ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Exzolt 10 mg/ml solution for use in drinking water for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Each ml contains 10 mg fluralaner.

Excipients:

Qualitative composition of excipients and other constituents
Alpha-tocopherol (all-*rac*-*alpha*-tocopherol)
Diethylene glycol monoethyl ether
Polysorbate 80

Light yellow to dark yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Chickens (pullets, chickens for reproduction and layer hens).

3.2 Indications for use for each target species

Treatment of poultry red mite (*Dermanyssus gallinae*) infestation in pullets, chickens for reproduction and layer hens.

3.3 Contraindications

None.

3.4 Special warnings

Unnecessary use of antiparasitics or use deviating from the instructions given may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of infestation based on its epidemiological features for each flock.

The following practices should be avoided because they increase the risk of development of resistance and could ultimately result in ineffective therapy:
- too frequent and repeated use of acaricides from the same class, over an extended period of time,
- underdosing, which may be due to underestimation of body weight, misadministration of the product, or lack of calibration of the volume measuring device.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Strict biosecurity measures at house and farm level should be implemented to prevent re-infestation of treated houses. To ensure long term control of the mite populations in a treated house, it is essential to treat any other infested poultry in houses in proximity to the treated one.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The veterinary medical product may be slightly irritating to skin and/or eyes.
Avoid contact with skin, eyes and mucous membranes.
Do not eat, drink or smoke while handling the product.
Wash hands and contacted skin with soap and water after use of the product.
In case of eye contact, immediately rinse thoroughly with water.
If the product is spilled, remove any affected clothes.

Special precautions for the protection of the environment:
Medicated drinking water should not enter surface waters.

3.6 Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See also the last section of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has been demonstrated in layers and breeders. The product can be used during lay.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

For use in drinking water.

The dose is 0.5 mg fluralaner per kg body weight (equivalent to 0.05 ml of product) administered twice, 7 days apart. The complete course of treatment must be administered for a full therapeutic effect.

If another course of treatment is indicated, the interval between two courses of treatment should be at least 3 months.

Determine the duration of time (between 4 and 24 hours) over which to administer the medicated water on the treatment day. This period of time must be long enough to allow all the birds to receive the required dose. Estimate how much water birds will consume during treatment based on the previous day's water consumption. The product should be added to a volume of water that the chickens will consume in one day. No other source of drinking water should be available during the medication period.

Calculate the volume of product needed based on the total weight of all birds in the house to be treated. To ensure administration of the correct dose, the body weight should be determined as accurately as possible, and an accurate measuring device should be used for measuring the calculated volume of the product to be administered.

The required volume of product for each treatment day is calculated from the total body weight (kg) of the entire group of chickens to be treated:

Volume of product (ml) per treatment day = Total body weight (kg) of chickens to be treated x 0.05 ml/kg

Therefore 500 ml of product treats 10,000 kg body weight (e.g., 5,000 chickens of 2 kg body weight each) per day of treatment administration.

The instructions below need to be followed, in the order described, to prepare the medicated water:

- Check the water system to ensure it works properly and is free of leaks; also ensure that water is available to all nipple or bell drinkers.
- For each day of treatment, medicated water must be freshly prepared.
    - Mix the required volume of the product with water into a large medication tank or create a stock solution in a small container. The stock solution must be further diluted with drinking water and administered over time, using a proportioner or dosing pump. Always add product and water simultaneously in order to avoid foaming. It is important to rinse the measuring device used to measure the required product volume during the filling phase in order to ensure that the complete dose is emptied into the medication tank or the stock solution and that no residues remain in the measuring device. Stir the stock solution or the content of the medication tank gently until the medicated water is homogeneous. Connect the medication tank or the proportioner or dosing pump to the drinking water system.
- Make sure the dosing pump is properly set to deliver the medicated water during the predetermined treatment period (hours).
- Prime the drinker lines with medicated water and check to see when medicated water has reached the end of the line. This procedure should be repeated on each day of administration.

After each treatment administration, fill the stock solution container with clean (unmedicated) water to rinse the water lines.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No adverse reactions were observed following the treatment of 3-week old and adult chickens dosed with up to 5 times the recommended dose for 3 times the recommended duration of treatment.
No negative effects on egg production were observed when layer hens were treated with up to 5 times the recommended dose for 3 times the recommended duration of treatment.
There were no adverse effects on reproductive performance when breeding chickens were treated with 3 times the recommended dose for twice the recommended duration of treatment.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: 14 days.
Eggs: zero days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP53BE02.

