PARTICULARS TO APPEAR ON THE IMMEDIATE LABEL

1L, & 5L Bottle Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

STARTECT Dual Active Oral Solution for Sheep

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Derquantel 10 mg/ml and abamectin 1 mg/ml. The solution also contains the following excipients: butylated hydroxytoluene

3. PHARMACEUTICAL FORM

Oral solution

4. PACKAGE SIZE

1 L
5 L

5. TARGET SPECIES

Sheep

6. INDICATION(S)

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.

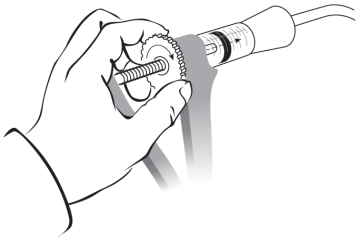
7. METHOD AND ROUTE(S) OF ADMINISTRATION, DOSAGE

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.

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 administration of a correct dose, 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

Mild transient coughing is very commonly reported (more than 1 in 10 animals) following drenching. STARTECT Dual Active has been shown to be safe for use in pregnant, lactating and breeding animals.

DOSE RATE: 1ml STARTECT Dual Active per 5 kg bodyweight.

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.

8. WITHDRAWAL PERIOD

Meat and offal: 14 days
Milk: do not use in lactating ewes producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

A representative sample of animals should be weighed before treatment.
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 underdose.
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.
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.
The safety of STARTECT Dual Active has not been established in sheep under six weeks of age or weighing less than 10 kg.
Accuracy and proper functioning of the dosage device should be checked.
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 known cases of hypersensitivity to the active substances or to any of the excipients.
Do not exceed the recommended dose rate.
Not to be mixed with other veterinary medicinal products before administration.

Do not eat, smoke or drink while handling the product. Wear impermeable rubber gloves during use.

Avoid ingestion, inhalation and eye and skin contact. Wash hands after handling the product. In case of accidental ingestion, seek medical advice immediately. Show package leaflet or 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.

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.

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.

Interactions: none known.

Not to be mixed with other veterinary medicinal products before administration.

10. EXPIRY DATE

EXP: end MM/YY. Once opened use the product within 12 months.
Once broached, use by:
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 carton should be discarded should be worked out. This discard date should be written in the space provided.

11. SPECIAL STORAGE CONDITIONS

Do not refrigerate or freeze.

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

Extremely dangerous to fish and aquatic life. Do not contaminate water courses with the product or used container. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

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

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

16. MARKETING AUTHORISATION NUMBER

Vm 42058/4135

17. MANUFACTURER'S BATCH NUMBER

Lot

PARTICULARS TO APPEAR ON THE IMMEDIATE LABEL

15L Bottle Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

STARTECT Dual Active Oral Solution for Sheep

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Derquantel 10 mg/ml and abamectin 1 mg/ml. The solution also contains the following excipients: butylated hydroxytoluene

3. PHARMACEUTICAL FORM

Oral solution

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

4. PACKAGE SIZE

15 L
Pack sizes: 1L, 5L and 15 L multi-dose packs. Not all pack sizes may be marketed.

5. TARGET SPECIES

Sheep

6. INDICATION(S)

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.

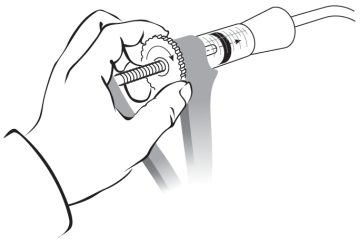
7. METHOD AND ROUTE(S) OF ADMINISTRATION, DOSAGE

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.

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 administration of a correct dose, 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

Mild transient coughing is very commonly reported (more than 1 in 10 animals) following drenching. STARTECT Dual Active has been shown to be safe for use in pregnant, lactating and breeding animals.

DOSE RATE: 1ml STARTECT Dual Active per 5 kg bodyweight.

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.

