

**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 10 mg chewable tablets for dogs  
pimobendan

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each tablet contains:  
Pimobendan 10 mg

**3. PHARMACEUTICAL FORM**

Chewable tablet

**4. PACKAGE SIZE**

30 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 2 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 15052/4137

**17. MANUFACTURER'S BATCH NUMBER**

<Batch><Lot> {number}

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

Cardboard box with 32 or 96 tablets

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

Zelys 10 mg chewable tablets for dogs  
pimobendan

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each tablet contains:  
Pimobendan 10 mg

**3. PHARMACEUTICAL FORM**

Chewable tablet

**4. PACKAGE SIZE**

32 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 15052/4137

**17. MANUFACTURER’S BATCH NUMBER**

<Batch><Lot> {number}

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS**

Blister

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

Zelys 10 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 10 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 10 mg chewable tablets for dogs  
pimobendan

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

Pimobendan 10 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 10 mg chewable tablet in the morning and one 10 mg chewable tablet in the evening for a body weight of 40 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: 2 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 bottle, or to the open blister space 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  $\beta$ -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 8 or 24 blisters of 4 tablets.

For bottle: 150 ml bottle containing 30 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

A handwritten signature in black ink, appearing to read "Hunter.", is positioned below the approval date. The signature is stylized and includes a period at the end.