

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE>**

{CARTON /2's}

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Johnson's One Dose Wormer for Dogs 500mg film-coated tablets  
Nitroscanate

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Each tablet contains 500 mg of Nitroscanate.

**3. PHARMACEUTICAL FORM**

Film-Coated Tablets

**4. PACKAGE SIZE**

2 tablets

**5. TARGET SPECIES**

For dogs

**6. INDICATION(S)**

Easy to use

Kills Tapeworm, Roundworm and Hookworm in a single dose.

Johnson's One Dose Wormer for Dogs 500mg is a broad spectrum anthelmintic for use in adult dogs for treatment of the following roundworms and tapeworms:

Roundworms: *Toxocara canis*, *Toxascaris leonina*, *Uncinaria stenocephala*, *Ancylostoma caninum*.

Tapeworms: *Taenia hydatigena*, *Taenia pisiformis*, and *Dipylidium caninum*.

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

Read the package leaflet before use.

**Directions for Use:**

Give the required number of tablets first thing in the morning when your dog's stomach is empty, with about one fifth of his daily food ration. The tablets should be given whole. This product can be an irritant to the skin and eyes. Tablets are film-coated and should not be broken or divided. To reduce the risk of vomiting, it is recommended that the remaining food ration is withheld for eight hours after the wormer dose.

**Dosage:** The dose of the product for the treatment of adult dogs is nitroscanate 50 mg/kg bodyweight, which is equivalent to 1 x 500 mg tablet per 10 kg (22 lb) bodyweight.

Repeat this treatment every three to six months as a preventative measure.

Follow the dosage chart below:

Dogs Weight	Example Breed (adult weight)	No. of Tablets
8 - 10 kg (17.6 – 22 lb)	Scottish Terrier	1
10.1 – 20 Kg (22.1 – 44 lb)	Springer Spaniel	2

For dogs weighing over 20 kg (44 lb) additional packs will be required. Give an additional tablet for every extra 10 kg (22 lb) in weight. For dogs weighing less than 8 kg (17.6 lb) use Johnson's One Dose Wormer for Puppies & Small Dogs 100mg Film-Coated Tablets.

#### 8. WITHDRAWAL PERIOD

N/A

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

Read the package leaflet before use.

#### **Contra-Indications:**

When administered as recommended, the product is unlikely to cause vomiting. However, in the unlikely event that vomiting does occur following treatment, do not repeat the dose. Do not administer if your pet is sick or recovering from an illness. Do not use in dogs with a known allergy (hypersensitivity) to nitroscanate or any of the other ingredients (excipients). If a hypersensitivity or any other adverse reaction occurs, cease treatment.

If symptoms of disease persist or appear consult your veterinary surgeon.

Tablets are film-coated and should not be broken or divided.

#### 10. EXPIRY DATE

<EXP >

#### 11. SPECIAL STORAGE CONDITIONS

Store in a dry place. Do not store above 25°C.  
Keep the blister in the outer carton.

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

Dispose of empty packaging and any remaining product 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

**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**

Chanelle Animal Health Ltd, 7 Rodney Street, Liverpool, L1 9HZ

Distributed by:

Johnson’s Veterinary Products Ltd, 5 Reddicap Trading Estate, Sutton Coldfield, West Midlands, B75 7DF, UK.

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 11990/4028

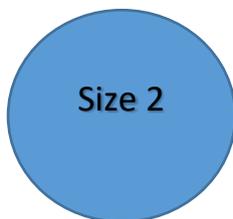
Legal category

AVM-GSL

**17. MANUFACTURER’S BATCH NUMBER**

<BN>

**2 pack size**



Medium dogs from 8kg up to 20kg

**PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE>**

{CARTON /3's}

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Johnson's One Dose Wormer for Dogs 500mg film-coated tablets  
Nitroscanate

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Each tablet contains 500 mg of Nitroscanate.