4.2 Pharmacodynamics

Fluralaner is an acaricide and an insecticide which has a high potency against poultry mites, mostly by exposure via feeding, i.e. it is systemically active against the target parasites.

Fluralaner is a potent inhibitor of parts of the arthropod nervous system by acting antagonistically on ligand-gated chloride channels (GABA-receptor and glutamate-receptor). In molecular on-target studies on insect gamma-aminobutyric acid (GABA) receptors of flea and fly, dieldrin resistance does not affect fluralaner.

The onset of activity against *Dermanyssus gallinae* is within four hours of the mites starting to feed on treated chickens.

The treatment kills mites feeding on treated chickens and stops egg production from female mites for 15 days after the first administration of the product. This activity breaks the mite life cycle.

In vitro bio-assays show that fluralaner is effective against parasites having proven field resistance, including organophosphates, pyrethroids and carbamates.

As demonstrated in a multi-site EU field study performed in commercial egg production farms, elimination of mites from infested chickens following treatment is associated with a statistically significant improvement in behavioural parameters indicative of animal welfare (reduction of night-time activity and head scratching, head shaking and preening of own plumage at night and during day-time) as well as a reduction of blood corticosterone concentration.

4.3 Pharmacokinetics

After oral administration, fluralaner is absorbed rapidly from the medicated drinking water, reaching maximum plasma concentrations 36 hours after the first dose and 12 hours after the second dose. The bioavailability is high, with approximately 91% of the dose absorbed following oral administration. Fluralaner is highly bound to protein. Fluralaner is widely distributed throughout the body, with the highest concentrations reported in the liver and skin/fat. No significant metabolites are observed in chickens, and fluralaner is mainly eliminated via the hepatic route. The apparent elimination half-life is approximately 5 days following oral administration.

Environmental properties
Fluralaner has been shown to be very persistent in soil under both, aerobic and anaerobic conditions. Fluralaner degrades in aquatic sediment under anaerobic conditions while it has been shown to be very persistent under aerobic conditions.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 1 year.
Shelf life of the medicated drinking water: 24 hours.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.
After first opening of the 4 ml bottle, store it in upright position.

5.4 Nature and composition of immediate packaging

Colourless high density polyethylene (HDPE) bottle closed with an aluminium/polyester foil seal and a blue child-resistant polypropylene screw cap (1 litre and 4 litre presentations)
or type III amber glass bottle with a white polypropylene/polyethylene (PP/PE) child-proof screw cap with expanded low density PE/aluminium foil/ PE faced liner (50 ml presentation)
or type III amber glass bottle with a white polyethylene (PE) child-proof screw cap with aluminium foil/PE/aluminium foil liner and a white polyethylene (PE)/polypropylene (PP) child-proof screw cap with PE PIBA (4 ml presentation).
Pack sizes: bottles of 4 ml, 50 ml, 1 litre or 4 litres.
Not all pack sizes may be marketed.

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

Medicines should not be disposed via wastewater.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.
The veterinary medicinal product should not enter water courses as this may be dangerous for aquatic invertebrates.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/17/212/001-004

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 18/08/2017

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{DD/MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database.

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX (4-ml presentation)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Exzolt 10 mg/ml solution for use in drinking water for chickens

2. STATEMENT OF ACTIVE SUBSTANCES

10 mg/ml fluralaner

3. PACKAGE SIZE

4 ml

4. TARGET SPECIES

For use in chickens (pullets, chickens for reproduction and layer hens).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Solution for use in drinking water

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 14 days
Eggs: 0 days

8. EXPIRY DATE

Exp {mm/yyyy}

Once opened, store in upright position and use within 1 year.
Once diluted use within 24 hours.

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

14. MARKETING AUTHORISATION NUMBERS

EU/2/17/212/004

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX (50-ml presentation)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Exzolt 10 mg/ml solution for use in drinking water for chickens

2. STATEMENT OF ACTIVE SUBSTANCES

10 mg/ml fluralaner

3. PACKAGE SIZE

50 ml

4. TARGET SPECIES

For use in chickens (pullets, chickens for reproduction and layer hens).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For use in drinking water.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 14 days
Eggs: 0 days

8. EXPIRY DATE

Exp {mm/yyyy}

Once opened, use within 1 year.
Once diluted use within 24 hours.

