

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Dermcusal cutaneous solution for dogs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 ml of solution contains:

Active Substances:

Copper hydroxide	1 mg
Salicylic Acid	7 mg

Excipients:

For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Cutaneous solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs

4.2 Indications for use, specifying the target species

The product is indicated as an aid in the treatment of tendon and ligament sprains and strains, shin and bone soreness, joint soreness and arthritis in dogs.

These therapeutic actions, targeting inflammation of bone and supportive tissue, rather than soft tissue, are based on the proposed mechanism of action as a mimic and ligand contributor to natural anti-inflammatory copper containing enzymes that scavenge superoxide radicals, which are the primary inflammatory mediator of musculo-skeletal structural tissues.

4.3 Contraindications

Do not use on animals with known hypersensitivity to the active ingredients.

Do not use on pregnant or lactating animals or male stud animals.

4.4 Special warnings for each target species

In animals with thick or long-haired coats, part the hair and paint the product onto the skin in two or three locations over the affected area or joint.

Do not apply to an area where the animal can lick the liniment immediately off the skin. Apply the dose to the upper neck to avoid the risk of licking and avoid the likelihood of dissociation and reduced activity of the product.

Do not use on Bedlington Terriers which can be genetically predisposed to copper associated hepatitis.

4.5 Special precautions for use

Special precautions for use in animals

Apply to dry skin only to minimise the risk of dissociation of the ligand to free salicylic acid which is a dermal irritant.

Do not apply to damaged or sensitive areas of skin, or immediately before or after exercise when transdermal absorption will be enhanced and increased skin moisture may hasten dissociation of the ligand to free salicylic acid.

Do not clip or shave the application site, as trauma to the skin surface may increase hypersensitivity to free salicylic acid and dimethyl sulphoxide.

Clean prior medications from the application site as dimethyl sulphoxide may transport irritant substances through the dermal layers.

Do not bandage the area after application as sweat and warmth may dissociate the complex or increase the rate of absorption.

Do not mix other medications with the preparation as their transdermal transport will be enhanced.

If skin reactions occur following repeated application to a single site, rotate the site of application in subsequent treatment, particularly in animals that have shown a prior hypersensitivity reaction.

The product should not be mixed with other medication except on veterinarian's advice, as the percutaneous transport of potentially irritant or hypersensitive compounds by dimethyl sulphoxide into deeper tissues may occur.

The product should not be applied to the skin of cats due to sensitivity of this species to salicylates.

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

Avoid contact with skin and eyes.

Avoid breathing vapour.

Wear protective gloves when applying Dermcusal.

If poisoning occurs, contact a doctor or Poisons Information Centre.

If skin contact occurs, remove contaminated clothing and wash skin thoroughly.

If swallowed, induce vomiting. Use Ipecac syrup (APF) if available.

If in eyes, hold eyelids open, flush with water for 15 minutes, and call a doctor.

4.6 Adverse reactions (frequency and seriousness)

The product has been observed to cause a transient inflammatory reaction at the site of application to the skin in 3 - 5% of dogs. The reaction appears to be irritant in nature, due to dissociation of the active ligand to free salicylic acid by moisture on the dermal surface. The reaction subsides within 12 - 24 hours once the site of application is moved to an adjacent area of skin. Certain individual animals can react in a similar way due to hypersensitivity to the ligand or dimethyl sulphoxide, and in these animals with repeat reaction, product use should be withdrawn.

4.7 Use during pregnancy, lactation or lay

Do not use during pregnancy or lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Do not use this product with other topical medications.

The product does not contain water, and contact with water or sweat causes dissociation of the active ligand to free salicylic acid, which reduces its effectiveness and increases the likelihood of skin reaction and irritation.

Use the plastic, non-ferrous brush provided for application as iron displaces copper and dissociates the active complex, rendering the product less active.

4.9 Amounts to be administered and administration route

For topical application to the skin of dogs.

The product is formulated for transport though the skin. Paint the product on with the brush provided, until the liniment has disappeared. Vigorous rubbing or massage is not required.

Dose Rate:

Dogs: up to 20 kg 1 ml
over 20 kg 2 ml

One capful holds 5 ml of solution.

Use cap for measurement to minimise contamination of the liniment with dust and moisture, and wastage from accidental spillage.

Use the application brush provided enclosed in each pack of the product.

Examples for use of the product as a topically applied anti-inflammatory, anti-arthritis liniment include:

Tendon and Ligament Strains/Sprains

Tendonitis, tendon sprain in greyhounds, sprain of ligaments in joints, collateral ligament sprain on toes of greyhounds. Apply 1 - 2 ml over the affected area twice daily for 3-5 days, then once daily as required.

Periosteal Inflammation

Metacarpal (shin) soreness in young greyhounds, localised injury to bones following vehicle accidents, falls or kicks. Apply 1 - 2 ml of the product over the affected area twice daily for 5 - 7 days, then once daily as required.

Arthritic Conditions

Old age arthritic conditions, arthritis associated with lumbo-sacral injury, sprung or dislocated toes, wrist injuries, and following joint surgery in dogs and greyhounds. Arthritis and pain associated with hip dysplasia and slipped disc syndrome in susceptible breeds. Apply 1 - 2 ml of the product over the affected area twice daily for 5 - 7 days, then once daily as required.

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

Not known.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Musculo-skeletal system, topical products for joint and muscular pain, preparations with salicylic acid derivatives, combinations.

ATC vet code: QM02AC99

Anti-inflammatory, anti-arthritic agent.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol
Methyl Salicylate
Ethanol
Dimethyl Salicylate

6.2 Incompatibilities

None known.

6.3 Shelf-life

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

6.4 Special precautions for storage

Do not store above 30°C.
Protect from light.

6.5 Nature and composition of immediate packaging

A 100 ml amber Type II glass container, with a plastic non-ferrous brush for application.

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

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

Shanagarry Greyhound Products Limited,
Shanagarry,
Newcastlewest,
Co. Limerick.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10920/002/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2010

10 DATE OF REVISION OF THE TEXT