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Aceprolab 5 mg/ml Solution for injection

Authorised

- Acepromazine maleate

Product identification

Medicine name:
Aceprolab 5 mg/ml Solution for injection

Active substance:
Acepromazine maleate

Target species:
Dog
Cat
Horse (non-food-producing)

Route of administration:
Intramuscular use
Intravenous use

Product details

Active substance and strength:
Acepromazine maleate
5.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Solution for injection

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QN05AA04

Legal status of supply:
Veterinary medicinal product subject to veterinary prescription

Authorisation status:
Valid

Authorised in:
Romania

Package description:
box containing 1 vial of 25 ml
box containing 1 vial of 100 ml

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:
Labiana Life Sciences S.A.

Marketing authorisation date:
19/01/2026

Manufacturing sites for batch release:
Labiana Life Sciences S.A.

Responsible authority:
Institute For Control Of Biological Products And Veterinary Medicines

Authorisation number:

260013

Date of authorisation status change:
19/01/2026

Reference member state:
Spain

Procedure number:
ES/V/0380/001

Concerned member states:
Belgium Denmark Hungary Luxembourg Romania

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: 14/04/2026
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Summary of Product Characteristics

Labelling

Package Leaflet

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