

Inflacam® 330 mg GRANULES FOR HORSES

NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE
Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland.

NAME OF THE VETERINARY MEDICINAL PRODUCT

Inflacam 330 mg granules for horses.
Meloxicam

STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

One sachet contains: 330 mg of meloxicam.
Pale yellow granules.

INDICATION

Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in horses weighing between 500 and 600 kg.

CONTRAINDICATIONS

Do not use in pregnant or lactating mares.
Do not use in horses suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use in horses less than 6 weeks of age.

ADVERSE REACTIONS

Isolated cases of adverse reactions typically associated with non-steroidal anti-inflammatory drugs (NSAIDs) were observed in clinical trials (slight urticaria, diarrhoea). Symptoms were reversible. In very rare cases loss of appetite, lethargy, abdominal pain and colitis have been reported. In very rare cases anaphylactoid reactions, which may be serious (including fatal), may occur and should be treated symptomatically.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

TARGET SPECIES

Horses.

DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

In-feed use.

To be administered mixed with food at a dose of 0.6 mg/kg body weight, once daily, up to 14 days. The product should be added to 250 g of muesli feed, prior to feeding.

Each sachet contains one dose for a horse weighing between 500 kg and 600 kg and the dose must not be divided into smaller doses.

ADVICE ON CORRECT ADMINISTRATION

Avoid introduction of contamination during use.

WITHDRAWAL PERIOD

Meat and offal: 3 days.

Not authorised for use in lactating animals producing milk for human consumption.

SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the sachet after EXP.

Shelf life after incorporation into muesli feed: use immediately.

SPECIAL WARNING(S)

Special precautions for use in animals:

Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of increased renal toxicity.

In order to minimise risk of intolerance, the product should be mixed into muesli feed.

This product is only for use in horses weighing between 500 and 600 kg.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

People with known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) should avoid contact with the veterinary medicinal product.

In case of accidental ingestion, seek medical advice immediately and show this package leaflet or the label to the physician.

Pregnancy and lactation:

Do not use in pregnant or lactating mares.

Interaction with other medicinal products and other forms of interaction:

Do not administer concurrently with glucocorticoids, other NSAIDs or with anti-coagulant agents.

Overdose (symptoms, emergency procedures, antidotes):

In the case of overdose symptomatic treatment should be initiated.

Incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment. Medicines should not be disposed of via wastewater or household waste.

DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED: 01/09/2022

Detailed information on this product is available on the website of the European Medicines Agency (<http://www.ema.europa.eu>).

OTHER INFORMATION

Pack size: 20 and 100 sachets. Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder. For animal treatment only.

United Kingdom (Northern Ireland):

POM-V To be supplied only on veterinary prescription

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