**3. PHARMACEUTICAL FORM**

Film-Coated Tablets

**4. PACKAGE SIZE**

3 tablets

**5. TARGET SPECIES**

For dogs

**6. INDICATION(S)**

Easy to use

Kills Tapeworm, Roundworm and Hookworm in a single dose.

Johnson's One Dose Wormer for Dogs 500mg is a broad spectrum anthelmintic for use in adult dogs for treatment of the following roundworms and tapeworms:

Roundworms: *Toxocara canis*, *Toxascaris leonina*, *Uncinaria stenocephala*, *Ancylostoma caninum*.

Tapeworms: *Taenia hydatigena*, *Taenia pisiformis*, and *Dipylidium caninum*.

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

Read the package leaflet before use.

**Directions for Use:**

Give the required number of tablets first thing in the morning when your dog's stomach is empty, with about one fifth of his daily food ration. The tablets should be given whole. This product can be an irritant to the skin and eyes. Tablets are film-coated and should not be broken or divided. To reduce the risk of vomiting, it is recommended that the remaining food ration is withheld for eight hours after the wormer dose.

**Dosage:** The dose of the product for the treatment of adult dogs is nitroscanate 50 mg/kg bodyweight, which is equivalent to 1 x 500 mg tablet per 10 kg (22 lb) bodyweight.

Repeat this treatment every three to six months as a preventative measure.

Follow the dosage chart below:

Dog's Weight	Example Breed (adult weight)	No. of Tablets
8 - 10 kg (17.6 – 22 lb)	Scottish Terrier	1
10.1 – 20 Kg (22.1 – 44 lb)	Springer Spaniel	2
20.1 – 30 Kg (44.1 – 66 lb)	Labrador	3

For dogs weighing over 30 kg (66 lb), additional packs will be required. Give an additional tablet for every extra 10 kg (22 lb) in weight. For dogs weighing less than 8 kg (17.6 lb) use Johnson's One Dose Wormer for Puppies & Small Dogs 100mg Film-Coated Tablets.

#### **8. WITHDRAWAL PERIOD**

N/A

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

Read the package leaflet before use.

#### **Contra-Indications:**

When administered as recommended, the product is unlikely to cause vomiting. However, in the unlikely event that vomiting does occur following treatment, do not repeat the dose. Do not administer if your pet is sick or recovering from an illness. Do not use in dogs with a known allergy (hypersensitivity) to nitroscanate or any of the other ingredients (excipients). If a hypersensitivity or any other adverse reaction occurs, cease treatment.

If symptoms of disease persist or appear consult your veterinary surgeon.

Tablets are film-coated and should not be broken or divided.

#### **10. EXPIRY DATE**

<EXP >

#### **11. SPECIAL STORAGE CONDITIONS**

Store in a dry place. Do not store above 25°C.  
Keep the blister in the outer carton.

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

Dispose of empty packaging and any remaining product 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

**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**

Chanelle Animal Health Ltd, 7 Rodney Street, Liverpool, L1 9HZ

Distributed by:

Johnson’s Veterinary Products Ltd, 5 Reddicap Trading Estate, Sutton Coldfield, West Midlands, B75 7DF, UK.

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 11990/4028

Legal category

AVM-GSL

**17. MANUFACTURER’S BATCH NUMBER**

<BN>

**PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE>**

{CARTON /4's}

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Johnson's One Dose Wormer for Dogs 500mg film-coated tablets  
Nitroscanate

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Each tablet contains 500 mg of Nitroscanate.

**3. PHARMACEUTICAL FORM**

Film-Coated Tablets

**4. PACKAGE SIZE**

4 tablets

**5. TARGET SPECIES**

For dogs

**6. INDICATION(S)**

Easy to use

Kills Tapeworm, Roundworm and Hookworm in a single dose.

Johnson's One Dose Wormer for Dogs 500mg is a broad spectrum anthelmintic for use in adult dogs for treatment of the following roundworms and tapeworms:

Roundworms: *Toxocara canis*, *Toxascaris leonina*, *Uncinaria stenocephala*, *Ancylostoma caninum*.

