LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON -100 ml bottle and 30 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EviVet IncoVet Syrup, 40 mg/ml, dogs
Phenylpropanolamine

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Phenylpropanolamine (as hydrochloride)…….40.28 mg/ml

3. PHARMACEUTICAL FORM

Syrup

4. PACKAGE SIZE

30 ml
100 ml

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral administration.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:
Once opened, use within 3 months
Once opened, use by: / /

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Keep the bottle in outer carton in order to protect from light.

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

Disposal: read package leaflet

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.
POM-V

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

VETOQUINOL UK Limited
Steadings Barn
Pury Hill Business Park
Nr Alderton
Towcester
Northamptonshire
NN12 7LS

16. MARKETING AUTHORISATION NUMBER

Vm 08007/5001

17. MANUFACTURER'S BATCH NUMBER

Lot

LABEL – 30 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EviVet IncoVet Syrup, 40 mg/ml, dogs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Phenylpropanolamine (as hydrochloride)…….40.28 mg/ml

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

30 ml

4. ROUTE(S) OF ADMINISTRATION

Oral administration.

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP:
Once opened, use within 3 months.
Once opened, use by: / /

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

LABEL – 100 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EviVet IncoVet Syrup, 40 mg/ml, dogs
Phenylpropanolamine

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Phenylpropanolamine (as hydrochloride)…….40.28 mg/ml

3. PHARMACEUTICAL FORM

Syrup

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral administration.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:
Once opened, used within 3 months.
Once opened, use by: / /

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Keep the bottle in outer carton in order to protect from light

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

Disposal: read package leaflet.

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.
POM-V

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

VETOQUINOL UK Limited
Steadings Barn
Pury Hill Business Park
Nr Alderton
Towcester
Northamptonshire
NN12 7LS

16. MARKETING AUTHORISATION NUMBER

Vm 08007/5001

17. MANUFACTURER'S BATCH NUMBER

Lot:

B. PACKAGE LEAFLET

PACKAGE LEAFLET

EviVet INCOVET, syrup for Dogs

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

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr Alderton
Towcester
Northamptonshire
NN12 7LS

VETOQUINOL S.A.
Magny-Vernois
F-70200 Lure
FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

EviVet IncoVet Syrup, 40 mg/ml, dogs
Phenylpropanolamine

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

Each ml contains:

Active substance:
Phenylpropanolamine 40.28 mg
(Equivalent to 50 mg phenylpropanolamine hydrochloride)
Excipients, q.s.

Colourless to slightly yellow-brown solution.

4. INDICATION(S)

Treatment of urinary incontinence associated with urethral sphincter incompetence in the bitch.
Efficacy has only been demonstrated in ovariohysterectomised bitches.

5. CONTRAINDICATIONS

The use of IncoVet is not appropriate for the treatment of behavioural causes of inappropriate urination. Do not administer to patients treated with non-selective monoamine oxidase inhibitors.
Do not use in case of known hypersensitivity to active substance or to any of the excipients.

6. ADVERSE REACTIONS

In the course of field clinical trials, loose stools, liquid diarrhoea, decrease in appetite, arrhythmia and collapse were reported in some dogs. Treatment was continued depending on the severity of the undesirable effect observed.
Sympathomimetics may produce a wide range of effects, most of which mimic the results of excessive stimulation of the sympathetic nervous system (e.g. effects on heart rate and blood pressure).
Dizziness and restlessness were also occasionally reported. Hypersensitivity may occur in very rare cases.

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 see:
https://www.gov.uk/report-veterinary-medicine-problem.

7. TARGET SPECIES

Dogs.

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

Oral use. The recommended dose for IncoVet is 1mg/kg bodyweight 3 times daily in the feed, corresponding to 0.1 ml IncoVet Syrup / 5 kg bodyweight 3 times daily.
The absorption rate is increased if the product is administered to fasted dogs.

9. ADVICE ON CORRECT ADMINISTRATION

None.

