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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:
Ireland

Available in:
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:
15/04/2016

Manufacturing sites for batch release:
Virbac

Responsible authority:
Health Products Regulatory Authority

Authorisation number:
VPA10988/099/002

Date of authorisation status change:
15/04/2016

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

Combined File of all Documents

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