

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:

Belgium

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:

9/01/2026

Manufacturing sites for batch release:

Labiana Life Sciences S.A.

Responsible authority:

Federal Agency For Medicines And Health Products

Authorisation number:

BE-V665566

Date of authorisation status change:

9/01/2026

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

Summary of Product Characteristics

English (PDF)

Published on: 14/04/2026

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Labelling

English (PDF)

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Package Leaflet

English (PDF)

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Combined File of all Documents

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