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# ZELYS 1,25 MG CHEWABLE TABLETS FOR DOGS

Authorised

Pimobendan

# Product identification

#### **Medicine name:**

ZELYS 1,25 MG CHEWABLE TABLETS FOR DOGS Zelys 1,25 mg Tabletka do rozgryzania i żucia

#### **Active substance:**

Pimobendan

## **Target species:**

Dog

#### Route of administration:

Oral use

# **Product details**

## **Active substance and strength:**

Pimobendan

1.25 milligram(s) / 1.00 Tablet

#### **Pharmaceutical form:**

Chewable tablet

## Anatomical therapeutic chemical veterinary (ATCvet) codes:

QC01CE90

## Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

#### **Authorisation status:**

Valid

#### **Authorised in:**

Poland

### Package description:

Box containing 1 vial of 60 tablets

Box containing 8 blisters of 12 tablets

Box containing 3 blisters of 12 tablets

## Additional information

## **Entitlement type:**

Marketing Authorisation

# Legal basis of product authorisation:

Hybrid application (Article 13(3) of Directive No 2001/82/EC)

# Marketing authorisation holder:

Ceva Animal Health Polska Sp. z o.o.

# Marketing authorisation date:

4/09/2018

# Manufacturing sites for batch release:

Ceva Sante Animale

# **Responsible authority:**

Office For Registration Of Medicinal Products Medical Devices And Biocidal Products

#### **Authorisation number:**

2811

Date of authorisation status change: 4/09/2018
Reference member state: France
Procedure number: FR/V/0356/001
Concerned member states: Austria Belgium Bulgaria Croatia Cyprus Czechia Denmark Estonia Finland Germany Greece Hungary Ireland Italy Latvia Lithuania Luxembourg Netherlands Norway Poland Portugal Romania Slovakia Slovenia Spain Sweden United Kingdom (Northern Ireland)
To consult adverse reactions on veterinary medicinal products please go to <a href="https://www.adrreports.eu/vet">www.adrreports.eu/vet</a>
Documents
Package Leaflet
This document does not exist in this language (English). You can find it in another language below.
Labelling
This document does not exist in this language (English). You can find it in another

language below.

Summary of Product Characteristics

This document does not exist in this language (English). You can find it in another language below.