

# Presedine 10 mg/ml solution for injection for horses and cattle

Authorised

- Dexmedetomidine hydrochloride

## Product identification

**Medicine name:**

Presedine 10 mg/ml solution for injection for horses and cattle

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**Active substance:**

Dexmedetomidine hydrochloride

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**Target species:**

Horse

Cattle

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**Route of administration:**

Intramuscular use

Intravenous use

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## Product details

**Active substance and strength:**

Dexmedetomidine hydrochloride

10.00 milligram(s) / 1.00 millilitre(s)

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**Pharmaceutical form:**

Solution for injection

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**Withdrawal period by route of administration:**

**Intramuscular use:**

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**Horse**

- Meat and offal. 2 day

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**Cattle**

- Meat and offal. 2 day

- Milk. 12 hour

**Intravenous use:**

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**Horse**

- Meat and offal. 2 day

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**Cattle**

- Meat and offal. 2 day

- Milk. 12 hour

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**Anatomical therapeutic chemical veterinary (ATCvet) codes:**

QN05CM90

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**Legal status of supply:**

Veterinary medicinal product subject to veterinary prescription

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**Authorisation status:**

Valid

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**Authorised in:**

Slovenia

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**Package description:**

Available only in Slovenian

Available only in Slovenian

Available only in [Slovenian](#)

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## Additional information

**Entitlement type:**

Marketing Authorisation

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**Legal basis of product authorisation:**

Generic application (Article 18 of Regulation (EU) 2019/6)

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**Marketing authorisation holder:**

Alfasan Nederland B.V.

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**Marketing authorisation date:**

31/05/2023

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**Manufacturing sites for batch release:**

Alfasan Nederland B.V.

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**Responsible authority:**

Agency For Medicinal Products And Medical Devices Of The Republic Of Slovenia

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**Authorisation number:**

DC/V/0775/001

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**Date of authorisation status change:**

31/05/2023

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**Reference member state:**

Netherlands

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**Procedure number:**

NL/V/0385/001

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**Concerned member states:**

Austria Belgium Bulgaria Croatia Cyprus Czechia Denmark Estonia Finland  
France Germany Greece Hungary Iceland Ireland Italy Latvia Lithuania  
Luxembourg Norway Poland Portugal Romania Slovakia Slovenia Spain  
Sweden United Kingdom (Northern Ireland)

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**Generic of:**

600000066141

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To consult adverse reactions on veterinary medicinal products please go to [www.adrreports.eu/vet](http://www.adrreports.eu/vet)

## Documents

### Summary of Product Characteristics

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### Combined File of all Documents

English (PDF)

Published on: 28/07/2023

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### Labelling

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### Package Leaflet

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