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Aceprolab 5 mg/ml Solution for injection

- Acepromazine maleate

Authorised

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:

- Hungary

Available in:

- Hungary

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:

- 28/07/2020

Manufacturing sites for batch release:

- Labiana Life Sciences S.A.

Responsible authority:

- Directorate Of Veterinary Medicinal Products

Authorisation number:

- 4200/X/20 NÉBIH ÁTI

Date of authorisation status change:

- 28/07/2020

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

Product information

Summary of Product Characteristics

English (PDF)

Published on: 20/05/2026

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Package Leaflet

English (PDF)

Published on: 20/05/2026

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Labelling

English (PDF)

Published on: 20/05/2026

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Combined File of all Documents

English (PDF)

Published on: 24/07/2025

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Public assessment report(s)

eu-PUAR-esv0380001-dcp-aceprolab-5-mg-ml-solution-for-injection-en.pdf

English (PDF)

Published on: 27/03/2026

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