SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Carofertin 10 mg/ml
Emulsion for injection for cattle and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:
Active substance:
Betacarotene .....10.00 mg
Excipients:
Benzyl alcohol (E1519).....10.00 mg
Ascorbyl palmitate (E304).....0.12 mg
All-rac-α-tocopherol.....0.10 mg
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection
Clear, dark red emulsion.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle (cows/heifers), pig (sows)

4.2 Indications for use, specifying the target species

For the prevention and treatment of beta-carotene deficiency and beta-carotene deficiency related fertility disorders, which can arise during phases of insufficient nutritional supply.

4.3 Contraindications

Do not use in newborn animals because of the presence of benzyl alcohol. Do not use in known cases of hypersensitivity to macrogol stearate, or in case of hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
None

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Care should be taken to avoid accidental self-injection.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
People with known hypersensitivity to betacarotene or to any of the excipients should administer the veterinary medicinal product with caution.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Swelling at the site of the injection occurs very rarely.. This usually resolves without the need for treatment.
Due to the content of macrogol-15-hydroxystearate, there is a rare possibility of allergy-related or pseudo-allergic hypersensitive reactions, particularly in animals which have previously received such a medication either by injection or by infusion. These reactions may vary considerably in terms of their duration and severity (e.g. marked local reactions, severe general reactions) and can very rarely result in life-threatening conditions.
Serious reactions and fatalities have been observed very rarely in spontaneous reports, particularly in cattle.
In case of adverse reactions the product must be suspended immediately and symptomatic treatment initiated.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For intramuscular or subcutaneous injection.

Cows/heifer:
Dose: 20 – 25 ml
The dosage should be divided and administered in several injections.

Maximum volume per injection site: 10 ml.
Pregnant cows/heifers: give 1 dose 1-2 weeks ante-partum.
Non-pregnant cows/heifers: give up to 3 doses a minimum of 14 days apart.

Sows:
Dose: 7 ml
Pregnant sows/gilts: give 1 dose 1-2 weeks ante-partum.
Non-pregnant sows/gilts: give up to 3 doses a minimum of 14 days apart.

The product should only be used in one run on several animals. Any product remaining in the container after one operating process should be discarded immediately after administration. The use of an aspirating needle is preferred.

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

Not applicable.

4.11 Withdrawal period(s)

Cattle:	Meat and offal:	zero days
	Milk:	zero hours
Pig:	Meat and offal:	zero days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Vitamin A, plain, betacarotene
ATCvet code: QA11CA02

5.1 Pharmacodynamic properties

The biological importance of betacarotene rests on its provitamin A function. Besides its importance for vision vitamin A plays a vital role in reproduction, pattern formation during embryogenesis, epithelial differentiation, growth, bone development, haematopoiesis and brain development. It is also important for the maintenance of the proper functioning of the immune system.
Conversion rate from beta-carotene to retinol decreases with an increasing supply. Beta-carotene is deposited in adipose tissues and the liver and thus acts as a reservoir for vitamin A which may be activated according to individual needs.

5.2 Pharmacokinetic particulars

Intramuscular or subcutaneous injection of betacarotene leads to a sustained increase of plasma levels and replenishment of the normal pool.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol (E1519)

Ascorbyl palmitate (E304)
All-rac-α-tocopherol
Macrogol-15-hydroxystearate
Isopropyl myristate
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: use immediately.
After first opening the product should be used immediately. The product should only be used in one run on several animals. Any product remaining in the container after one operating process should be discarded immediately after administration.

6.4 Special precautions for storage

Do not store above 25°C. Do not freeze.
Keep the container in the outer carton in order to protect from light.

6.5 Nature and composition of immediate packaging

Brown glass vials type II, bromobutyl rubber stoppers, aluminium caps
Pack of 1 vial of 100 ml emulsion for injection.
Pack of 10 vials of 100 ml emulsion for injection.
Not all pack sizes may be marketed.

6.6 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 product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

VMD NV
Hoge Mauw 900
2370 Arendonk
Belgium

8. MARKETING AUTHORISATION NUMBER

Vm 19968/4009

9. DATE OF FIRST AUTHORISATION

22 June 2016

10. DATE OF REVISION OF THE TEXT

January 2021

Approved: 20/01/21