

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

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

290.86 milligram(s) / 1.00 Bottle

Zolazepam hydrochloride

281.88 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:

United Kingdom (Northern Ireland)

Available in:

United Kingdom (Northern Ireland)

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

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:

20/04/2016

Manufacturing sites for batch release:

Virbac

Responsible authority:

The Veterinary Medicines Directorate

Authorisation number:

Vm 05653/3048

Date of authorisation status change:

14/09/2023

Reference member state:

France

Procedure number:

FR/V/0283/002

Concerned member states:

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

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

Documents

Combined File of all Documents

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