PARTICULARS TO APPEAR ON THE OUTER PACKAGE {1 L & 5 L Carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Startect Dual Active oral solution.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Derquantel 10 mg/ml and abamectin 1 mg/ml.

3. PACKAGE SIZE

1 L
5 L

4. TARGET SPECIES

Sheep.

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Oral solution.

7. WITHDRAWAL PERIODS

Withdrawal period:

Meat and offal: 14 days.
Milk: Not authorised for use in animals producing milk for human consumption.

8. EXPIRY DATE

Exp {mm/yyyy}
Once opened use within 1 year.

9. SPECIAL STORAGE PRECAUTIONS

Do not refrigerate or freeze.
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

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

14. MARKETING AUTHORISATION NUMBERS

Vm 42058/5099

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

Disposal: read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-VPS

To be supplied only on veterinary prescription.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {1 L & 5 L label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Startect Dual Active oral solution.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Derquantel 10 mg/ml and abamectin 1 mg/ml.

3. TARGET SPECIES

Sheep.

4. ROUTES OF ADMINISTRATION

Oral solution.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period(s):

Meat and offal: 14 days.
Milk: Not authorised for use in animals producing milk for human consumption.

6. EXPIRY DATE

Exp {mm/yyyy}
Once broached use by …
Once opened use within 1 year.

7. SPECIAL STORAGE PRECAUTIONS

Do not refrigerate or freeze.
Keep the bottle in the outer carton.

8. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

9. BATCH NUMBER

Lot {number}

10. PACKAGE SIZE

1 L
5 L

11. INDICATION(S)

12. SPECIAL WARNING(S), IF NECESSARY

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

Disposal: Read package leaflet.

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

POM-VPS

To be supplied only on veterinary prescription.

15. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/5099

MINIMUM PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE THERE IS NO PACKAGE LEAFLET, I.e. Combined label and package leaflet {15 L label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Startect Dual Active oral solution for sheep

2. COMPOSITION

Derquantel 10 mg/ml and abamectin 1 mg/ml. The solution also contains the following excipient: butylated hydroxytoluene (0.5 mg/ml).

Oral solution.
A clear to hazy, colourless to yellow-brown solution.

3. PACKAGE SIZE

15 L

4. TARGET SPECIES

Sheep.

5. INDICATIONS FOR USE

Startect Dual Active is a broad spectrum anthelmintic for the treatment and control of mixed gastro-intestinal nematode infections and associated diseases of sheep. The spectrum of activity is as follows:

Adult and Immature Gastro-intestinal Nematodes:
Haemonchus contortus, Teladorsagia (Ostertagia) circumcincta*,Teladorsagia (Ostertagia) trifurcata, Trichostrongylus axei,Trichostrongylus colubriformis,Trichostrongylus vitrinus, Cooperia curticei, Cooperia oncophora, Nematodirus spathiger, Nematodirus filicollis, Nematodirus battus, Strongyloides papillosus, Oesophagostomum venulosum[1], Trichuris ovis, Chabertia ovina*

Lungworms:
Dictyocaulus filaria[1]
* - including inhibited larval stages, [1] – adults only

This product is effective against strains of parasites resistant to benzimidazoles, levamisole, macrocyclic lactones, and combinations of these.

6. CONTRAINDICATIONS

Do not use in horses as severe adverse reactions, including fatalities, will occur.
Do not use in dogs as severe adverse reactions may occur.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

Do not exceed the recommended dose rate.

7. SPECIAL WARNINGS

Special warnings:
Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:

- Underdosing, which may be due to underestimation of bodyweight, misadministration of the product or lack of calibration of the dosing device.
- Too frequent and repeated use of anthelmintics from the same class over an extended period of time.

Assess bodyweight as accurately as possible before calculating dosage. Suspected clinical cases of resistance should be further investigated using the appropriate tests, e.g. (Faecal Egg Count Reduction Test). Where the results of the test(s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

Special precautions for safe use in the target species:
The recommended dose of Startect Dual Active is 0.2 ml/kg; doses of 0.9 ml/kg and higher (4.5X the recommended dose) can cause symptoms of toxicity and may lead to fatalities.
If animals are batched for dosing, careful consideration should be given to the weight range within each group to avoid the risk of overdosing smaller animals. Do not under dose. A representative sample of animals should be weighed before treatment.
Accuracy and proper functioning of the dosage device should be checked.
The safety of Startect Dual Active has not been established in sheep under six weeks of age or weighing less than 10 kg.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Do not eat, smoke or drink while handling the product.
Personal protective equipment consisting of impermeable rubber gloves should be worn when handling the veterinary medicinal product.
Avoid ingestion, inhalation and eye and skin contact. Wash hands after handling the product. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
In case of accidental eye or skin contact, wash affected areas immediately with clean running water and seek medical attention if irritation persists.

Special precautions for the protection of the environment:
The product is toxic to dung insects. It is excreted mainly in faeces and it cannot be excluded that insects using dung excreted after treatment may be adversely affected. Using the product strictly as recommended will keep this risk to a minimum.

