File downloaded on 2026-11-22
Source URL: https://medicines.health.europa.eu/veterinary/en/600000030227

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:
Netherlands

Available in:
Netherlands

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:
21/01/2016

Manufacturing sites for batch release:
Virbac

Responsible authority:
Medicines Evaluation Board

Authorisation number:
REG NL 115911

Date of authorisation status change:
26/04/2022

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

Combined File of all Documents

English (PDF)

Published on: 14/03/2025
Updated on: 14/03/2026
Download

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