

IRISH MEDICINES BOARD ACT 1995, as amended

European Communities (Animal Remedies) (No. 2) Regulations 2007

VPA: **10277/009/001**
Case No: 7006161

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Schering Plough Limited

Shire Park, Welwyn Garden City, Hertfordshire AL7 1TW, United Kingdom

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Finadyne Granules 25mg/g

The particulars of which are set out in the attached Schedule. The authorisation is also subject to any special conditions as may be specified in the Schedule.

The authorisation,unless revoked, shall continue in force from **30/09/2009**.

Signed on behalf of the Irish Medicines Board

A person authorised in that behalf by the said Board.

(NOTE: This authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Finadyne Granules 25mg/g

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active Substance

Flunixin	25 mg
(As Flunixin Meglumine)	

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Granules
White to cream coloured.

4 CLINICAL PARTICULARS

4.1 Target Species

Horses

4.2 Indications for use, specifying the target species

For the alleviation of inflammation and pain associated with musculoskeletal disorders in the horse.

4.3 Contraindications

Do not exceed the stated dose or duration of treatment.

Do not administer to pregnant mares.

Use is contraindicated in animals suffering from cardiac, hepatic or renal disease, where there is the possibility of gastrointestinal ulceration or bleeding, or where there is hypersensitivity to the product.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Use in animals less than 6 weeks of age or in aged animals may involve additional risk, if such use cannot be avoided animals may require a reduced dosage and careful clinical management.

Avoid use in dehydrated, hypovolaemic or hypotensive animals as there is a potential risk of increased renal toxicity. Some NSAID's may be highly bound to plasma proteins and compete with other highly bound drugs which can lead to toxic effects.

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

Direct contact with the skin should be kept to a minimum. Avoid contact with eyes. If contact occurs, rinse immediately with clean running water.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Flunixin meglumine is a non-steroidal anti-inflammatory drug (NSAID).

Untoward effects include gastro-intestinal irritation, ulceration and, in dehydrated or hypovolaemic animals, potential for renal damage.

However, these effects have not been reported for this product in actual use.

Very rarely, anaphylactic-type reactions may occur.

4.7 Use during pregnancy, lactation or lay

Do not administer to pregnant mares. Safety studies in pregnant mares have not been conducted.

4.8 Interaction with other medicinal products and other forms of interaction

Do not administer other NSAIDs concurrently or within 24 hours of each other.

Concurrent administration of potentially nephrotoxic drugs should be avoided.

Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs which can lead to toxic effects.

4.9 Amounts to be administered and administration route

For oral administration only.

One 10g sachet per 227 kg (500 lbs) bodyweight (1.1mg flunixin per kg) once daily for up to five days, according to clinical response.

Sprinkle on a small amount of food.

Administration of flunixin should not exceed five consecutive days.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Overdosage studies in the target species have shown the product to be well-tolerated.

Flunixin meglumine is a non-steroidal anti-inflammatory drug. Overdosage is associated with gastrointestinal toxicity.

4.11 Withdrawal Period(s)

Animals must not be slaughtered for human consumption during treatment.

Meat and offal: 7 Days. Horses may be slaughtered for human consumption only after 7 days from the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anti-inflammatory and antirheumatic products, non-steroids; Flunixin.

ATCvet code: QM01AG90.

5.1 Pharmacodynamic properties

Flunixin meglumine is a potent non-steroidal, non-narcotic analgesic with anti-inflammatory, anti-endotoxic and anti-pyretic activities.

Flunixin is a potent cyclo-oxygenase inhibitor effecting a major reduction in prostaglandin synthesis. This activity is also important in relation to toxic side effects in certain organ systems.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch
Sucrose
Calcium Hydrogen Phosphate Dihydrate
Povidone K30
Colloidal Hydrated Silica

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf-life after incorporation into feed: Use immediately.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and composition of immediate packaging

Carton of 10 laminated foil sachets each containing 10g granules.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Schering-Plough Limited
Shire Park
Welwyn Garden City
Herts
AL7 1TW
UK

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10277/009/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2009

10 DATE OF REVISION OF THE TEXT