

ZOLETIL 50 (25 MG/ML + 25 MG/ML) LYOPHILISATE AND SOLVENT FOR SOLUTION FOR INJECTION FOR DOGS AND CATS

Authorised

- Tiletamine hydrochloride
- Zolazepam hydrochloride

Product identification

Medicine name:

ZOLETIL 50 (25 MG/ML + 25 MG/ML) LYOPHILISATE AND SOLVENT FOR SOLUTION FOR INJECTION FOR DOGS AND CATS

Active substance:

Tiletamine hydrochloride

Zolazepam hydrochloride

Target species:

Dog

Cat

Route of administration:

Intramuscular use

Intravenous use

Product details

Active substance and strength:

Tiletamine hydrochloride

145.43 milligram(s) / 1.00 Bottle

Zolazepam hydrochloride

140.94 milligram(s) / 1.00 Bottle

Pharmaceutical form:

Lyophilisate and solvent for solution for injection

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QN01AX99

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Poland

Available in:

Poland

Package description:

1 vial of 675 mg lyophilisate and 1 vial of 5 ml solvent

10 vials of 675 mg lyophilisate and 10 vials of 5 ml solvent

Additional information

Entitlement type:

Marketing Authorisation

Legal basis of product authorisation:

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

Marketing authorisation holder:

Virbac

Marketing authorisation date:

9/01/2017

Manufacturing sites for batch release:

Virbac

Responsible authority:

Office For Registration Of Medicinal Products Medical Devices And Biocidal Products

Authorisation number:

2612

Date of authorisation status change:

9/01/2017

Reference member state:

France

Procedure number:

FR/V/0283/001

Concerned member states:

Finland Ireland Netherlands Poland Sweden

To consult adverse reactions on veterinary medicinal products please go to
www.adrreports.eu/vet

Documents

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.

Labelling

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

Combined File of all Documents

eu-puar-frv0283001-mr-rpe365-en.pdf