[Version 8, 10/2012]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Multivitamin Pro Inj., solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:

Vitamin A	15,000	IE
Cholecalciferol	1,000	IE
Alpha-tocopherol acetate	20.0	mg
Thiamine hydrochloride	10.0	mg
Riboflavin sodium phosphate	6.85	mg
Pyridoxine hydrochloride	3.0	mg
Cyanocobalamin	50.0	µg
Nicotinamide	35.0	mg
D-panthenol	25.0	mg

Excipient:

Benzylalcohol	9.0	mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, lambs, pigs and piglets.

4.2 Indications for use, specifying the target species

Vitamins deficiency.

4.3 Contraindications

Do not use in food producing animals with sufficient supply of vitamin A due to the possibility of accumulation in edible tissues.

4.4 Special warnings for each target species

The product must be sterile.

4.5 Special precautions for use

Special precautions for use in animals

Not applicable.

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

In case of accidental self-injection, a risk of hypervitaminosis related to vitamin A cannot be excluded. Therefore, administration should be done with great caution. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or label.
Research with vitamin A in laboratory animals has shown evidence of teratogenic effects. Therefore, this veterinary medicinal product should not be administered to pregnant women.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and/or lactation.

4.8 Interaction with other medicinal products and other forms of interaction

No data available.

4.9 Amounts to be administered and administration route

Single intramuscular administration.
This veterinary medicinal product should not be administered by subcutaneous route to food-producing animal species.

Per animal:
- cattle: 7-10 ml
- lamb: 3-5 ml
- pig: 5 ml
- piglet (up to 10 kg): 0.5-2 ml
- piglet (10-50 kg): 2-4 ml

In food-producing species, this veterinary medicinal product should be administered only once and the recommended dose should not be exceeded.

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

Of the fat-soluble vitamins (A, D, E and K), A and D in particular can be toxic in overdose. Different animal species have different sensitivity to the (side) effects of vitamins A and D. In case of overdose of vitamin A, both acute and chronic symptoms of intoxication occur. Acute symptoms include lethargy, anorexia, muscle weakness, vomiting and diarrhea; the most important chronic effect is the development of bone abnormalities. The most important intoxication symptom that occurs with an overdose of vitamin D is hypercalcemia, in which calcium is removed from the body and the calcium balance in the body is disrupted. Consequences of this include osteoporosis, effects on the cardiovascular system, kidney stones and calcium deposition in soft tissues.

4.11 Withdrawal period(s)

Meat and offal:
Cattle: 166 days
Sheep: 138 days
Pigs: 138 days
Milk: 120 hours (5 days)

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Vitamins
ATCvet code: QA11BA

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzylalcohol
Water for injection

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 12 months

Use immediately.

6.4. Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).

Do not freeze.
Protect from light and frost.

6.5 Nature and composition of immediate packaging

Brown glass vial, type II, with rubber stopper and metal cap.
1 x 100 ml vial, in a cardboard box.
12 x 100 ml vials, in a polystyrene outer carton.

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

Alfasan International B.V.
Kuipersweg 9
3449 JA WOERDEN

8. MARKETING AUTHORISATION NUMBER(S)

REG NL 3190

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first Authorisation 16 January 1992

Date of latest renewal 6 September 2001

10 DATE OF REVISION OF THE TEXT

15 December 2023

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

CHANNELIZATION

URA