Other precautions:
None.

Pregnancy and lactation:
Can be used in pregnant and lactating animals.

Fertility:
Can be used in breeding animals.

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

Overdose:
Doses of 0.9 ml/kg and higher have been associated with symptoms of toxicity. Signs of toxicity include dullness, depression, incoordination, weakness, decreased gastrointestinal motility and abnormal breathing pattern, recumbency and death. Non-fatal adverse events have been shown to be fully reversible. Supportive veterinary care is indicated; there is no known antidote.

Special restrictions for use and special conditions for use:
Not applicable.

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

8. ADVERSE REACTIONS

Sheep:

Very common (>1 animal / 10 animals treated):
coughing[1]

[1]Mild and transient.

- Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, 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 marketing authorisation holder using the contact details on this label, or via your national reporting system.

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

Startect Dual Active is a ready-to-use oral solution.
The dose for sheep is 2 mg derquantel and 0.2 mg abamectin per kg bodyweight. i.e. 1 ml of product per 5 kg bodyweight.

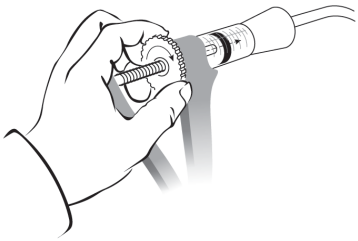
10. ADVICE ON CORRECT ADMINISTRATION

Drench sheep orally, using a drench gun with silicone sealed ‘o’ rings. Check dose rates and the accuracy of the drench gun before treatment commences.
Do not under-or over-dose. To ensure a correct dosage, body weight should be determined as accurately as possible. If animals are to be treated collectively rather

than individually, they should be grouped according to their bodyweight and dosed accordingly.

Set the dosing gun to deliver the correct dose volume for the weight of sheep to be treated (see figure 1).

Figure 1



Gently place the nozzle of the drench gun over the back of the tongue and depress the trigger (see figure 2).

Figure 2

11. WITHDRAWAL PERIOD

Meat and offal: 14 days.
Milk: Not authorised for use in animals producing milk for human consumption.

12. SPECIAL STORAGE PRECAUTIONS

Do not refrigerate or freeze.
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.
When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this label, the date on which any product remaining in the bottle should be discarded should be worked out. This discard date should be written in the space provided.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater or household waste.

This veterinary medicinal product should not enter water courses as abamectin is extremely dangerous for fish and other aquatic organisms.

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

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

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

POM-VPS

To be supplied only on veterinary prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 42058/5099

Purple square bottom backpack HDPE polymer bottles (1 L and 5 L) with draw off tubes (white LDPE, tube with EDPM valve) and child resistant lids. Purple jerrycan, (15 L) HDPE polymer, with white cap. 15 L jerrycan has polypropylene tap with O-ring silicone seal with tamper proof lid.

Pack sizes
1 L, 5 L and 15 L multi-dose packs.

Not all pack sizes may be marketed.

16. DATE ON WHICH THE LABEL WAS LAST REVISED

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

17. CONTACT DETAILS

Marketing authorisation holder and contact details to report suspected adverse reactions:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Manufacturer responsible for batch release:
Zoetis Belgium
Rue Laid Burniat 1
1348 Louvain-La-Neuve
Belgium

18. OTHER INFORMATION

19. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

20. EXPIRY DATE

Exp: {mm/yyyy}
Once opened use within 1 year.
Once broached use by:

21. BATCH NUMBER

Lot {number}

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

Keep out of the sight and reach of children.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Startect Dual Active oral solution for sheep

2. COMPOSITION

Each ml contains:

Active substances:

Derquantel 10 mg
Abamectin 1.0 mg

Excipient:
Butylhydroxytoluene 0.5 mg

Oral solution.
A clear to hazy, colourless to yellow-brown solution.

3. TARGET SPECIES

Sheep.

4. INDICATIONS FOR USE

Startect Dual Active is a broad spectrum anthelmintic for the treatment and control of mixed gastro-intestinal nematode infections and associated diseases of sheep. The spectrum of activity is as follows:

Adult and Immature Gastro-intestinal Nematodes:

Haemonchus contortus (including inhibited larval stages)
Teladorsagia (Ostertagia) circumcincta (including inhibited larval stages)
Teladorsagia (Ostertagia) trifurcata
Trichostrongylus axei
Trichostrongylus colubriformis
Trichostrongylus vitrinus
Cooperia curticei
Cooperia oncophora
Nematodirus spathiger
Nematodirus filicollis
Nematodirus battus
Strongyloides papillosus
Oesophagostomum venulosum (adult)
Trichuris ovis
Chabertia ovina

Lungworms:

Dictyocaulus filaria (adult)
This product is effective against strains of parasites resistant to benzimidazoles, levamisole, macrocyclic lactones, and combinations of these.

