ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE:

Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains:
Active substance: Betacarotene 10.00 mg

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle (cows/heifers), pig (sows)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular or subcutaneous injection.

8. WITHDRAWAL PERIOD

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

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. The use of an aspirating needle is preferred.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read the package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VMD NV
Hoge Mauw 900
2370 Arendonk
Belgium

16. MARKETING AUTHORISATION NUMBER(S)

Vm 19968/4009

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE:

Label 100 ml brown glass vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains:

Active substance:	Betacarotene	10.00 mg

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle (cows/heifers), pig (sows)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For i.m. or s.c. injection.

8. WITHDRAWAL PERIOD

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

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. The use of an aspirating needle is preferred.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VMD NV
Hoge Mauw 900
2370 Arendonk
Belgium

16. MARKETING AUTHORISATION NUMBER(S)

Vm 19968/4009

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
Carofertin 10 mg/ml emulsion for injection for cattle and pigs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
VMD NV
Hoge Mauw 900
2370 Arendonk
Belgium

Manufacturer responsible for batch release:
Sanochemia Pharmazeutika AG, Landegger Strasse 7, 2491 Neufeld/Leitha, Austria

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

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

Clear, dark red emulsion.

4. INDICATION(S)

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.

5. 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.

6. ADVERSE REACTIONS

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 animalstreated)
- 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, including isolated reports treated)

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle (cows/heifers), pig (sows)

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For intramuscular or subcutaneous injection.
Cow/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.

Sow:
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.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIOD

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

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25°C. Do not freeze.
Keep the container in the outer carton in order to protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.
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.

12. SPECIAL WARNING(S)

Special warnings for each target species:
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.

Pregnancy and lactation:
Can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
None known.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

January 2021

15. OTHER INFORMATION

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.

To be supplied only on veterinary prescription.
For animal treatment only.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved: 20/01/21