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

14. MARKETING AUTHORISATION NUMBERS

EU/2/17/212/003

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BOTTLE LABEL (4-ml presentation)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Exzolt

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

10 mg/ml fluralaner

4 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp {mm/yyyy}
Once opened, store in upright position and use within 1 year. Once diluted, use within 24 hours.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BOTTLE LABEL (50-ml presentation)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Exzolt

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

10 mg/ml fluralaner

50 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp {mm/yyyy}
Once opened, use within 1 year. Once diluted, use within 24 hours.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Bottle (1 and 4-litre presentations) *[text appearing on label as no carton box will be used]*

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Exzolt 10 mg/ml solution for use in drinking water for chickens

2. STATEMENT OF ACTIVE SUBSTANCES

10 mg/ml fluralaner

3. PACKAGE SIZE

1 litre
4 litres

4. TARGET SPECIES

For use in chickens (pullets, chickens for reproduction and layer hens).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For use in drinking water.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 14 days.
Eggs: zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within 1 year.
Once diluted use within 24 hours.

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

14. MARKETING AUTHORISATION NUMBERS

EU/2/17/212/001 (1 litre)
EU/2/17/212/002 (4 litres)

15. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET (4- and 50-ml presentations):

1. Name of the veterinary medicinal product

Exzolt 10 mg/ml solution for use in drinking water for chickens

2. Composition

Active substance:
Each ml contains 10 mg fluralaner.

Light yellow to dark yellow solution.

3. Target species

Chickens (pullets, chickens for reproduction and layer hens).

4. Indications for use

Treatment of poultry red mite (*Dermanyssus gallinae*) infestation.

5. Contraindications

None.

6. Special warnings

Special warnings:
Unnecessary use of antiparasitics or use deviating from the instructions given may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of infestation based on its epidemiological features for each flock.

The following practices should be avoided because they increase the risk of development of resistance and could ultimately result in ineffective therapy:
- too frequent and repeated use of acaricides from the same class, over an extended period of time
- underdosing, which may be due to underestimation of body weight, misadministration of the product, or lack of calibration of the volume measuring device.

Special precautions for safe use in the target species:
To ensure long term control of the mite populations in a flock, suitable measures should be implemented to prevent re-infestation of the treated flock. It is essential to avoid any contact to potentially infested birds and to treat any other infested poultry in flocks in proximity to the treated one.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The veterinary medicinal product may be slightly irritating to skin and/or eyes.
Avoid contact with skin, eyes and mucous membranes.
Do not eat, drink or smoke while handling the product.
Wash hands and contacted skin with soap and water after use of the product.

In case of eye contact, immediately rinse thoroughly with water.
If the product is spilled, remove any affected clothes.

Special precautions for the protection of the environment:
Medicated drinking water should not enter surface waters.

Laying birds:
The safety of the veterinary medicinal product has been demonstrated in layers and breeders. The product can be used during lay.

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

Overdose:
Safety was demonstrated in 3-week-old and adult chickens treated with overdoses of up to 5 times the recommended dose for 3 times the recommended duration of treatment.
No negative effects on egg production were observed when layer hens were treated with overdoses of up to 5 times the recommended dose for 3 times the recommended duration of treatment.
There were no adverse effects on reproductive performance when breeding chickens were treated with overdoses of 3 times the recommended dose for twice the recommended duration of treatment.

Major incompatibilities:
In the absence of compatibility studies, do not mix this veterinary medicinal product with other veterinary medicinal products.

Environmental properties:
Fluralaner has been shown to be very persistent in soil under both, aerobic and anaerobic conditions. Fluralaner degrades in aquatic sediment under anaerobic conditions while it has been shown to be very persistent under aerobic conditions.

7. Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

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

For use in drinking water.

The dose is 0.5 mg fluralaner per kg body weight (equivalent to 0.05 ml of solution) administered twice, 7 days apart. The complete course of treatment must be administered for a full therapeutic effect. If another course of treatment is indicated, the interval between two courses of treatment should be at least 3 months.

