

COFACALCIUM SOLUTION FOR INJECTION

Composition/ml:

Calcium gluconate 280 mg
Magnesium hypophosphite 90 mg

Product Description: A clear colourless solution, odourless, acid taste.

Pharmacodynamics: The concentrated solute of calcium and magnesium hypophosphite supplies the body in salts of calcium, magnesium and phosphorous directly metabolisable. Their parenteral administration allows to increase quickly the plasma concentration of these ions for the treatment of hypocalcaemia associated with hypomagnesia and/or hypophosphatemia.

Pharmacokinetics: After parenteral administration, calcium, magnesium and phosphorous are quickly distributed in the body. The binding rate to plasma proteins is about 50% for calcium and from 30 to 50% for magnesium. Calcium is mainly eliminated in faeces and magnesium by urinary route.

Indication: Cattle, sheep, goats, horses, pigs, dogs and cats:

Preventive and curative treatment of hypocalcemia and/or hypomagnesia and/or hypophosphatemia such as milk fever, parturient paresis, grass tetany, eclampsia.

Routes of administration: Intramuscular, subcutaneous or slow intravenous routes.

Dosage: 12.5 to 25 mg of calcium and 26.5 to 52.9 mg of magnesium hypophosphite per kg of body weight per administration, equivalent to 0.5 ml to 1 ml per kg of body weight by slow intravenous, intramuscular or subcutaneous injection.

The administration may be repeated every 12 hours for 1 to 2 consecutive days if necessary.

Contraindications: Do not use in animals having cardiac disorders.

Warnings and Precautions:

Special warnings for each target species

None.

Special precautions for use in animals

The solution must be warmed to body temperature before administration.

Administer the product by slow intravenous administration, as a infusion, and stop immediately if any adverse reactions appears.

When the product is administered by intramuscular or sub-cutaneous route, divide the total dose into multiple injection sites in order to minimize local reactions.

The use or reuse of this product may be subject to a benefit/ risks assessment based upon eventual previous treatment, notably those with calcium.

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

None.

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

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

Interactions with other medicaments: None known.

Statement on usage during pregnancy and lactation: The safety of the veterinary medicinal product in target species during pregnancy or lactation has not been investigated. However, the use of the veterinary medicinal product during pregnancy or lactation should not lead to particular problem.

Adverse Effects: When administered intramuscularly or subcutaneously, local tissue reactions at the injection site may occur. Too rapid intravenous administration may cause cardiac arrhythmia and lead to fatal collapse. Symptoms of hypercalcemia may occur within 30 minutes after administration (tremor, agitation, sweating, hypotonia until collapse).

Overdose: When administered intramuscularly or subcutaneously, local tissue reactions at the injection site may occur. Too rapid intravenous administration may cause cardiac arrhythmia and lead to fatal collapse. Symptoms of hypercalcemia may occur within 30 minutes after administration (tremor, agitation, sweating, hypotonia until collapse).

Storage Conditions: Do not store above 30°C.

Withdrawal Period:

Meat and offal : Zero days

Milk : Zero days

Packing: 500ml polyethylene bottle.

FOR VETERINARY USE ONLY

Manufactured by:



DOPHARMA FRANCE

23 rue du Prieuré, Saint Herblon, 44150 Vair sur Loire, France

Registration holder and repacker:



Rhona Ma Malaysia Sdn Bhd (200001023279)

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Date of revision : January 2020
5LCOFACA3-500 03/XXX

LABEL CODE:	VERSION	COLORS
5LCOFACA3-500 PRODUCT: COFACALCIUM SOLUTION FOR INJECTION PACK SIZE: 500 ML COUNTRY: MY DIMENSIONS: cm = 14 x 20	VERSION: 3 MMM/YY: XXX	BLACK ! Please use the official PANTONE® (P) matching system for accurate colour representation.

Marketing approval:	Regulatory approval:	GMP approval:
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