

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Albex Gold 200 mg/ml oral suspension for cattle

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains:

### Active substance:

Albendazole 200.0 mg

### Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Methyl Parahydroxybenzoate (E218)	2.0 mg
Propyl Parahydroxybenzoate	0.2 mg
Citric Acid Monohydrate	
Sodium Citrate	
Xanthan Gum	
Povidone 90	
Polysorbate 20	
Propylene Glycol	
Simethicone Emulsion	

White to off white suspension.

## 3. CLINICAL PARTICULARS

### 3.1 Target species

Cattle.

### 3.2 Indications for use for each target species

For the treatment of benzimidazole susceptible mature and developing immature forms of gastrointestinal roundworms, lungworms, tapeworms and adult liver fluke in cattle. The product is also ovicidal against fluke and roundworm eggs.

**Roundworms:** *Ostertagia*, *Chabertia*, *Haemonchus*, *Trichostrongylus*, *Nematodirus*, *Oesophagostomum*, *Bunostomum*, *Cooperia* and *Strongyloides* spp.

It is usually effective against inhibited larvae of *Cooperia* and *Ostertagia*.

**Lungworms:** *Dictyocaulus viviparus*.

**Tapeworms:** *Moniezia* spp.

**Adult liver fluke:** *Fasciola hepatica*.

The product is ovicidal and will kill fluke and roundworm eggs.

### 3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

### 3.4 Special warnings

Cattle suffering from severe lung damage due to heavy lungworm infection may continue to cough for some weeks after treatment.

Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:

- Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
- Underdosing, which may be due to underestimation of body weight, misadministration of the product, or lack of calibration of the dosing device (if any).

Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g. Faecal Egg Count Reduction Test). Where the results of the test(s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

Care must be taken not to damage the pharyngeal region when dosing.

Resistance to benzimidazoles (which includes albendazole) has been reported in *Teladorsagia*, *Haemonchus*, *Cooperia* and *Trichostrongylus* species in small ruminants in a number of countries, including the EU. Resistance to albendazole has been reported in *Cooperia* and *Teladorsagia* species in cattle in developed countries such as New Zealand. Therefore the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

### **3.5 Special precautions for use**

#### Special precautions for safe use in the target species:

Avoid the introduction of contamination during use.

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

This product may be irritating to human skin and eyes and may cause dermal sensitisation.

Avoid contact with the eyes. Wear protective glasses.

Direct contact with the skin should be kept to a minimum. Wear suitable protective clothing including impermeable rubber gloves. Wash hands after use.

Laboratory studies in rats and rabbits have shown evidence of teratogenic effects.

#### Special precautions for the protection of the environment:

Albendazole is toxic to dung fauna and aquatic organisms.

Due to the risk to dung organisms, the product should not be used more than once per year.

Treated animals (cattle) should not have access to surface water for 7 days after treatment to avoid adverse effects on aquatic organisms.

### **3.6 Adverse events**

None 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 the package leaflet for respective contact details.

### **3.7 Use during pregnancy, lactation or lay**

#### Pregnancy and lactation:

Developmental studies in mice, rats, rabbits, and sheep showed albendazole to be teratogenic.

The malformations included visceral, craniofacial and bone defects.

Therefore, do not dose during the first trimester of pregnancy. Use only according to the benefit/risk assessment by the responsible veterinarian during last two parts of pregnancy and during lactation.

### **3.8 Interaction with other medicinal products and other forms of interaction**

None known.

### **3.9 Administration routes and dosage**

For single oral use. Shake well before use.

#### **Lungworms and gastro-intestinal roundworms:**

The recommended dose is 7.5 mg albendazole per kg bodyweight corresponding to 3.75 ml of the product per 100 kg bodyweight.

#### **For the additional treatment of adult liver fluke (chronic fasciolosis)**

The recommended dose is 10 mg albendazole per kg bodyweight corresponding to 5 ml of the product per 100 kg bodyweight.

A suitable graduated drenching gun should be used.

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible. If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- or overdosing.

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

Not applicable.

### **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:**

Meat and offal: 7 days.

Milk: 84 hours.

## **4. PHARMACOLOGICAL PROPERTIES**

### **4.1 ATCvet code:**

QP52AC11.

### **4.1 Pharmacodynamics**

The product is a broad spectrum multi-purpose anthelmintic for the control of mature and developing immature forms of gastrointestinal roundworms, lungworms, tapeworms and adult liver fluke in cattle. The product is also ovicidal against fluke and roundworm eggs.

Benzimidazoles bind to nematode tubulin, a protein necessary for the formation and viability of microtubules. This occurs primarily in absorptive intestinal cells resulting in the absence of microtubules in the intestinal cells of the nematode, with the result that these cells cannot absorb nutrients, thus causing a consequent reduction in glycogen and effective starvation of the parasites. Structural differences have been shown to exist between tubulin from mammalian and helminth sources, resulting in the preferential toxicity of albendazole to the helminth and not to the host. Benzimidazoles have also been shown to inhibit the fumarate reductase system of helminths and impair energy production.

### **4.2 Pharmacokinetics**

Albendazole is quickly metabolised to albendazole sulphoxide which persists at higher levels in bovine plasma for a longer duration after oral administration with peak plasma levels approximately 15 hours after dosing. After oral administration of the product to cattle at a dose rate of 10 mg albendazole sulphoxide per kg bodyweight the following parameters were observed:  $C_{max}$  of 1951.43 ng/ml,  $t_{1/2}$  of 2.4 hours and AUC of 32319.0 ng.h/ml. Excretion is predominantly faecal, biliary excretion being the most important route of elimination (cattle studies only).

### **Environmental properties**

Faeces containing albendazole excreted onto pasture by treated cattle reduce the abundance of dung fauna feeding organisms which may impact on dung degradation. Albendazole is toxic to aquatic organisms from direct exposure and from drainage and/or run-off of albendazole from

the soil. The main metabolite of albendazole, albendazole sulfoxide have been shown to be very persistent.

## **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: 3 years.

Shelf life after first opening the immediate packaging: 12 months.

### **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**

1L, 2.5L, 3L & 5L: Container and Closure: White HDPE flexi containers with a Polypropylene cap and an aluminium foil seal.

10 L: Container and Closure: High Density Polyethylene (HDPE) white container with a HDPE cap and an aluminium foil seal.

Not all pack sizes may be marketed.

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

Dispose of used containers safely.

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

The veterinary medicinal product should not enter water courses as albendazole may be dangerous for fish and other aquatic organisms.

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**

Chanelle Pharmaceuticals Manufacturing Ltd.,

**7. MARKETING AUTHORISATION NUMBER(S)**

VPA10987/123/001

**8. DATE OF FIRST AUTHORISATION**

19/07/2019

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

06/12/2023

**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>).