9. Advice on correct administration

Determine the duration of time (between 4 and 24 hours) over which to administer the medicated water on the treatment day. This period of time must be long enough to allow all the birds to receive the required dose. Estimate how much water birds will consume during treatment based on the

previous day's water consumption. The product should be added to a volume of water that the chickens will consume in one day. No other source of drinking water should be available during the medication period.

Calculate the volume of product needed based on the total weight of all birds to be treated. To ensure administration of the correct dose, the body weight should be determined as accurately as possible and the calculated volume of the product to be administered should be measured as accurately as possible.

The required volume of product for each treatment day is calculated from the total body weight (kg) of the entire group of chickens to be treated:

Volume of product (ml) per treatment day = Total body weight (kg) of chickens to be treated x 0.05 ml/kg

As an example, 1 ml of product treats 20 kg body weight (e.g., 10 chickens of 2 kg body weight each) per day of administration. A full treatment consists of two administrations, 7 days apart.

The instructions below need to be followed to prepare the medicated water:

- Check that the water system functions properly and is free of leaks
- For each day of treatment, medicated water must be freshly prepared.
    - Mix the required volume of the product with the determined amount of water in a measuring device.
    - Add product and water simultaneously in order to avoid foaming.
    - Stir stock solution gently but thoroughly until the medicated water is homogeneous.
    - It is important to rinse the measuring device to ensure that the complete dose is provided to the chickens and that no residues remain. Add the rinse water to the drinkers.
    - Ensure that medicated water is evenly divided to all drinkers.

10. Withdrawal periods

Meat and offal: 14 days.
Eggs: zero days.

11. Special storage precautions

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
After first opening of the 4 ml bottle, store it in upright position.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp.
Shelf life after first opening the container: 1 year.
Shelf life after dilution according to directions: 24 hours.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems.
This veterinary medicinal product should not enter water courses as fluralaner may be dangerous for aquatic invertebrates.

These measures should help to protect the environment. Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/17/212/001-004
One bottle of 4 ml, 50 ml, 1 litre or 4 litres.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{DD/MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database.

16. Contact details

Marketing authorisation holder:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

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

Contact details to report suspected adverse reactions:

België/Belgique/Belgien
MSD Animal Health Belgium BV-SRL
Tél/Tel: + 32 (0)2 370 94 01

Република България
Intervet International B.V.
Тел: + 359 28193749

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Intervet s.r.o.
Tel: + 420 233 010 242

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MSD Animal Health A/S
Tlf: + 45 44 82 42 00

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Intervet International B.V.
Tel: + 37052196111

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MSD Animal Health Belgium BV-SRL
Tél/Tel: + 32 (0)2 370 94 01

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Intervet Hungaria Kft./ Intervet Hungaria Értékesítő Kft.
Tel.: + 36 1 439 4597

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Tel: + 39 02 516861

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France
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România
Intervet Romania S.R.L.
Tel: + 40 21 311 83 11

Slovenija
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Tel: + 385 1 6611339

Slovenská republika
Intervet s.r.o.
Tel: + 420 233 010 242

Suomi/Finland
MSD Animal Health Oy
Puh/Tel: + 358 10 2310 750

Sverige
MSD Animal Health Sweden AB
Tel: + 46 (0)8 522 216 60

United Kingdom (Northern Ireland)
Intervet (Ireland) Limited
Tel: + 353 (0) 1 2970220

PACKAGE LEAFLET (1- and 4-litre presentation):

1. Name of the veterinary medicinal product

Exzolt 10 mg/ml solution for use in drinking water for chickens

2. Composition

Active substance:
Each ml contains 10 mg fluralaner.

Light yellow to dark yellow solution.

3. Target species

Chickens (pullets, chickens for reproduction and layer hens).

4. Indications for use

Treatment of poultry red mite (*Dermanyssus gallinae*) infestation.

5. Contraindications

None.

6. Special warnings

Special warnings:
Unnecessary use of antiparasitics or use deviating from the instructions given may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of infestation based on its epidemiological features for each flock.

The following practices should be avoided because they increase the risk of development of resistance and could ultimately result in ineffective therapy:
- too frequent and repeated use of acaricides from the same class, over an extended period of time
- underdosing, which may be due to underestimation of body weight, misadministration of the product, or lack of calibration of the volume measuring device.

