Summary of Product Characteristics

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

Excipient:

Methyl Parahydroxybenzoate (E218)	2.0 mg
Propyl Parahydroxybenzoate	0.2 mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension
White to off white suspension

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle

4.2 Indications for use, specifying the target species

Indications:
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: *Dictyocaulusviviparus*
Tapeworms: *Moniezia* spp.
Adult liver fluke: *Fasciola hepatica*.
The product is ovicidal and will kill fluke and roundworm eggs.

4.3 Contraindications

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

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

Special precautions for use in animals
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.

Other precautions
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.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

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 accordingly to the benefit/risk assessment by the responsible veterinarian during last two parts of pregnancy and during lactation.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Not applicable

4.11 Withdrawal period(s)

Cattle:
Meat and offal: 7 days.
Milk: 84 hours.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, benzimidazoles and related substances, Albendazole
ATCvet code: QP52AC11.

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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, t½ 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).

5.3 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl Parahydroxybenzoate (E218)
Propyl Parahydroxybenzoate
Citric Acid Monohydrate
Sodium Citrate
Xanthan Gum
Povidone 90
Polysorbate 20
Propylene Glycol
Simethicone Emulsion

6.2 Major incompatibilities

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

6.3 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.

6.4 Special precautions for storage

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

6.5 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.

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

Do not contaminate ponds, waterways or ditches with the product or used containers.
Dispose of used containers safely.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Limited
Loughrea
Co. Galway
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10987/123/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19 July 2019

10 DATE OF REVISION OF THE TEXT

April 2021