions:

- administer the product in a well-ventilated area;
- do not handle recently 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;
- avoid contact with eyes, as the product may cause moderate eye irritation. If it occurs, the eyes should be rinsed slowly and gently with water.

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

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

Pregnancy and Fertility:
Do not use on pregnant cats and breeding cats.

Lactation:
Do not use on lactating cats.

Interaction with other medicinal products and other forms of interaction:
Consult a veterinarian if you intend to use the product on cats with other products or medication.

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

Medicines should not be disposed of via wastewater or household waste.
Activyl should not enter water courses as this may be dangerous for fish and other aquatic organisms.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

## 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

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

## 15. OTHER INFORMATION

Cardboard box with 1, 4 or 6 sachets; each sachet contains one unit-dose pipette.

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.

**België/Belgique/Belgien:**
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