



# Dilaterol<sup>®</sup>

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25 microgrammes/ml syrup  
for horses

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Clenbuterol hydrochloride

## DATA SHEET

<b>Presentation</b>	A clear colourless syrup containing 25 µg clenbuterol hydrochloride per ml.
<b>Uses</b>	<p>For treatment of respiratory disease in horses when airway obstruction due to bronchospasm and/or accumulation of mucus is a contributory factor and when improved muco-ciliary clearance is desirable. To be used alone or as an adjuvant therapy.</p> <p>Particular uses are as follows.</p> <ol style="list-style-type: none"><li>Acute, sub-acute and chronic respiratory allergies.</li><li>Acute, sub-acute and chronic infections in which 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.</li><li>Recurrent airway obstruction (formerly known as chronic obstructive pulmonary disease).</li></ol>
<b>Dosage and administration</b>	Add the syrup to the horse's feed to provide 4 ml per 125 kg bodyweight twice daily. This provides 0.8 µg clenbuterol hydrochloride per kg bodyweight twice daily. One depression of the pump delivers 4 ml. Treatment should continue for as long as necessary.
<b>Contra-indications and warnings</b>	<p>Do not use Dilaterol in horses known to be hypersensitive to clenbuterol or parabens excipients, or in horses known to have cardiac disease.</p> <p>Clenbuterol may cause side effects such as sweating (mainly on the neck), muscle tremor, tachycardia, slight hypotension or restlessness. These are typical for β-agonists and occur rarely.</p> <p>Dilaterol antagonises the effects of prostaglandin F<sub>2</sub>-α and oxytocin. If Dilaterol is used during pregnancy, treatment must be discontinued at the expected time of delivery, since uterine contractions may be abolished under its influence.</p> <p>Dilaterol is antagonised by β-adrenergic blocking agents.</p> <p>Doses of clenbuterol hydrochloride up to four times the therapeutic dose, administered orally for a period of 90 days, have been found to cause transient side-effects typical for β<sub>2</sub>-adrenoceptor agonists (sweating, tachycardia, muscle tremor), which require no treatment.</p> <p>In case of accidental overdose, a β-blocker, such as propranolol, may be used as antidote.</p>

**Withdrawal period** Horses must not be slaughtered for human consumption during treatment or within 28 days thereafter. The British Horseracing Authority's published Detection Time for clenbuterol hydrochloride given as an oral syrup at a dose of 1.6 µg/kg/day for 10 days is 312 hours (May 2013).

**Precautions to be taken by the person administering Dilaterol** Do not allow Dilaterol to come into contact with the skin or eye. In case of accidental contact with the skin, wash the affected area thoroughly. If irritation occurs, seek medical advice. In case of accidental contact with eye, flush it thoroughly with clean water and seek medical advice. To avoid accidental intake of the product, do not eat, drink or smoke when using it. In case of accidental ingestion, immediately seek medical advice and show the package leaflet to the doctor.

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

**Pharmaceutical precautions**

Do not store at temperatures above 25°C. Protect from light. The contents of the pack should be used within 3 months of opening it.

**Legal category**

POM-V

**Package quantities**

355-ml screw-top polyethylene bottle with a 4-ml pump dispenser.

**Marketing authorization no.**

41821/4001

**Marketed by**

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