

ALFADEXX 2 MG/ML SOLUTION FOR INJECTION FOR HORSES, CATTLE, GOATS, PIGS, DOGS AND CATS

Authorised

- DEXAMETHASONE DISODIUM PHOSPHATE

Product identification

Medicine name:

ALFADEXX 2 MG/ML SOLUTION FOR INJECTION FOR HORSES, CATTLE, GOATS, PIGS, DOGS AND CATS

Active substance:

DEXAMETHASONE DISODIUM PHOSPHATE

Target species:

Cattle

Pig

Cat

Horse

Goat

Dog

Route of administration:

Intramuscular use

Subcutaneous use

Periarticular use
Intravenous use
Intraarticular use

Product details

Active substance and strength:

DEXAMETHASONE DISODIUM PHOSPHATE
2.63 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:

Solution for injection

Withdrawal period by route of administration:

Intramuscular use:

-

Cattle

- Meat and offal. 8 day
- Milk. 72 hour

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Pig

- Meat and offal. 2 day

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Horse

- Meat and offal. 8 day
- Milk. no withdrawal period

Not authorized for use in horses producing milk for human consumption.

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Goat

- Meat and offal. 8 day
- Milk. 72 hour

Periarticular use:

-

Horse

- Meat and offal. 8 day
- Milk. no withdrawal period

Not authorized for use in horses producing milk for human consumption.

Intravenous use:

-

Cattle

- Meat and offal. 8 day
- Milk. 72 hour

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Pig

- Meat and offal. 6 day

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Horse

- Meat and offal. 8 day
- Milk. no withdrawal period

Not authorized for use in horses producing milk for human consumption.

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Goat

- Meat and offal. 8 day
- Milk. 72 hour

Intraarticular use:

-

Horse

- Meat and offal. 8 day
- Milk. no withdrawal period

Not authorized for use in horses producing milk for human consumption.

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QH02AB02

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

France

Package description:

50 ml vial in a cardboard box

100 ml vial in a cardboard box

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:

Alfasan Nederland B.V.

Marketing authorisation date:

8/09/2021

Manufacturing sites for batch release:

Produlab Pharma B.V.

Alfasan Nederland B.V.

Responsible authority:

French Agency For Food, Environmental And Occupational Health & Safety

Authorisation number:

FR/V/3586735 5/2021

Date of authorisation status change:

8/09/2021

Reference member state:

France

Procedure number:

FR/V/0430/001

Concerned member states:

Austria Belgium Bulgaria Croatia Cyprus Czechia Denmark Estonia Finland
Germany Greece Hungary Iceland Ireland Italy Latvia Lithuania
Luxembourg Netherlands Norway Poland Portugal Romania Slovakia
Slovenia Spain Sweden

To consult adverse reactions on veterinary medicinal products please go to
www.adrreports.eu/vet

Documents

Summary of Product Characteristics

This document does not exist in this language (English). You can find it in another language below.

Package Leaflet and Labelling

This document does not exist in this language (English). You can find it in another language below.

Combined File of all Documents

eu-puar-frv0430001-mr-rpe652-en.pdf