

SUMMARY OF PRODUCT CHARACTERISTICS OF THE VMP WITH MA LICENSE

№ 0022-2395/17.10.2014

1. NAME OF THE VETERINARY MEDICINE PRODUCT

INTROVIT B- complex

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances and excipients in 1 ml:

Active substance	Contents	Pharmacopoeia
Thiamine hydrochloride	10.0 mg/ml	Ph. Eur.
Riboflavin sodium phosphate	5.0 mg/ml	Ph. Eur.
Pyridoxine hydrochloride	5.0 mg/ml	Ph. Eur.
Cyanocobalamin	20 µg /ml	Ph. Eur.
Dexpanthenol	12.5 mg/ml	Ph. Eur.
Nicotinamide	50.0 mg/ml	Ph. Eur.
Biotin	100.0 µg /ml	Ph. Eur.
Choline chloride	10 mg/ml	USP

Excipients:

For full list on excipients, see item 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, sheep, goats, pigs and horses.

4.2 Indications for use, specifying the target species

As a supplemental nutritional source of B complex vitamins in cases of vitamin deficiencies in cattle, horses, sheep, goats and swine, during periods of illness, convalescence and stress conditions (caused by vaccination, transport, high humidity, extreme temperature changes).

4.3 Contraindications

None.

4.4 Special warnings for each target species

There may be slight irritation at the injection site.

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

Aseptic precautions must be observed when using the product.

Care should be taken to avoid accidental self-injection.

4.6 Adverse reactions (frequency and seriousness)

See 4.4.

4.7 Use during pregnancy, lactation or lay

INTROVIT B-complex can be safely administered to pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Posology and method of administration

Administer by subcutaneous, deep intramuscular or slow intravenous injection. The dose might be repeated 2-3 times weekly according to the condition of the animal. Normal aseptic precautions should be observed.

Horses, cattle: 10 - 15 ml

Calves, foals: 5 - 10 ml

Sheep, goats: 5 - 10 ml

Lambs: 5 – 8 ml

Swine: 2 -10 ml.

If dose volume exceeds 20 ml, it should be divided and injected into two sites.

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

Not applicable.

4.11 Withdrawal periods:

Meat: zero days.

Milk: zero days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Vitamins, vitamin B complex.

ATC VetCode: QA11EA

B group of vitamins are organic substances with different chemical structure that are vitally important for the normal functioning of the organism. They are biologically active in low concentration and take part in the regulation of the cell functions. They are included in the composition of some enzyme systems, thus taking part in the regulation of the carbohydrate, protein and lipid metabolism and nucleic acids synthesis.

B vitamins work together to promote growth, reproductive health, nervous system function, resistance to disease, feather and skin health, and many other functions.

The combined administration of the vitamins of B group determines their synergic effects.

If too much of one or a few B vitamins is given over time, it can bring about a deficiency in other B vitamins. Thus, the complete spectrum of B vitamins needs to be consumed.

Vitamin B1 acts as a co-enzyme in the breakdown of glucose and glycogen, takes part in the transport of acetaldehyde and participates in carbohydrates metabolism mechanism, and to fatty acids synthesis.

Vitamin B2 Sodium Phosphate is phosphorylated to form the co-enzymes Riboflavin-5-phosphate and Flavin Adenine Dinucleotide (FAD) which act as hydrogen recipients and donors, thus contributing oxidation-reduction processes.

Vitamin B6 is converted to pyridoxal phosphate which functions as a co-enzyme with the transaminases and decarboxylases in the metabolism of proteins and amino acids.

Nicotinamide is converted to the essential co-enzymes Nicotinamide Adenine Dinucleotide (NAD) and Nicotinamide Adenine Dinucleotide Phosphate (NADP), that participate in the hydrogen transport (oxidation-reduction) and in Carbohydrates, amino-acids and fatty acids biosynthesis and degradation.

Pantothenol or pantothenic acid is converted to Co-enzyme A which has a key role in the metabolism of carbohydrates and amino acids and in the synthesis of fatty acids, steroids and acetyl co-enzyme A.

Vitamin B12 is required for the synthesis of nucleic acid components, synthesis of red blood cells and the metabolism of propionate. Takes part in ethyl- group transport, methionine formation, oxidation of carbohydrates with odd carbon number and in branched amino-acids catabolism.

Biotin (Vitamin B7) is used in the conversion of food to energy and in the metabolism of fats, carbohydrates, and proteins. Vitamin B7 (biotin) is also important for health hair, skin, and nails.

It is also involved in stabilizing amino acid levels in the blood and it is used in DNA synthesis to allow cells to divide normally. Vitamin B9 (folic acid) is also needed in the formation of protein and hemoglobin.

Choline chloride influences the metabolism of carotene and vitamin A in animals. It is in fact an essential component for ensuring the proper functioning of the nervous system.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol
Sodium citrate
Sodium hydroxide
Water for injections

6.2 Incompatibilities

None known.

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: 14 days.

6.4 Special precautions for storage

Store at room temperature between 15 - 25 °C, protected from light.

6.5 Nature and composition of immediate packaging

Amber type II glass bottles of 100 ml, closed with rubber (bromobutyl) stoppers and aluminium seals.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if any:

Unused preparation or waste material must be disposed according to the local legislation.

7. MARKETING AUTHORIZATION HOLDER

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8. MARKETING AUTHORISATION NUMBER

No. 0022- 2395/17.10.2014

9. DATE OF FIRST AUTHORISATION

09.11.2009

10. DATE OF THE LAST REVISION OF THE TEXT

08/05/2014

PROHIBITION FOR SALE, SUPPLY AND/OR USE

Not applicable.