Special precautions for safe use in the target species:
Strict biosecurity measures at house and farm level should be implemented to prevent re-infestation of treated houses. To ensure long term control of the mite populations in a treated house, it is essential to treat any other infested poultry in houses in proximity to the treated one.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The veterinary medicinal product may be slightly irritating to skin and/or eyes.
Avoid contact with skin, eyes and mucous membranes.
Do not eat, drink or smoke while handling the product.
Wash hands and contacted skin with soap and water after use of the product.
In case of eye contact, immediately rinse thoroughly with water.

If the product is spilled, remove any affected clothes.

Special precautions for the protection of the environment:
Medicated drinking water should not enter surface waters.

Laying birds:
The safety of the veterinary medicinal product has been demonstrated in layers and breeders. The product can be used during lay.

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

Overdose:
Safety was demonstrated in 3-week-old and adult chickens treated with overdoses of up to 5 times the recommended dose for 3 times the recommended duration of treatment.
No negative effects on egg production were observed when layer hens were treated with overdoses of up to 5 times the recommended dose for 3 times the recommended duration of treatment.
There were no adverse effects on reproductive performance when breeding chickens were treated with overdoses of 3 times the recommended dose for twice the recommended duration of treatment.

Major incompatibilities:
In the absence of compatibility studies, do not mix this veterinary medicinal product with other veterinary medicinal products.

Environmental properties:
Fluralaner has been shown to be very persistent in soil under both, aerobic and anaerobic conditions. Fluralaner degrades in aquatic sediment under anaerobic conditions while it has been shown to be very persistent under aerobic conditions.

7. Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

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

For use in drinking water.

The dose is 0.5 mg fluralaner per kg body weight (equivalent to 0.05 ml of solution) administered twice, 7 days apart. The complete course of treatment must be administered for a full therapeutic effect. If another course of treatment is indicated, the interval between two courses of treatment should be at least 3 months.

9. Advice on correct administration

Determine the duration of time (between 4 and 24 hours) over which to administer the medicated water on the treatment day. This period of time must be long enough to allow all the birds to receive the required dose. Estimate how much water birds will consume during treatment based on the previous day’s water consumption. The product should be added to a volume of water that the

chickens will consume in one day. No other source of drinking water should be available during the medication period.

Calculate the volume of product needed based on the total weight of all birds in the house to be treated. To ensure administration of the correct dose, the body weight should be determined as accurately as possible and an accurate measuring device should be used for measuring the calculated volume of the product to be administered.

The required volume of product for each treatment day is calculated from the total body weight (kg) of the entire group of chickens to be treated:

Volume of product (ml) per treatment day = Total body weight (kg) of chickens to be treated x 0.05 ml/kg

Therefore 500 ml of product treats 10,000 kg body weight (e.g., 5,000 chickens of 2 kg body weight each) per day of treatment administration.

The instructions below need to be followed, in the order described, to prepare the medicated water:

- Check the water system to ensure it works properly and is free of leaks; also ensure that water is available to all nipple or bell drinkers.
- For each day of treatment, medicated water must be freshly prepared.
  - Mix the required volume of the product with water into a large medication tank or create a stock solution in a small container. The stock solution must be further diluted with drinking water and administered over time, using a proportioner or dosing pump. Always add product and water simultaneously in order to avoid foaming. It is important to rinse the measuring device used to measure the required product volume during the filling phase in order to ensure that the complete dose is emptied into the medication tank or the stock solution and that no residues remain in the measuring device. Stir the stock solution or the content of the medication tank gently until the medicated water is homogeneous. Connect the medication tank or the proportioner or dosing pump to the drinking water system.
- Make sure the dosing pump is properly set to deliver the medicated water during the predetermined treatment period (hours).
- Prime the drinker lines with medicated water and check to see when medicated water has reached the end of the line. This procedure should be repeated on each day of administration.

After each treatment administration, fill the stock solution container with clean (unmedicated) water to rinse the water lines.

10. Withdrawal periods

Meat and offal: 14 days.
Eggs: zero days.

11. Special storage precautions

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp.
Shelf life after first opening the container: 1 year.
Shelf life after dilution according to directions: 24 hours.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.
This veterinary medicinal product should not enter water courses as fluralaner may be dangerous for aquatic invertebrates.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems.
These measures should help to protect the environment. Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/17/212/001-004
One bottle of 4 ml, 50 ml, 1 litre or 4 litres.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{DD/MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database.

16. Contact details

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

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

Contact details to report suspected adverse reactions:

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