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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:
Sweden

Available in:
Sweden

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:
20/10/2016

Manufacturing sites for batch release:
Virbac

Responsible authority:
Swedish Medical Products Agency

Authorisation number:
51564

Date of authorisation status change:
20/10/2016

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

Summary of Product Characteristics

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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

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