Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Phenylarthrite solution for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance
Phenylbutazone 20 % w/v

Excipient
Benzyl Alcohol 1 % w/v

3 PHARMACEUTICAL FORM

Solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs
Horses declared as not being intended for slaughter for human consumption.

4.2 Indications for use, specifying the 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).

4.3 Contraindications

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

4.4 Special warnings for each target species

The intravenous injections should be done slowly. In case of intravenous injection, avoid mixing blood and 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

4.5 Special precautions for use

Special precautions for use in animals

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.

4.6 Adverse reactions (frequency and seriousness)

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

4.7 Use during pregnancy, lactation or lay

The use is not recommended during pregnancy or lactation.

4.8 Interaction with other medicinal products and other forms of interactions

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 (eg aminoglycoside antibiotics) should be avoided.

4.9 Amounts to be administered and administration route

Administration is by slow intravenous route or deep intramuscular route, according to the following schedule:

HORSES:

* **Intravenous route:**
Adult animals: 10 ml/500kg, i.e. 4 mg/kg of phenylbutazone, twice a day, every day or every two days according to the severity of the case.

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

* **Deep intramuscular route:**
Adult animals: 10ml/500kg, ie 4 mg/kg of phenylbutazone, twice a day the first and second day, once on the following days for 1-4 days.
Foals: 1 ml/50kg, i.e. 4 mg/kg of phenylbutazone, twice a day; repeat 24 to 48 hours later according to the severity of the case.

DOGS:

***Intravenous route or deep intramuscular route:**1 ml per 15 kg – i.e. approximately 13 mg/kg – of bodyweight daily.

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

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.

4.11 Withdrawal period(s)

Treated horses may never be slaughtered for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Musculo-skeletal system, antiinflammatory and antirheumatic products, non-steroids, butylpyrazolidines, phenylbutazone.
ATC vet code: QM01AA01Phenylbutazone is a non-steroidal drug with a powerful anti-inflammatory, antirrheumatic, analgesic and antipyretic activity. Like the other pyrazolated derivates to which it belongs, it intervenes mainly in the early stage of the inflammatory process, against the resultant vascular permeability, oedema and diapedesis.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl Alcohol
Disodium Edetate
Sodium Hydroxide
Propylene Glycol
Dimethylacetamide
Water for Injections

6.2 Major incompatibilities

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

6.3 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.

6.4 Special precautions for storage

Do not store above 25^{o}C.

6.5 Nature and composition of immediate packaging

A sterile aqueous solution for injection, supplied in a 100 ml yellow type II vial closed with a chlorobutyl rubber and sealed with an aluminium cap.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Vetoquinol Ireland Limited
12 Northbrook Road
Ranelagh
Dublin 6
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10983/013/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1989
Date of last renewal: 30th September 2009

10 DATE OF REVISION OF THE TEXT

August 2019