Tapeworms: *Taenia hydatigena*, *Taenia pisiformis*, and *Dipylidium caninum*.

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

Read the package leaflet before use.

**Directions for Use:**

Give the required number of tablets first thing in the morning when your dog's stomach is empty, with about one fifth of his daily food ration. The tablets should be given whole. This product can be an irritant to the skin and eyes. Tablets are film-coated and should not be broken or divided. To reduce the risk of vomiting, it is recommended that the remaining food ration is withheld for eight hours after the wormer dose.

**Dosage:** The dose of the product for the treatment of adult dogs is nitroscanate 50 mg/kg bodyweight, which is equivalent to 1 x 500 mg tablet per 10 kg (22 lb) bodyweight.

Repeat this treatment every three to six months as a preventative measure.

Follow the dosage chart below:

Dog's Weight	Example Breed (adult weight)	No. of Tablets
8 - 10 kg (17.6 – 22 lb)	Scottish Terrier	1
10.1 – 20 Kg (22.1 – 44 lb)	Springer Spaniel	2
20.1 – 30 Kg (44.1 – 66 lb)	Labrador	3
30.1 – 40 Kg (66.1 – 88 lb)	German Shepherd	4

For dogs weighing over 40 kg (88 lb), additional packs will be required. Give an additional tablet for every extra 10 kg (22 lb) in weight. For dogs weighing less than 8 kg (17.6 lb) use Johnson's One Dose Wormer for Puppies & Small Dogs 100mg Film-Coated Tablets.

#### 8. WITHDRAWAL PERIOD

N/A

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

Read the package leaflet before use.

##### **Contra-Indications:**

When administered as recommended, the product is unlikely to cause vomiting. However, in the unlikely event that vomiting does occur following treatment, do not repeat the dose. Do not administer if your pet is sick or recovering from an illness. Do not use in dogs with a known allergy (hypersensitivity) to nitroscanate or any of the other ingredients (excipients). If a hypersensitivity or any other adverse reaction occurs, cease treatment.

If symptoms of disease persist or appear consult your veterinary surgeon.

Tablets are film-coated and should not be broken or divided.

#### 10. EXPIRY DATE

<EXP >

#### 11. SPECIAL STORAGE CONDITIONS

Store in a dry place. Do not store above 25°C.  
Keep the blister in the outer carton.

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

Dispose of empty packaging and any remaining product 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

**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**

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Distributed by:

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**16. MARKETING AUTHORISATION NUMBER(S)**

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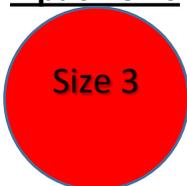
Legal category

AVM-GSL

**17. MANUFACTURER’S BATCH NUMBER**

<BN>

**4 pack size**



Medium and Large dogs from 8kg up to 40kg

**PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE>**

{Carton/8's pack size}

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Johnson's One Dose Wormer for Dogs 500mg film-coated tablets  
Nitroscanate

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Each tablet contains 500 mg of Nitroscanate.

**3. PHARMACEUTICAL FORM**

Film-Coated Tablets

**4. PACKAGE SIZE**

8 tablets

**5. TARGET SPECIES**

For dogs

**6. INDICATION(S)**

Easy to use

Kills Tapeworm, Roundworm and Hookworm in a single dose.

Johnson's One Dose Wormer for Dogs 500mg is a broad spectrum anthelmintic for use in adult dogs for treatment of the following roundworms and tapeworms:

Roundworms: *Toxocara canis*, *Toxascaris leonina*, *Uncinaria stenocephala*, *Ancylostoma caninum*.

Tapeworms: *Taenia hydatigena*, *Taenia pisiformis*, and *Dipylidium caninum*.

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

Read the package leaflet before use.

