ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Bottles of 1 l and bottles of 5 l

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Albendazole 100 mg

3. PACKAGE SIZE

1 l
5 l

4. TARGET SPECIES

Cattle and sheep.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

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

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

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within 2 years
Once opened, use by…

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Industrial Veterinaria, S.A.

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

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. Composition

Each ml contains:

Active substance:
Albendazole 100 mg

Excipients:
Sodium methyl parahydroxybenzoate (E219) 1.5 mg
Sodium propyl parahydroxybenzoate 0.2 mg

White to cream white suspension.

3. Target species

Cattle and sheep.

4. Indications for use

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.

5. Contraindications

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

6. Special warnings

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.

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.

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.

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

7. Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:

8. Dosage for each species, routes and method of administration

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.

9. Advice on correct administration

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.

10. Withdrawal periods

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

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

11. Special storage precautions

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 2 years.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
This 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 applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Pack sizes:
Bottle of 1 l
Bottle of 5 l

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release <and contact details to report suspected adverse events>:
Industrial Veterinaria, S.A.
Esmeralda 19,
08950 Esplugues de Llobregat
(Barcelona), Spain
<+34 93 470 62 70>

Manufacturer responsible for batch release:

aniMedica GmbH
Im Südfeld 9

48308 Senden-Bösensell Germany

aniMedica Herstellungs GmbH
Im Südfeld 9
48308 Senden-Bösensell Germany

Local representatives <and contact details to report suspected adverse reactions>:
To be completed nationally

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

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.