PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box containing 1 bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zelys 5 mg chewable tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
Pimobendan 5.00 mg

3. PACKAGE SIZE

60 tablets

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 4 months.
Once opened, use by:…

9. SPECIAL STORAGE PRECAUTIONS

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.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Sante Animale

14. MARKETING AUTHORISATION NUMBERS

Vm 14966/5086

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zelys 5 mg chewable tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
Pimobendan 5.00 mg

3. TARGET SPECIES

Dogs

4. ROUTES OF ADMINISTRATION

Oral use. Read the package leaflet before use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 4 months.

7. SPECIAL STORAGE PRECAUTIONS

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.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Sante Animale

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box containing 30 or 96 tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zelys 5 mg chewable tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
Pimobendan 5.00 mg

3. PACKAGE SIZE

30 tablets
96 tablets

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Sante Animale

14. MARKETING AUTHORISATION NUMBERS

Vm 14966/5086

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zelys

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

5 mg pimobendan

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Zelys 5 mg chewable tablets for dogs

2. Composition

Each tablet contains:
Active substance
Pimobendan 5.00 mg
Round in shape beige to light brown tablet, with single score line on one side.
The tablets can be divided into two equal parts.

3. Target species

Dogs

4. Indications for use

For the treatment of canine congestive heart failure originating from valvular insufficiency (mitral and/or tricuspid valve regurgitation) or dilated cardiomyopathy. (See also section “Administration routes and dosage**”**).

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).
Do not use in dogs with severe impairment of liver function since pimobendan is metabolised mainly via the liver.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
(See also section “Pregnancy and lactation”).

6. Special warnings

Special warnings:
None.

Special precautions for safe use in the target species:
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 “Adverse events”)

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. Laboratory studies in rats and rabbits have shown evidence of maternotoxic and embryotoxic effects at high doses. Pimobendan is excreted into milk.The safety of the veterinary medicinal product has not been established during pregnancy and lactation.Use only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
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:
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.

7. Adverse events

Dogs

Rare(1 to 10 animals / 10,000 animals treated):
Vomiting[1], Diarrhoea[2], Anorexia[2], Lethargy[2], Increased heart rate[1], Heart valve disorder[3]
Very rare(<1 animal / 10,000 animals treated, including isolated reports):
Mucosa petechiae[4,5], Haemorrhage[4,6]

[1] Dose-dependent and can be avoided by reducing the dose.
[2] Transient

[3] An increase in mitral valve regurgitation has been observed during chronic pimobendan treatment in dogs with mitral valve disease.
[4] Although a relationship with pimobendan has not been clearly established, these signs of effects on primary haemostasis disappear when the treatment is withdrawn.
[5] Pinpoint discolouration of mucosae due to bleeding
[6] Subcutaneous

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Oral use.
Do not exceed the recommended dosage.
To ensure a correct dosage, body weight should be determined as accurately as possible. The tablets should be administered 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 (1.25, 5 and 10 mg tablet) are divisible in two equal parts The veterinary medicinal 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 directly in the mouth.

10. Withdrawal periods

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 precautions for disposal

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

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 14966/5086

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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder:
Ceva Sante Animale
8 rue de Logrono
33500 Libourne
France

Contact details to report suspected adverse reactions:
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 LOUVERNE
FRANCE

17. Other information

POM-V

Veterinary Medicinal product subject to prescription

For animal treatment only

Gavin Hall
Approved: 05 November 2025