[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. Itis a derivate of theophylline, its analeptic and cardiorespiratory action stimulates the central cortex and the vagal, vasomotor and respiratory bulber 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 (Vd = 1.0 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 µg/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).

ANNEX II

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Analeptol 50 mg/ml + 50 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PACKAGE SIZE

20 ml
50 ml

4. TARGET SPECIES

Cattle, horses, pigs, dogs and cats

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

IV, IP
IM (in calves, foals, piglets, dogs and cats only)

7. WITHDRAWAL PERIODS

Withdrawal periods:
Cattle, horses, pigs, calves, foals, piglets:
Meat and offal: 2 days after IV or IP administration

Calves, foals and piglets:
Meat and offal: 7 days after IM administration

Cattle and horses:
Milk: 48 hours.

8. EXPIRY DATE

Exp.
Once broached use within 56 days.
Once broached use by…

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

CP-Pharma Handelsgesellschaft mbH

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

GLASS VIALS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Analeptol

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

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

3. BATCH NUMBER

Lot

4. EXPIRY DATE

Exp. {month/year}
Once broached use within 56 days.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

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. Composition

Each ml contains
Active substances:

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

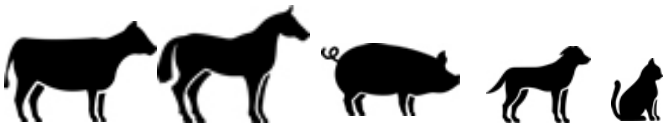
Excipients:

Benzyl alcohol (E1519)	20 mg

Clear, colourless to slightly yellow solution for injection.

3. Target species

Cattle, horses, pigs, dogs and cats.



4. Indications for use

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

5. Contraindications

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

6. Special warnings

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.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.
Use only according to the benefit/ risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
Synergistic effects of diprophylline with other xanthines, such as caffeine and propentofylline, might be possible.

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

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

7. Adverse events

Not known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder, the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

8. Dosage for each species, routes and method of administration

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.

9. Advise on correct administration

10. 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

11. Special storage precautions

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 56 days

12. Special precautions for disposal

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. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Carton box containing 1 vial of 20 ml or 1 vial of 50 ml.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

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

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:
CP-Pharma Handelsgesellschaft mbH
Ostlandring 13
31303 Burgdorf
Germany

Local representatives < and contact details to report suspected adverse reactions>:

17. Other information