Instructions for use

1. Remove the childproof safety cap by pushing down firmly and turning anti-clockwise.

2. Take the dosage syringe, with plunger pushed inwards, and insert the end into the opening of the stopper. Push down firmly.

3. Hold at an angle, do not fully invert the bottle, draw IncoVet Syrup into the syringe slowly to avoid air bubbles. Stop at the relevant mark on the plunger for the volume of IncoVet Syrup required.

4. Turn bottle the right way up and take hold of the lower part of the syringe, close to the neck of the bottle. Carefully remove the syringe from the bottle using a turning action.

5. Hold the syringe over your dog's food and push the plunger inwards as far as it will go to ensure you use the full dose of IncoVet Syrup required.

6. Replace the cap onto the bottle and turn clockwise to tighten. Store bottle safely, at room temperature, out of the sight and reach of children.

7. Wipe the end of the syringe with a clean tissue or paper towel and keep in a clean place. If the syringe needs cleaning, remove the plunger and rinse both parts with warm water.

8. Dry thoroughly, ensuring that the inside of the syringe is dry before replacing the plunger.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children
Do not store above 25°C.
Keep the bottle in outer carton in order to protect from light.
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: 3 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 WARNING(S)

For Animal Treatment Only

Special precautions for use in animals

Phenylpropanolamine, a sympathomimetic drug, may affect the cardiovascular system, especially blood pressure and heart rate, and should be used with caution in animals with cardiovascular diseases.
Care should be exercised in treating animals with severe renal or hepatic insufficiency, diabetes mellitus, hyperadrenocorticism, glaucoma, hyperthyroidism or other metabolic disorders.
In bitches less than 1 year old the possibility of anatomical disorders contributing to incontinence should be considered prior to treatment.

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

Phenylpropanolamine Hydrochloride is toxic when overdoses are ingested. Adverse effects may include dizziness, headache, nausea, insomnia or restlessness, and increased blood pressure. High overdose may be fatal, especially in children.

To avoid accidental ingestion, the product must be used and kept out of reach of children. Always replace the cap securely after use.

In the event of accidental ingestion, seek immediate medical attention showing the physician the package insert.

In the event of accidental skin contact, wash the contaminated area with soap and water. Wash hands after use of the product.

In the event of accidental eye contact, rinse the eye with clean water for about 15 minutes and seek medical advice.

Pregnancy and lactation

Do not administer to pregnant or lactating bitches.

Interaction with other medicinal products and other forms of interaction

Care should be exercised in administering IncoVet Syrup with other sympathomimetic drugs, anticholinergic drugs, tricyclic antidepressants or specific type B monoamine oxidase inhibitors. It should not be used in patients treated with non-selective monoamine oxidase inhibitors.

Overdose (symptoms, emergency procedures, antidotes)

In healthy dogs, no side effects were observed at up to 5 times the recommended dosage. However, an overdose of phenylpropanolamine could produce symptoms of excessive stimulation of the sympathic nervous system. Treatment should be symptomatic. Alpha-adrenergic blockers may be appropriate in the case of severe overdose. However, no specific recommendation on drugs or dosages can be given.

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

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

For animal treatment only.

Pharmacodynamic properties
The clinical effect of phenylpropanolamine in urinary incontinence is based on its stimulation effect on α-adrenergic receptors. This causes an increase in, and a stabilisation of, the closure pressure in the urethra, which is innervated mainly by adrenergic nerves.
Phenylpropanolamine is a racemic mixture of D and L enantiomers

Pharmacokinetic particulars
In the dog, the mean half-life of Phenylpropanolamine is approximately 3 hours with maximal plasma concentrations being found after approximately 1 hour. No accumulation of phenylpropanolamine has been observed after a dose of 1 mg/kg 3 times daily over 15 days.
When the product is administered to a fasted dog, bioavailability is increased significantly

Package sizes:
Box with 1bottle of 30 ml with a syringe of 1.5 ml
Box with 1 bottle of 100 ml with a syringe of 1.5 ml

Not all pack sizes may be marketed.

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Vm 08007/5001

Approved 25 February 2022