8. WITHDRAWAL PERIOD

Meat and offal: 14 days
Milk: do not use in lactating ewes producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

A representative sample of animals should be weighed before treatment.
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 underdose.
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.
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.
The safety of STARTECT Dual Active has not been established in sheep under six weeks of age or weighing less than 10 kg.
Accuracy and proper functioning of the dosage device should be checked.
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 known cases of hypersensitivity to the active substances or to any of the excipients.
Do not exceed the recommended dose rate.
Not to be mixed with other veterinary medicinal products before administration.

Do not eat, smoke or drink while handling the product. Wear impermeable rubber gloves during use.

Avoid ingestion, inhalation and eye and skin contact. Wash hands after handling the product. In case of accidental ingestion, seek medical advice immediately. Show package leaflet or 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.

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.

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.

Interactions: none known.

Not to be mixed with other veterinary medicinal products before administration.

10. EXPIRY DATE

EXP: end MM/YY. Once opened use the product within 12 months.
Once broached, use by:
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 carton should be discarded should be worked out. This discard date should be written in the space provided.

11. SPECIAL STORAGE CONDITIONS

Do not refrigerate or freeze.

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

Extremely dangerous to fish and aquatic life. Do not contaminate water courses with the product or used container. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

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

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

NAME OF MANUFACTURER RESPONSIBLE FOR BATCH RELEASE:
Pfizer Service Company BVBA
Hoge Wei 10
1930 Zaventem
Belgium

or

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
Belgium

16. MARKETING AUTHORISATION NUMBER

Vm 42058/4135

17. MANUFACTURER'S BATCH NUMBER

Lot

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

1L & 5L Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

STARTECT Dual Active Oral Solution for Sheep

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Derquantel 10 mg/ml and abamectin 1 mg/ml. The solution also contains the following excipients: butylated hydroxytoluene.

3. PHARMACEUTICAL FORM

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

4. PACKAGE SIZE

1 L
5 L

Pack sizes: 1L, 5L and 15 L multi-dose packs. Not all pack sizes may be marketed.

5. TARGET SPECIES

Sheep

6. INDICATION(S)

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.

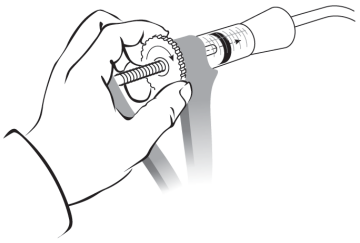
7. METHOD AND ROUTE(S) OF ADMINISTRATION, DOSAGE

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.

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 administration of a correct dose, 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

Mild transient coughing is very commonly reported (more than 1 in 10 animals) following drenching. STARTECT Dual Active has been shown to be safe for use in pregnant, lactating and breeding animals.

DOSE RATE: 1ml STARTECT Dual Active per 5 kg bodyweight.

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.

8. WITHDRAWAL PERIOD

Meat and offal: 14 days
Milk: do not use in lactating ewes producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

A representative sample of animals should be weighed before treatment.
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 underdose.
The recommended dose of STARTECT Dual Active is 0.2 ml/kg; doses of 0.9 ml/kg and higher can cause symptoms of toxicity.
Accuracy and proper functioning of the dosage device should be checked.
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 known cases of hypersensitivity to the active substances or to any of the excipients.
Do not exceed the recommended dose rate.
Not to be mixed with other veterinary medicinal products before administration

Do not eat, smoke or drink while handling the product. Wear impermeable rubber gloves during use.

Avoid ingestion, inhalation and eye and skin contact. Wash hands after handling the product. In case of accidental ingestion, seek medical advice immediately. Show package leaflet or 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.

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.

10. EXPIRY DATE

EXP: end MM/YY. Once opened use the product within 12 months.
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.

11. SPECIAL STORAGE CONDITIONS

Do not refrigerate or freeze.

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

Extremely dangerous to fish and aquatic life. Do not contaminate water courses with the product or used container. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

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

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

NAME OF MANUFACTURER RESPONSIBLE FOR BATCH RELEASE:
Pfizer Service Company BVBA
Hoge Wei 10
1930 Zaventem
Belgium

Or

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
Belgium

16. MARKETING AUTHORISATION NUMBER

Vm 42058/4135

17. MANUFACTURER'S BATCH NUMBER

Lot

Approved 03 December 2019