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Ventipulmin Solution for Injection 30 micrograms/ml

Species: Horses only

Therapeutic indication:Pharmaceuticals: Cardiovascular and respiratory preparations

Active ingredient: Clenbuterol

Product: Ventipulmin® Solution for Injection 30 micrograms/ml

Product index: Ventipulmin Injection

Withdrawal notes: Horse meat and offal: 28 days. Do not use in animals producing milk for human consumption.

Incorporating:

Presentation

Clear colourless solution for injection. Each ml contains 30 micrograms clenbuterol hydrochloride as active substance and 10 mg benzyl alcohol as preservative.

Uses

Treatment of respiratory disease in horses where it is considered that airway obstruction due to bronchospasm and/or accumulation of mucus is a contributing factor, and improved muco-ciliary clearance is desirable. To be used alone or as adjuvant therapy.

In particular:

1Acute, sub-acute and chronic respiratory allergies.

2Acute, sub-acute and chronic infections where the presence of mucus and/or micro-organisms may stimulate bronchospasm or cause airway obstruction and thus increase airway resistance. For example, bronchitis, bronchiolitis and bronchopneumonia alone, or associated with equine influenza and other viral respiratory diseases.

3Chronic obstructive pulmonary disease (COPD).In cases accompanied by bacterial infection the administration of anti microbial agents is recommended.

Dosage and administration

Administer by slow intravenous injection at a dose of 2.7ml per 100kg bodyweight twice daily for as long as necessary. This is equivalent to twice daily administration of 0.8 micrograms clenbuterol hydrochloride per kg bodyweight.

Contra-indications, warnings, etc

Do not use in horses with known cardiac disease.

Special precautions for use in animals

Do not use in cases of known hypersensitivity to clenbuterol

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

This product contains clenbuterol, a β-agonist. Take care to avoid skin contact. In case of skin contact wash affected area thoroughly. If irritation occurs/persists seek medical advice. Take care to avoid accidental eye contact. In the case of accidental eye contact, flush thoroughly with clean water and seek medical advice. When using do not eat, drink or smoke. Wash hands thoroughly after using the product.

Accidental self-injection may produce tachycardia and tremor. These effects may be reversed by the use of a non-selective beta-blocker. If accidental self-injection occurs seek medical advice immediately, avoiding driving if possible.

In clinical use, it has been noted that following intravenous administration to horses, cases of transient mild muscle tremor and sweating were observed. It is suggested that a 'bolus' effect may have occurred in these cases and caused transient peripheral vasodilation. This vasodilation is a feature exhibited by all beta-adrenergic drugs to a greater or lesser degree. These effects may be minimised by administering the product slowly.

If used during pregnancy, treatment must be discontinued at the expected time of delivery since uterine contractions may be abolished under its influence.

This product antagonises the effects of prostaglandin F2-alpha and oxytocin. This product is antagonised by beta-adrenergic blocking agents.

In case of accidental overdose, a β-blocker such as propanolol may be used.

Withdrawal period

Meat and offal: 28 days.

Do not use in animals producing milk for human consumption.

Pharmaceutical precautions

Shelf life of the medicinal product as packaged for sale **:** 3 years.

Shelf life after first opening the immediate packaging : 28 days.

Do not store above 25°C. Protect from light. Following withdrawal of the first dose use the product within 28 days. Discard unused material. Avoid the introduction of contamination during use. Should any growth or discolouration occur the product should be discarded.

To be supplied only on veterinary prescription.

Keep out of the reach and sight of children. For animal treatment only.

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Legal category

Legal category:POM-V

Legal category description:CD(Sch 4 Pt 2)

Packaging quantities

50ml amber glass injection vial (Ph Eur. Type II), with pink bromobutyl rubber stopper and aluminium crimp cap.

Further information

The product contains the active ingredient clenbuterol hydrochloride, which is a sympathomimetic amine with a high degree of selectivity for the B2-receptor sites in the body, thus providing intense bronchodilating properties with minimum effect on the cardiovascular system. It has been shown to stimulate muco-ciliary clearance in horses.

The effects on pulmonary function and clinical response have been assessed in clinical trials with horses suffering from a variety of respiratory conditions.

A marked decrease in intrathoracic pressure, a decrease in respiratory rate, an initial decrease followed by an increase in arterial oxygen partial pressure and clinical improvements were observed. In addition, a significant reduction in resistance to airflow and a clinical improvement in the animals respiratory pattern were seen.

Marketing Authorisation Number

GB:Vm 08327/5067
NI: Vm 04491/3043

Significant changes

GTIN

NOAH Compendium

GTIN description: Ventipulmin Solution for Injection 30 micrograms/ml

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