ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box & 150 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zelys 5 mg chewable tablets for dogs
pimobendan

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
Pimobendan 5 mg

3. PHARMACEUTICAL FORM

Chewable tablet

4. PACKAGE SIZE

60 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD (S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened use within 4 months.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.
Keep the bottle tightly closed in order to protect from moisture.
Any unused tablet portion should be returned to the bottle and be used for the next administration.

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.

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

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 15052/4138

17. MANUFACTURER'S BATCH NUMBER

<Batch><Lot> {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box with 30 or 96 tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zelys 5 mg chewable tablets for dogs
pimobendan

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
Pimobendan 5 mg

3. PHARMACEUTICAL FORM

Chewable tablet

4. PACKAGE SIZE

30 tablets
96 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD (S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 30 °C.
Any unused tablet portion should be returned to the blister and be used for the next administration.

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.

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

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 15052/4138

17. MANUFACTURER'S BATCH NUMBER

<Batch><Lot> {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zelys 5 mg chewable tablets
pimobendan

2. NAME OF THE MARKETING AUTHORISATION HOLDER

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

<Batch><Lot> {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Zelys 5 mg chewable tablets for dogs

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

Marketing authorisation holder:
Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

Manufacturer responsible for batch release:
Ceva Santé Animale
Boulevard de la Communication
Zone Autoroutière
53950 Louverné
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zelys 5 mg chewable tablets for dogs
pimobendan

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

Pimobendan 5 mg
Chewable tablet
Round in shape beige to light brown tablet, with single score line on one side.
The tablets can be divided into two equal parts.

4. INDICATION(S)

For the treatment of canine congestive heart failure originating from valvular insufficiency (mitral and/or tricuspid valve regurgitation) or dilated cardiomyopathy. (See also section “Amounts to be administered and administration route”).

5. CONTRAINDICATIONS

Do not use pimobendan in hypertrophic cardiomyopathies or in diseases in which an improvement in cardiac output cannot be achieved for functional or anatomical reasons (e.g. aortic stenosis).

Since pimobendan is metabolised mainly via the liver, it should not be used in dogs with severe impairment of liver function.
(See also section “Use during pregnancy, lactation or lay”).

6. ADVERSE REACTIONS

In rare cases a slight positively chronotropic effect (rise in heart rate) and vomiting can occur. However, these effects are dose-dependent and can be avoided by reducing the dose.
In rare cases transient diarrhoea, anorexia or lethargy have been observed.
Although a relationship with pimobendan has not been clearly established, in very rare cases, signs of effects on primary haemostasis (petechiae on mucous membranes, subcutaneous haemorrhages) may be observed during treatment. These signs disappear when the treatment is withdrawn. In rare cases, an increase in mitral valve regurgitation has been observed during chronic pimobendan treatment in dogs with mitral valve disease.
The frequency of adverse reactions is defined using the following convention:

- very common (*more than 1 in 10 animals treated displaying adverse reactions(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 {national system details}.

7. TARGET SPECIES

Dogs

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

Do not exceed the recommended dosage.

Determine the bodyweight accurately before treatment to ensure correct dosage.
The tablets should be administered orally at a dose range of 0.2 mg to 0.6 mg pimobendan/kg body weight per day. The preferable daily dose is 0.5 mg pimobendan/kg body weight. The dose should be divided into two administrations (0.25 mg/kg body weight each), using a suitable combination of whole, or half of tablets. One half of the dose in the morning and the other half approximately 12 hours later.
Each dose should be given approximately one hour before feeding.
This corresponds to:
One 5 mg chewable tablet in the morning and one 5 mg chewable tablet in the evening for a body weight of 20 kg.
Tablets are divisible in 2 for the 1.25, 5 and 10 mg tablet.

The product may be combined with a diuretic treatment such as furosemide.

9. ADVICE ON CORRECT ADMINISTRATION

Spontaneous intake by the animal or place the tablet behind the lingual torus.

10. WITHDRAWAL PERIOD (S)

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

For blisters: Any unused tablet portion should be returned to the blister and be used for the next administration.
Do not store above 30°C.

For bottle: Shelf life after first opening the immediate packaging: 4 months
Keep the bottle tightly closed in order to protect from moisture.
Any unused tablet portion should be returned to the bottle and be used for the next administration.
Do not store above 25°C.

Do not use this veterinary medicinal product after the expiry date which is stated on the blister or bottle and carton after “EXP”. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for each target species:
None.

Special precautions for use in animals
The chewable tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of the animals.

For veterinarians only
The blood glucose should be tested regularly during treatment in dogs with existing diabetes mellitus.

Monitoring of cardiac function and morphology is recommended in animals treated with pimobendan (See also section “Adverses Reactions”)

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Accidental ingestion, especially by a child, may lead to the occurrence of tachycardia, orthostatic hypotension, flushing of the face and headaches.

Unused part-tablets should be returned to the open blister space, or to the bottle and inserted back into the outer packaging. Keep in a safe place out of the sight and reach of children.
Close bottle tightly with cap directly after removal of the required number of tablets or part-tablets.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use.

Pregnancy and lactation

Laboratory studies in rats and rabbits have not produced any evidence of teratogenic or foetotoxic effects. However, these studies have shown evidence of maternotoxic and embryotoxic effects at high doses, and have also shown that pimobendan is excreted into milk. The safety of the product has not been assessed in pregnant or nursing bitches. Use only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

For veterinarians only
In pharmacological studies no interaction between the cardiac glycosides strophanthin and pimobendan was observed. The pimobendan-induced increase in cardiac contractility is attenuated by the calcium antagonists verapamil and diltiazem and by the β-antagonist propranolol.

Overdose (symptoms, emergency procedures, antidotes):

In case of overdose, please contact your veterinarian.

For veterinarians only
In the case of overdose, a positive chronotropic effect, vomiting, apathy, ataxia, heart murmurs or hypotension may occur. In this situation, the dosage should be reduced and appropriate symptomatic treatment should be initiated.
In prolonged exposure (6 months) of healthy beagle dogs at 3 and 5 times the recommended dose, mitral valve thickening and left ventricular hypertrophy were observed in some dogs. These changes are of pharmacodynamic origin.

Incompatibilities:
Not applicable.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2022

15. OTHER INFORMATION

For blisters: Cardboard box with 5 or 16 blisters of 6 tablets.
For bottle: 150 ml bottle containing 60 tablets

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved 21 October 2022