

# ZOLETIL 100 (50 MG/ML + 50 MG/ML) LYOPHILISATE AND SOLVENT FOR SOLUTION FOR INJECTION FOR DOGS AND CATS

Authorised

- Tiletamine hydrochloride
- Zolazepam hydrochloride

## Product identification

### **Medicine name:**

ZOLETIL 100 (50 MG/ML + 50 MG/ML) LYOPHILISATE AND SOLVENT FOR SOLUTION FOR INJECTION FOR DOGS AND CATS

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### **Active substance:**

Tiletamine hydrochloride  
Zolazepam hydrochloride

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### **Target species:**

Dog  
Cat

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### **Route of administration:**

Intramuscular use  
Intravenous use

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## Product details

**Active substance and strength:**

Tiletamine hydrochloride

290.86 milligram(s) / 1.00 Bottle

Zolazepam hydrochloride

281.88 milligram(s) / 1.00 Bottle

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**Pharmaceutical form:**

Lyophilisate and solvent for solution for injection

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**Anatomical therapeutic chemical veterinary (ATCvet) codes:**

QN01AX99

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**Legal status of supply:**

Veterinary medicinal product subject to veterinary prescription

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**Authorisation status:**

Valid

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**Authorised in:**

Poland

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**Available in:**

Poland

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**Package description:**

1 vial of 970 mg lyophilisate and 1 vial of 5 ml solvent

10 vials of 970 mg lyophilisate and 10 vials of 5 ml solvent

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## Additional information

**Entitlement type:**

Marketing Authorisation

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**Legal basis of product authorisation:**

Generic application (Article 13(1) of Directive No 2001/82/EC)

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**Marketing authorisation holder:**

Virbac

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**Marketing authorisation date:**

9/01/2017

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**Manufacturing sites for batch release:**

Virbac

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**Responsible authority:**

Office For Registration Of Medicinal Products Medical Devices And Biocidal Products

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**Authorisation number:**

2613

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**Date of authorisation status change:**

9/01/2017

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**Reference member state:**

France

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**Procedure number:**

FR/V/0283/002

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**Concerned member states:**

Austria Finland Germany Ireland Malta Netherlands Poland Romania  
Sweden United Kingdom (Northern Ireland)

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To consult adverse reactions on veterinary medicinal products please go to  
[www.adrreports.eu/vet](http://www.adrreports.eu/vet)

## Documents

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.

Package Leaflet

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

Combined File of all Documents

eu-puar-frv0283002-mr-rpe366-en.pdf