

PROFESSIONAL INFORMATION
REGAL® JOINT HEALTH REMEDY

- Complementary Medicine.
- D.29.13. Veterinary Complementary Medicines: Supplements – Other
- This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS
[S0]

1. NAME OF THE VETERINARY MEDICINE
REGAL® JOINT HEALTH REMEDY liquid for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Each 10 ml contains:

Active ingredients	Per 10 ml
Glucosamine hydrochloride (Vegan)	300 mg
Rosa canina L. (rosehip fruit) [fruct, 4:1 extract]	125 mg
Harpagophytum procumbens DC. (devil's claw) [tuber, 1:10 tincture]	100 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicine
Citric acid	-
Colourant (caramel) (E150d)	-
Flavour (beef)	-
Potassium sorbate	0,06 % m/v
Alcohol	0,79 % m/v
Sorbitol (sugar)	7,80 g/ 10 ml
Water	-

REGAL® JOINT HEALTH REMEDY is a dark viscous liquid with a sweet taste, meaty flavour and aroma.

3. CLINICAL PARTICULARS

3.1 Target species

Dogs

3.2 Indications for use for each target species

REGAL® JOINT HEALTH REMEDY includes herbal and nutritional ingredients known for supporting muscle and joint health. It is formulated to help promote joint flexibility, encourage more active mobility while reducing stiffness and discomfort for enhanced overall joint functioning.

3.3 Contraindications

- Do not use in cases of hypersensitivity to any of the ingredients in REGAL® JOINT HEALTH REMEDY (see section 2).
- Must not be given to dogs with gastric or duodenal ulcers as REGAL® JOINT HEALTH REMEDY contains devil's claw.

3.4 Special warnings

None

3.5 Special precautions for use

Special precautions for use in the target species:

- Consult a veterinarian before use if the dog has articular pain accompanied by swelling of joints, redness or fever in order to rule out alternative causes.
- Use with caution if the dog has gallstones or a history of kidney stones as REGAL® JOINT HEALTH REMEDY contains devil's claw and rosehip.
- Use with caution if the dog has diabetes or impaired glucose tolerance, as their blood glucose levels may need to be monitored as REGAL® JOINT HEALTH REMEDY contains glucosamine.
- Use with caution if the dog has known risk factors for cardiovascular disease, since elevated cholesterol levels have been observed in humans treated with glucosamine.
- Not suitable for cats
- This product does not replace veterinary care.
- Where symptoms persist, discontinue use and consult a veterinarian.

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

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

Special precautions for the protection of the environment:

Not applicable.

Other precautions:

Not applicable.

3.6 Adverse events

Adverse events are based on data from human clinical trials.

Discontinue use if adverse events or sensitivity to any of the ingredients are experienced.

Adverse reactions reported in the literature are listed below, by system organ class and frequency. Frequencies cannot be established from the available data.

Adverse events table		
System organ class	Frequency	Adverse Events
Immune system disorders	not known	Hypersensitivity (allergic) reactions: anaphylaxis.
Neurological disorders	not known	Dizziness, disorientation, headache.
Digestive tract disorders	not known	Abdominal pain, constipation, diarrhoea, nausea, vomiting.

Reporting of suspected adverse reactions

Reporting of suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "Adverse Drug Reactions and Quality Problem Reporting Form," found online under SAHPRA's publications: https://sahpra.org.za/wp-content/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf.

3.6 Use during pregnancy, lactation or lay

Pregnancy

The use of REGAL® JOINT HEALTH REMEDY is not recommended during pregnancy.

Lactation

The use of REGAL® JOINT HEALTH REMEDY is not recommended during lactation.

Fertility

No data available.

3.8 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed on REGAL® JOINT HEALTH REMEDY, see below interactions reported in literature.

Active ingredient	Medicine	Description
Glucosamine, devil's claw, rosehip	Anticoagulant or antiplatelet medicines (e.g. warfarin, aspirin)	Concomitant use may increase the risk of bleeding.

3.9 Administration routes and dosage

SHAKE WELL BEFORE USE

The recommended daily dosage is

Dogs 6 months and older:

Weigh the dog and administer using the dosage guidelines below.

