ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Albendis 100 mg/ml oral suspension for cattle and sheep [CY, CZ, EL, ES, FR, HR, HU, IT, PL, PT, RO, SI, SK]
Valbendis, 100 mg/ml oral suspension for cattle and sheep [EE]
Valbendis 100 mg/ml oral suspension for cattle and sheep [AT, DE, LT, LV]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Albendazole 100 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Sodium methyl parahydroxybenzoate (E219)	1.5 mg
Sodium propyl parahydroxybenzoate	0.2 mg
Hydroxyethylcellulose	
Polysorbate 80	
Propylene glycol	
Aluminium magnesium silicate	
Sodium citrate	
Citric acid monohydrate	
Simethicone emulsion	
Purified water	

White to cream white suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle and sheep.

3.2 Indications for use for each target species

For the treatment of infections caused by gastrointestinal roundworms and tapeworms, lungworms and adult liver flukes in cattle and sheep.

Cattle:
Gastrointestinal roundworms: *Ostertagia Ostertagi,* inhibited larval stages of *Ostertagia* spp., *Haemonchus contortus, Cooperia* spp., *Nematodirus* spp., *Oesophagostomum radiatum, Bunostomum phlebotomum, Strongyloides papellosus, Trichuris* spp.
Tapeworms: *Moniezia* spp.
Lungworms: *Dictyocaulus* spp.

Adult liver flukes: *Fasciola* spp., *Fascioloides* spp.

Sheep:
Gastrointestinal roundworms: *Ostertagia* spp., *Haemonchus contortus, Nematodirus* spp., *Chabertia ovina, Gaigeria* spp., *Oesophagostomum* spp., *Bunostomum* spp., *Trichostrongylus* spp.
Tapeworms: *Moniezia* spp.
Lungworms: *Dictyocaulus* spp., *Muellerius* spp., *Protostrongylus* spp.
Adult liver flukes: *Fasciola* spp., *Fascioloides* spp., *Dicrocoelium* spp.

3.3 Contraindications

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

3.4 Special warnings

Animals suffering from severe lung damage due to heavy lungworm infestation may continue to cough for some weeks after treatment.
Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the veterinary medicinal product should be based on confirmation of the parasitic species and burden, or of the risk of infection based on its epidemiological features, for each herd/flock.
Repeated use for an extended period, particularly when using the same class of substances, increases the risk of resistance development. Within a herd/flock, maintenance of susceptible refugia is essential to reduce that risk. Systematically applied interval-based treatment and treatment of a whole herd/flock should be avoided. Instead, if feasible, only selected individual animals or subgroups should be treated (targeted selective treatment). This should be combined with appropriate husbandry and pasture management measures. Guidance for each specific herd/flock should be sought from the responsible veterinarian.
Resistance to benzimidazoles (which includes albendazole) has been reported in *Haemonchus, Cooperia, Trichostrongylus* and *D. dendriticum* species in small ruminants in a number of countries, including the EU. The use of this veterinary medicinal product should take into account local information about susceptibility of the target parasites, where available.
It is recommended to further investigate cases of suspected resistance, using an appropriate diagnostic method (e.g. Faecal Egg Count Reduction Test).
Confirmed resistance should be reported to the marketing authorisation holder or to the competent authorities.

3.5 Special precautions for use

Special precautions for safe use in the target species:
None.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Albendazole and esters of parahydroxibenzoic acid may cause allergic reactions. People with known hypersensitivity to albendazole or parahydroxibenzoates should avoid contact with the veterinary medicinal product.
Albendazole may be teratogenic. Therefore, the veterinary medicinal product should not be administered by pregnant women or women who are intending to become pregnant.
This veterinary medicinal product may cause skin and eye irritation. Avoid skin and eye contact with the veterinary medicinal product. Personal protective equipment consisting of impermeable rubber gloves should be worn when handling the veterinary medicinal product.
In case of accidental contact, wash immediately the exposed area with plenty of clean water. If eye or dermal irritation persists, seek medical advice immediately and show the package leaflet or the label to the physician.
Do not smoke, eat or drink while handling the veterinary medicinal product.
Wash hands after use.

