

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Phenylarthrite 200 mg/ml solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Phenylbutazone 200.00 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Benzyl alcohol	0.01 ml
Disodium edetate	
Sodium hydroxide	
Propylene glycol	
Dimethylacetamide	
Water for injections	

Colourless to pale yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs

Horses (non food-producing).

3.2 Indications for use for each target species

For the treatment of arthritis, tendinitis, muscular and articular rheumatisms, congestive processes, hyperthermia, heatstroke, inflammatory complications of various traumatic or bacterial infections (with approved antibiotic if necessary).

3.3 Contraindications

Do not use in treatment of animals suffering from cardiac, hepatic and renal deficiencies.

Do not use in cats.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Do not administer other non-steroidal anti-inflammatory drugs concurrently or within 24 hours of each other.

3.4 Special warnings

The intravenous injections should be done slowly. In case of intravenous injection, avoid mixing blood and veterinary medicinal product in the syringe.

Intramuscular injections should be done deeply in the muscular tissues.

In all cases the injections should be performed under rigorous asepsis.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use in very young or old animals may involve additional risk. If such use cannot be avoided, animals require careful clinical management.

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

Response to long term therapy should be monitored at regular intervals by a veterinary surgeon.

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

None.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

None known.

Horses (non food-producing):

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Injection site reaction ¹
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¹ In response to the deep intramuscular route, which should only be used in exceptional cases in horses.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

The use is not recommended during pregnancy or lactation.

3.8 Interaction with other medicinal products and other forms of interaction

Some nonsteroidal anti-inflammatory drugs may be highly bound to plasma proteins and compete with other highly bound drugs which can lead to toxic effects.

Phenylbutazone is known to interact with penicillins, sulfonamides, aspirin and coumarin anticoagulants.

Gastrointestinal tract ulceration may be exacerbated by corticosteroids in patients given nonsteroidal anti-inflammatory drugs.

Concurrent use of potentially nephrotoxic drugs (e.g. aminoglycoside antibiotics) should be avoided.

3.9 Administration routes and dosage

Slow intravenous or deep intramuscular injection.

Use according to the following schedule:

HORSES:

Adult animals:

Intravenous route: 1 ml/50 kg, i.e. 4 mg/kg of phenylbutazone twice a day, every day or every two days according to the severity of the case.

Deep intramuscular route: 1 ml/50 kg, i.e. 4 mg/kg of phenylbutazone twice a day, the first day and the 2nd day, once on the following days for 1 to 4 days.

Foals :

Intravenous and deep intramuscular route: 1 ml/50 kg, i.e. 4 mg/kg of phenylbutazone twice a day, repeat 24 or 48 hours later according to the severity of the case.

Note: The deep intramuscular route should be used only in exceptional cases in horses, as some undesirable local reactions might show.

DOGS:

Intravenous route or deep intramuscular route: 1 ml per 15 kg of body weight daily, i.e. approximately 13 mg/kg.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Overdose may induce CNS depression, colic, diarrhoea, melaena, petechial haemorrhages of mucous membranes, oral and gastrointestinal tract erosions and ulcers, renal papillary necrosis and death.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Treated horses may never be slaughtered for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QM01AA01

4.2 Pharmacodynamics

Phenylbutazone is a non-steroidal drug with a powerful anti-inflammatory, antirheumatic, analgesic and antipyretic activity.

4.3 Pharmacokinetics

Like the other pyrazolated derivatives to which it belongs, it intervenes mainly in the early stage of the inflammatory process, against the resultant vascular permeability, oedema and diapedesis.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf life after first opening the immediate packaging: 3 months.

5.3 Special precautions for storage

Do not store above 25 °C.

5.4 Nature and composition of immediate packaging

Cardboard box containing yellow glass type II vial of 100 ml closed with a chlorobutyl rubber stopper oversealed with an aluminium cap.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol S.A.

7. MARKETING AUTHORISATION NUMBER

VPA10521/020/001

8. DATE OF FIRST AUTHORISATION

01/10/1989

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

19/06/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).