

[Version 9,07/2021]

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Analeptol 50 mg/ml + 50 mg/ml solution for injection for cattle, horses, pigs, dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains

Active substances:

Heptaminol 50 mg
(equivalent to 62.6 mg heptaminol hydrochloride)
Diprophylline 50 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Benzyl alcohol (E1519)	20 mg
Sodium hydroxide (E524), for pH adjustment	
Hydrochloric acid, diluted (E507), for pH adjustment	
Water for injections	

Clear, colourless to slightly yellow solution for injection.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, horses, pigs, dogs and cats

3.2 Indications for use for each target species

Supportive (analeptic) treatment of acute cardiovascular and / or respiratory failures

3.3 Contraindications

Do not use in animals with known hypersensitivity to benzyl alcohol.
Do not use in hypertensive animals.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Not applicable.

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

The veterinary medicinal product may cause hypersensitivity reactions due to the presence of benzyl alcohol. People with known hypersensitivity to benzyl alcohol should avoid contact with the veterinary medicinal product. In case of skin contact, rinse immediately with water. If you develop symptoms such as a skin rash following exposure, seek medical advice and show the package leaflet to the physician.

The veterinary medicinal product may cause irritation to the skin and/or eyes. Avoid contact with skin and eyes. If the veterinary medicinal product comes into contact with the skin or eyes, rinse immediately with water. If irritation persists, seek medical advice. Wash hands after use.

The veterinary medicinal product may cause adverse effects after accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Not known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See also section 'contact details' of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

Pregnancy and lactation:

Use only according to the benefit/ risk assessment by the responsible veterinarian.

3.8 Interactions with other medicinal products and other forms of interaction

Synergistic effects of diprophylline with other xanthines, such as caffeine and propentofylline, might be possible.

3.9 Administration routes and dosage

In adults, cattle, horses and pigs:

For slow intravenous or intraperitoneal use.

In calves, foals, piglets, dogs and cats:

For slow intravenous, intramuscular or intraperitoneal use.

10 mg heptaminol and 10 mg diprophylline per KG bodyweight, i.e. 2 ml of the solution for 10 kg bodyweight.

The treatment may be repeated 4 to 5 hours later and for 4 to 5 days.

When administering the veterinary medicinal product via the intramuscular route, care should be taken not to exceed the maximum volume per injection site of 10 ml. In case the total amount of product exceeds the maximum volume for one injection site, multiple injection sites should be used.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

An excessive dose may cause hyperventilation resulting in a respiratory alkalosis, hypertension, tachycardia, muscle spasms, generalized excitation of the central nervous system.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Cattle and horses:

Meat and offal: 2 days after IV or IP administration

Milk: 48 hours

Pigs:

Meat and offal: 2 days after IV or IP administration

Calves, foals and piglets:

Meat and offal: 2 days after IV or IP administration

Meat and offal: 7 days after IM administration

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QR03DA51

4.2 Pharmacodynamics

The veterinary medicinal product simultaneously stimulates the heart, vessels and respiration. It contains 2 active substances: heptaminol and diprophylline

Heptaminol is a cardiovascular analeptic, its activity is related to peripheral norepinephrine release. It increases the aortic flow and has a positive inotropic and chronotropic effect, especially on the depressed heart. Heptaminol also increases coronary flow.

Diprophylline, a methylxanthine, is a phosphodiesterase inhibitor which prevents the breakdown of cyclic adenosine monophosphate. It is a derivative of theophylline, its analeptic and cardiorespiratory action stimulates the central cortex and the vagal, vasomotor and respiratory bulbar centres. It induces relaxation of bronchial spasm, dilates coronary arteries, stimulates respiration and myocardium, and increases cardiac flow.

4.3 Pharmacokinetics

The bioavailability of heptaminol is complete. This molecule will bind a little to plasma proteins and is eliminated mainly through the urine.

The bioavailability of diprophylline is also close to 100%. It is not metabolized *in vivo* and most of the product is excreted in the urine in unchanged form.

Plasma elimination half-life is very short (about 2 hours) and diprophylline is widely distributed in the body ($V_d = 1.0 \text{ l/kg}$). In horses, the elimination was so rapid that, 8 hours after an intravenous injection of 20 mg/kg (2 times the therapeutic level), plasma concentrations were of about 1 $\mu\text{g/ml}$.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 30 months

Shelf life after first opening the immediate packaging: 56 days

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

Clear type I glass vials containing 20 ml or 50 ml closed with a grey bromobutyl rubber stopper and aluminium cap. Carton box containing 1 vial of 20 ml or 1 vial of 50 ml.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

CP-Pharma Handelsgesellschaft mbH.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