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 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:
Laboratory studies in mice, rats and rabbits have shown evidence of teratogenic effects.
Do not use 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

Oral use.
Shake well before use.

Cattle:
Gastrointestinal roundworms and tapeworms: 7.5 mg albendazole / kg bw (7.5 ml of veterinary medicinal product / 100 kg bw) in a single treatment.

Lungworms: 7.5 mg albendazole / kg bw (7.5 ml of veterinary medicinal product / 100 kg bw) in a single treatment.

Adult liver flukes: 10-15 mg albendazole / kg bw (10-15 ml of veterinary medicinal product / 100 kg bw) in a single treatment. In case of strong infection repeat the treatment after 21 days.

Sheep:
Gastrointestinal roundworms and tapeworms: 3.75 mg albendazole / kg bw (1.5 ml of veterinary medicinal product / 40 kg bw) in a single treatment.

Lungworms:
- *Dictyocaulus* spp.: 3.75 mg albendazole / kg bw (1.5 ml of veterinary medicinal product / 40 kg bw) in a single treatment.
- *Muellerius* spp. and *Protostrongylus* spp.: 7.5-10 mg albendazole / kg bw (3-4 ml of veterinary medicinal product / 40 kg bw). Repeat the treatment after 7 days.

Adult liver flukes:
- *Fasciola* spp. and *Fascioloides* spp.: 7.5-10 mg albendazole / kg bw (3-4 ml of veterinary medicinal product / 40 kg bw) in a single treatment.
- *Dicrocoelium* spp.: 7.5-10 mg albendazole / kg bw (3-4 ml of veterinary medicinal product / 40 kg bw). Repeat the treatment after 7 days.

Underdosing could result in ineffective use and may favour resistance development.
To ensure a correct dosage, body weight should be determined as accurately as possible. If animals are to be treated collectively, reasonably homogeneous groups should be set up, and all animals of a group should be dosed at the rate corresponding to the heaviest one.
A suitable graduated drenching gun should be used.

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

None known.

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.

Sheep:
Meat and offal: 4 days.
Milk: 96 hours.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP52AC11

4.2 Pharmacodynamics

Albendazole is a broad spectrum anthelmintic of the benzimidazole class for the control of gastrointestinal roundworms, lungworms, tapeworms and adult liver flukes.
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.
The mechanism of benzimidazole anthelmintic resistance is principally linked to alterations in the gene that encodes for β- tubulin isotype 1 that prevent drug binding.

4.3 Pharmacokinetics

Albendazole is quickly metabolised to albendazole sulphoxide which persists at higher levels in cattle and sheep plasma for a longer duration after oral administration with peak plasma levels approximately 16 and 14 hours after dosing, respectively.
After oral administration of the veterinary medicinal product to cattle at a dose range of 15 mg albendazole / kg bw, the following parameters were observed: C_{max} of 2.19 µg/mL, $t_{½}$ of 2.09 h and AUC_t of 42.33 µg·h/mL.

And after oral administration of the veterinary medicinal product to sheep at a dose range of 10 mg albendazole / kg bw, the following parameters were observed: C_{max} of 2.41 µg/mL, $t_{½}$ of 4.85 hours and AUC_t of 69.61 µg·h/mL.

Environmental properties
Faeces containing albendazole excreted onto pasture by treated cattle and sheep 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: 42 months.
Shelf life after first opening the immediate packaging: 2 years.

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

High-density polyethylene (HDPE) bottles sealed with a polyethylene (PE) foil and closed with a HDPE screw cap.

Pack sizes:
Bottle of 1 l
Bottle of 5 l

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

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

Industrial Veterinaria, S.A.

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

{MM/YYYY}

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).