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 AND OTHER SUBSTANCES

10 mg/ml fluralaner

3. PACKAGE SIZE

4 ml
4 syringes

4. TARGET SPECIES

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

5. INDICATION(S)

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 diluted use within 24 hours.
Once opened, use by:

9. SPECIAL STORAGE PRECAUTIONS

Once opened do not store above 30°C.
Once opened store in upright position and use within 1 year.
Keep the bottle in the outer carton.

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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
MK7 7AJ

14. MARKETING AUTHORISATION NUMBERS

Vm 01708/5036

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V

To be supplied only on veterinary prescription

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 AND OTHER 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. INDICATION(S)

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.
Once opened, use by:

9. SPECIAL STORAGE PRECAUTIONS

Keep the bottle in the outer carton.

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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
MK7 7AJ

14. MARKETING AUTHORISATION NUMBERS

Vm 01708/5036

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V

To be supplied only on veterinary prescription

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BOTTLE LABEL (4-ml presentation)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Exzolt

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

10 mg/ml fluralaner

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.

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

4 ml

6. ROUTE(S) OF ADMINISTRATION

7. WITHDRAWAL PERIOD

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BOTTLE LABEL (50-ml presentation)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Exzolt

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

10 mg/ml fluralaner

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

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

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

50 ml

6. ROUTE(S) OF ADMINISTRATION

7. WITHDRAWAL PERIOD

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle (1 and 4-litre presentations)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

10 mg/ml fluralaner

3. TARGET SPECIES

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

4. ROUTES OF ADMINISTRATION

For use in drinking water.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

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

6. EXPIRY DATE

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

7. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

8. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
MK7 7AJ

9. BATCH NUMBER

Lot {number}

10. PACKAGE SIZE

1 litre
4 litres

11. INDICATION(S)

12. SPECIAL WARNING(S), IF NECESSARY

13. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

For animal treatment only.

15. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/5036

PARTICULARS TO APPEAR ON THE 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 WARNING(S)

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 (symptoms, emergency procedures, antidotes):
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, ROUTE(S) 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.
- At time of initial use, remove the original cap from the bottle and discard it. Twist on the in-use cap provided in the carton box. Doing so will permanently insert the syringe adaptor into the neck of the bottle.

- To dose:
    - Remove the in-use cap.
    - Attach a 1-ml dosing syringe to the bottle by gently pushing the end of the syringe into the syringe adapter.
    - Turn the bottle/syringe upside down. Pull down on the plunger to withdraw the correct dose volume. If any air bubbles are seen in the syringe, push them out and pull down again on the plunger until the correct volume is withdrawn.
    - Turn the bottle/syringe upright. Remove the syringe from the syringe adaptor.
    - Replace the in-use cap.
    - Administer the dose in the drinking water.

10. WITHDRAWAL PERIOD(S)

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. The expiry date refers to the last day of that month.

Shelf life after first opening the container: 1 year.
Shelf life after dilution according to directions: 24 hours.

50 ml, 1 litre and 4 litre bottles: This veterinary medicinal product does not require any special storage conditions.
4ml bottle: After first opening of the 4 ml bottle, do not store above 30°C and, store in an upright position and use within 6 months.

When the container is broached/opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided.

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

Vm 01708/5036
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

September 2023

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

16. CONTACT DETAILS

Marketing authorisation holder:
MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

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

Contact details to report suspected adverse reactions:

UK(GB)	UK(NI)
MSD Animal Health UK Ltd.	Intervet Ireland Ltd.
Tel.: +44 (0)1908 685685	Tel.: +353 (0)1 2970220

17. OTHER INFORMATION

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET
(1- and 4-litre 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 WARNING(S)

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, ROUTE(S) 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 PERIOD(S)

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. The expiry date refers to the last day of that month.
Shelf life after first opening the container: 1 year.
Shelf life after dilution according to directions: 24 hours.
When the container is broached/opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided.

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

Vm 01708/5036
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

September 2023

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

16. CONTACT DETAILS

Marketing authorisation holder:
MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

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

Contact details to report suspected adverse reactions:

UK(GB)	UK(NI)
MSD Animal Health UK Ltd.	Intervet Ireland Ltd.
Tel.: +44 (0)1908 685685	Tel.: +353 (0)1 2970220

17. OTHER INFORMATION

Approved 07 September 2023