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 ALFADEXX 2 MG/ML ΕΝΕΣΙΜΟ ΔΙΑΛΥΜΑ

Active substance:

DEXAMETHASONE DISODIUM PHOSPHATE

Target species:

Cattle	
Pig	
Cat	
Horse	
Goat	
Dog	

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Route of administration:

Intramuscular use Subcutaneous use Periarticular 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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Cat

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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

Dog

Subcutaneous use:

Dog

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Cat

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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

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- Meat and offal. 8 day

- Milk. 72 hour

• Pig

- Meat and offal. 6 day

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Cat

Horse

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

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

Goat

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

Dog

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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:

This information is not available for this product.

Authorisation status:

Valid

Authorised in:

Greece

Package description:

Available only in <u>French</u> Available only in <u>French</u>

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:

20/09/2021

Manufacturing sites for batch release:

Produlab Pharma B.V. Alfasan Nederland B.V.

Responsible authority:

National Organization For Medicines

Authorisation number:

84804/21-09-2021/K-0246601

Date of authorisation status change:

7/02/2022

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 <u>www.adrreports.eu/vet</u>

Documents

Combined File of all Documents

Source URL: https://medicines.health.europa.eu/veterinary/60000031895