**Directions for Use:**

Give the required number of tablets first thing in the morning when your dog's stomach is empty, with about one fifth of his daily food ration. The tablets should be given whole. This product can be an irritant to the skin and eyes. Tablets are film-coated and should not be broken or divided. To reduce the risk of vomiting, it is recommended that the remaining food ration is withheld for eight hours after the wormer dose.

**Dosage:** The dose of the product for the treatment of adult dogs is nitroscanate 50 mg/kg bodyweight, which is equivalent to 1 x 500 mg tablet per 10 kg (22 lb) bodyweight.  
Repeat this treatment every three to six months as a preventative measure.

Follow the dosage chart below:

Dog's Weight	Example Breed (adult weight)	No. of Tablets
8 - 10 kg (17.6 – 22 lb)	Scottish Terrier	1
10.1 – 20 Kg (22.1 – 44 lb)	Springer Spaniel	2
20.1 – 30 Kg (44.1 – 66 lb)	Labrador	3
30.1 – 40 Kg (66.1 – 88 lb)	German Shepherd	4

For dogs weighing over 40 kg (88 lb), give an additional tablet for every extra 10 kg (22 lb) in weight. For dogs weighing less than 8 kg (17.6 lb) use Johnson's One Dose Wormer for Puppies & Small Dogs 100mg Film-Coated Tablets.

#### 8. WITHDRAWAL PERIOD

N/A

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

Read the package leaflet before use.

##### **Contra-Indications:**

When administered as recommended, the product is unlikely to cause vomiting. However, in the unlikely event that vomiting does occur following treatment, do not repeat the dose. Do not administer if your pet is sick or recovering from an illness. Do not use in dogs with a known allergy (hypersensitivity) to nitroscanate or any of the other ingredients (excipients). If a hypersensitivity or any other adverse reaction occurs, cease treatment.

If symptoms of disease persist or appear consult your veterinary surgeon.

Tablets are film-coated and should not be broken or divided.

#### 10. EXPIRY DATE

<EXP >

#### 11. SPECIAL STORAGE CONDITIONS

Store in a dry place. Do not store above 25°C.  
Keep the blister in the outer carton.

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

Dispose of empty packaging and any remaining product 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

**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**

Chanelle Animal Health Ltd, 7 Rodney Street, Liverpool, L1 9HZ

Distributed by:

Johnson’s Veterinary Products Ltd, 5 Reddicap Trading Estate, Sutton Coldfield, West Midlands, B75 7DF, UK.

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 11990/4028

Legal category

AVM-GSL

**17. MANUFACTURER’S BATCH NUMBER**

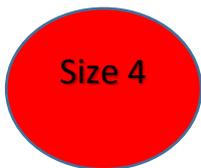
<BN>

**8 pack size**

MULTI-PACK

for homes with more than 1 dog or extra-large dogs up to 80 kg.

Eight tablets.



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

**{NATURE/TYPE}  
BLISTERS**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Johnson's One Dose Wormer for Dogs 500mg Film-Coated Tablets  
Nitroscanate

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

Chanelle Animal Health Ltd.

**3. EXPIRY DATE**

<EXP END>

**4. BATCH NUMBER**

<BN>

**5. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.

**B. PACKAGE LEAFLET**

**PACKAGE LEAFLET:**  
**Johnson's One Dose Wormer for Dogs 500mg Film-Coated Tablets**  
**Nitroscanate**

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

**M.A Holder:** Chanelle Animal Health Ltd, 7 Rodney Street, Liverpool, L1 9HZ, UK.

**Manufacturer responsible for batch release:**

Chanelle Pharmaceuticals Manufacturing Ltd, Loughrea, Co. Galway, Ireland.