5. CONTRAINDICATIONS

Do not use in dogs as severe adverse reactions may occur.
Do not use in horses as severe adverse reactions, including fatalities, will occur.
Do not exceed the recommended dose rate.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

6. SPECIAL WARNING(S)

For animal treatment only.

Special warnings:
Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:
- Underdosing, which may be due to underestimation of bodyweight, misadministration of the product or lack of calibration of the dosing device.
- Too frequent and repeated use of anthelmintics from the same class over an extended period of time.

Assess bodyweight as accurately as possible before calculating dosage. Suspected clinical cases of resistance should be further investigated using the appropriate tests, e.g. (Faecal Egg Count Reduction Test). Where the results of the test(s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

Special precautions for safe use in the target species:
The recommended dose of Startect Dual Active is 0.2 ml/kg; doses of 0.9 ml/kg and higher (4.5X the recommended dose) can cause signs of toxicity and may lead to fatalities.
If animals are batched for dosing it is very important that careful consideration be given to the weight range within each group, to avoid the risk of overdosing smaller animals. A representative sample of animals should be weighed before treatment. Accuracy and proper functioning of the dosage device should be checked.
The safety of Startect Dual Active has not been established in sheep under six weeks of age or weighing less than 10 kg.

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

Do not eat, smoke or drink while handling the product.
Personal protective equipment consisting of impermeable rubber gloves should be worn when handling the veterinary medicinal product.

Avoid ingestion, inhalation and eye and skin contact. Wash hands after handling the product. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
In case of accidental eye or skin contact, wash affected areas immediately with clean running water and seek medical attention if irritation persists.

Special precautions for the protection of the environment:
The product is toxic to dung insects. It is excreted mainly in faeces and it cannot be excluded that insects using dung excreted after treatment may be adversely affected. Using the product strictly as recommended will keep this risk to a minimum.

Other precautions:
None.

Pregnancy and lactation:
Can be used in pregnant and lactating animals.

Fertility:
Can be used in breeding animals.

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

Overdose:
Doses of 0.9 ml/kg and higher have been associated with symptoms of toxicity. Signs of toxicity include dullness, depression, incoordination, weakness, decreased gastrointestinal motility and abnormal breathing pattern, recumbency and death. Non-fatal adverse events have been shown to be fully reversible. Supportive veterinary care is indicated; there is no known antidote.

Special restrictions for use and special conditions for use:
Not applicable.

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

7. ADVERSE EVENTS

Sheep:

Very common (>1 animal / 10 animals treated):
coughing[1]

[1]Mild and transient.

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 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

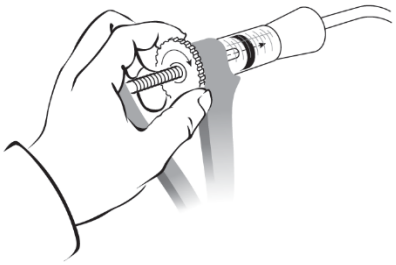
Startect Dual Active is a ready-to-use oral solution.

The dose for sheep is 2 mg derquantel and 0.2 mg abamectin per kg bodyweight. i.e. 1 ml of product per 5 kg bodyweight.

9. ADVICE ON CORRECT ADMINISTRATION

Drench sheep orally, using a drench gun with silicone sealed ‘o’ rings.
Check dose rates and the accuracy of the drench gun before treatment commences. Do not under-or over-dose. To ensure a correct dosage, body weight should be determined as accurately as possible. If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly. Set the dosing gun to deliver the correct dose volume for the weight of sheep to be treated (see figure 1).

Figure 1



Gently place the nozzle of the drench gun over the back of the tongue and depress the trigger (see figure 2).

Figure 2

10. WITHDRAWAL PERIOD(S)

Meat and offal: 14 days.

Milk: Not authorised for use in animals producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not refrigerate or freeze.

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 immediate packaging: 1 year

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 bottle 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 or household waste.

This veterinary medicinal product should not enter water courses as abamectin is extremely dangerous for fish and other aquatic organisms.

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

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

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Veterinary medicinal product subject to prescription.

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Vm 42058/5099

Purple square bottom backpack HDPE polymer bottles (1 L and 5 L) with draw off tubes (white LDPE, tube with EDPM valve) and child resistant lids. Purple jerrycan, (15 L) HDPE polymer, with white cap. 15 L jerrycan has polypropylene tap with O-ring silicone seal with tamper proof lid.

Pack sizes: 1 L, 5 L and 15 L multi-dose packs.

Not all pack sizes may be marketed.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

May 2023

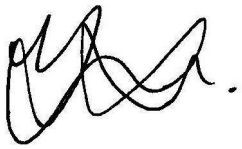
Detailed information on this veterinary medicinal product is available in the Union Product Database.

16. CONTACT DETAILS

Marketing authorisation holder and contact details to report suspected adverse reactions:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Manufacturer responsible for batch release:
Zoetis Belgium
Rue Laid Burniat 1
1348 Louvain-La-Neuve
Belgium

17. OTHER INFORMATION



Approved: 25 May 2023