SMALL DOGS (1 – 4,5 kg): give 5 ml three times per day.

SMALL TO MEDIUM DOGS (5 – 10 kg): give 10 ml three times per day.

MEDIUM DOGS (11 - 20 kg): give 15 ml three times per day.

LARGE DOGS (21 kg and larger): give 20 ml three times per day.

Directions: Give the liquid directly in the dog's mouth, place into a bowl, or add to a small amount of the dog's favourite food or snack such as pellets, milk or yoghurt.

For best results, use strictly as per dosage recommendation. Use until symptoms clear or continue as required.

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

Symptoms

In overdose, adverse events can be precipitated and/or be of increased severity (see 3.6).

There is no evidence that this product can lead to an overdose when used as recommended.

Treatment

If an accidental overdose occurs, treatment is symptomatic and supportive.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicines in order to limit the risk of development of resistance
Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QM01AX05

Category and class: D.29.13. Veterinary Complementary Medicines: Supplements

4.2 Pharmacodynamics

Glucosamine

In animals, glucosamine appears to decrease CTX-II, a marker of type II collagen degradation, and increase CPII, a marker of type II collagen synthesis.

Glucosamine is an endogenous substance, a normal constituent of the polysaccharide chains of cartilage matrix and synovial fluid glucosaminoglycans. Both *in vitro* and *in vivo* studies have evidenced that glucosamine stimulates the synthesis of physiological glycosaminoglycans and proteoglycans by chondrocytes and of hyaluronic acid by synoviocytes.

Devil's claw

Devil's claw is used in traditional African medicine for arthritis. Studies suggest that devil's claw may suppress prostaglandin E2 (PGE2) synthesis and nitric oxide production by inhibiting lipopolysaccharide-stimulated enhancement of cyclooxygenase (COX)-2 and inducible nitric oxide synthase mRNA expression. Human clinical trials show that it is clearly effective in the treatment of low back pain.

Rosehip

In human research, rose hip decreases C-reactive protein levels in patients with osteoarthritis. Other *in vitro* research shows that rose hip inhibits the production of pro-inflammatory cytokines.

4.3 Pharmacokinetic

Glucosamine

Absorption: Glucosamine is absorbed from the small intestine.

Distribution: Glucosamine is incorporated into plasma proteins during first-pass metabolism, and unbound glucosamine is concentrated in the articular cartilage. Free glucosamine is undetectable in the plasma. Metabolism: Glucosamine sulphate is extensively metabolized in the liver. A significant amount is catabolized by first-pass metabolism in the liver and ultimately converted to carbon dioxide, water, and urea.

Excretion: Glucosamine is thought to be excreted mainly in the urine. However, some may also be excreted in the faeces, or metabolized to carbon dioxide and excreted in expired air.

Devil's claw

The pharmacokinetics of devil's claw is scarce and the published data are related to *in vitro* analysis.

Absorption: Preliminary evidence suggests that devil's claw extract might be inactivated by stomach acid. However, other research shows that gastric pH does not significantly affect devil's claw.

Distribution: In humans, two hours after ingesting a devil's claw extract containing 44 mg harpagoside, the harpagoside level was found to reach 15,4 ng/ml.

Excretion: Harpagoside elimination half-life has been reported as 5,6 hours.

Rosehip

Insufficient information available.

Environmental properties

Not applicable.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

24 months.

6.3 Shelf life

24 months

5.3 Special precautions for storage

- Store in a dry place at or below 25 °C.
- Protect from light and moisture.
- Keep in original packaging until required for use.

5.4 Nature and composition of immediate packaging

REGAL® JOINT HEALTH REMEDY is available in 400 ml liquid in an amber polyethylene terephthalate (PET) plastic bottle with a white cap.

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

No special requirements.

6. HOLDER OF CERTIFICATE OF REGISTRATION

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7. REGISTRATION NUMBER(S)

To be allocated

8. DATE OF FIRST AUTHORISATION

To be allocated

9. DATE OF REVISION OF THE TEXT

January 2022