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

**Johnson's One Dose Wormer for Dogs 500mg Film-Coated Tablets**  
Nitroscanate

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

Each tablet contains Nitroscanate 500 mg.  
Smooth yellow coloured film coated tablets, convex shaped (plain round concave)

**4. INDICATION(S)**

The product is a broad spectrum anthelmintic for use in adult dogs for the treatment of the following nematodes (roundworms) and cestodes (tapeworms):.Nematodes: *Toxocara canis*, *Toxascaris leonina*, *Uncinaria stenocephala*, *Ancylostoma caninum*  
Cestodes: *Taenia hydatigena*, *Taenia pisiformis*, and *Dipylidium caninum*.

**5. CONTRAINDICATIONS**

Do not repeat treatment if vomiting occurs shortly after dosing. Do not administer if your pet is sick or recovering from an illness. Do not use in known cases of allergy (hypersensitivity) to the active substance nitroscanate or to any of the other ingredients (excipients). If a hypersensitivity or any other adverse reaction occurs, treatment with the product should be discontinued.

**6. ADVERSE REACTIONS**

During the post-marketing surveillance, transient gastrointestinal signs (vomiting and diarrhoea); systemic sign (lethargy) and neurological sign (ataxia) have been observed very rarely.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon. Alternatively you can report via your national reporting system: <https://www.gov.uk/report-veterinary-medicine-problem>

## 7. TARGET SPECIES

For adult dogs

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

Give the required number of tablets first thing in the morning when your dog's stomach is empty, with about one fifth of his daily food ration. The tablets should be given whole. Tablets are film coated and should not be broken or divided. To reduce the risk of vomiting, it is recommended that the remaining food ration is withheld for eight hours after the wormer dose.

The dose of the product for the treatment of adult dogs is 1 x 500 mg tablet per 10 kg (22 lb) of bodyweight. Repeat this treatment every three to six months as a preventative measure.

Follow the dosage chart below:

Dog's Weight	Example Breed	Number of Tablets
8 -10 kg (17.6 - 22 lb)	West Highland Terrier	One
10.1 - 20 kg (22.1 - 44 lb)	Springer Spaniel	Two
20.1 - 30 kg (44.1 - 66 lb)	Labrador	Three

For dogs weighing over 30 kg (66 lb), give one additional tablet for every extra 10 kg (22 lb) in weight.

For smaller dogs weighing less than 8 kg (17.6 lb) use Johnson's One Dose Wormer for Puppies & Small Dogs 100mg Film-Coated Tablets

## 9. ADVICE ON CORRECT ADMINISTRATION

The product when administered as recommended is unlikely to cause vomiting. Do not repeat treatment if vomiting occurs shortly after dosing,

## 10. WITHDRAWAL PERIOD

N/A

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children. Store in a dry place. Do not store above 25°C. 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. Keep blister strips in outer carton.

## 12. SPECIAL WARNING(S)

- i) The product is not indicated for the treatment of *Trichuris vulpis*.
- ii) It is recommended that adult dogs should be wormed routinely 2 - 4 times a year. Since the most common tapeworm of the dog (*Dipylidium caninum*) is transmitted by a flea and has a very short pre-patent period, it is important to pay attention to flea control to reduce the incidence of tapeworm in your pet.
- iii) It is important to worm young puppies very regularly for roundworm with a suitable product. Johnson's One Dose Wormer for Puppies & Small Dogs 100mg Film-Coated Tablets can be used at 12, 16, and 24 weeks of age. Nursing bitches should be treated at 2, 4, 6, 8 and 12 weeks after whelping. Thereafter the adult worming regime of 2 - 4 times a year is recommended.
- iv) If symptoms of disease persist or appear, consult your veterinary surgeon.

Can be used safely during pregnancy and lactation.

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

This product can be an irritant to the skin and eyes. Tablets are film-coated and should not be broken or divided.

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

Dispose of empty packaging and any remaining product in accordance with local requirements.

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

December 2021

## 15. OTHER INFORMATION

Pack sizes: 2, 3, 4 and 8 tablets  
Not all pack sizes may be marketed.  
Distributor: Johnson's Veterinary Products Ltd

**Legal category**

AVM-GSL

Vm 11990/4028

Approved 29 December 2021

