

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE MEDICINAL PRODUCT**

SHANU-ZOLE 250 (Albendazole 250mg Bolus)

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

(a) Attached list of all ingredients in the format illustrated below:

<b>Ingredients</b>	<b>Strength</b>
Albendazole	250mg
Sucrose	975mg
Dextrin	650mg
Magnesium stearate	65mg
Talc	1300mg
Green colorant	32.5mg
Corn starch	3227.5mg

### **3. PHARMACEUTICAL FORM**

Bolus

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Cattle, calves, sheep and goats

#### **4.2 Therapeutic indications**

Prophylaxis and treatment of worm infections in cattle, calves, sheep and goats like:

Gastrointestinal worms: Bunostomum, Cooperia, Chabertia, Haemonchus, Nematodirus, Oesophagostomum, Ostertagia, Strongyloides and Trichostrongylus spp.

Lung worms: Dictyocaulus viviparus and D. filarial.

Tapeworms: Moniezia spp.

Liver-fluke: adult Fasciola hepatica

#### **4.3 Contraindications**

Contraindicated when administered in the first 45 days of gestation.

Not administered to dairy cow.



#### **4.4. Special warnings**

Intensive use or misuse of anthelmintics can give rise to resistance. To reduce this risk, dosing programmes should be discussed with your veterinary surgeon.

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,
- Under dosing, this may be due to underestimation of bodyweight, misadministration of the product or lack of calibration of the dosing device (if any).

#### **4.5 Special precautions for use**

Not administering to female cattle during the first 45 days of pregnancy or for 45 days after removal of bulls. Albendazole has been associated with teratogenic and embryo toxic effects in rats, rabbits and sheep when given early in pregnancy.

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

Direct contact with the skin should be kept to a minimum.

Wear suitable protective clothing including impermeable rubber gloves.

Wash hands after use.

#### **4.6 Adverse reactions**

Albendazole is tolerated without significant adverse effects when dosed in cattle at recommended dosages.

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

Not administered in the first 45 days of gestation.

Not administered to dairy cow.

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

No drug interactions are reported in animals.

#### **4.9 Amounts to be administered and administration route**

For oral administration:



Cattle and sheep: 10-15mg per kg body weight, calculated as Albendazole, equivalent to 1 bolus per 16.7-25kg body weight.

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

No treatment specified.

#### **4.11 Withdrawal period(s)**

For meat: Cattle: 14 days.

Sheep: 4 days.

For milk: 60 hours.

### **5. PHARMACOLOGICAL PROPERTIES**

ATCvet Code QP52AC11

Albendazole is a broad-spectrum anthelmintic.

#### **Mechanism of action of albendazole**

The molecular mode of action of all benzimidazoles, including albendazole, consists in binding to tubulin, a structural protein of microtubules. These microtubules are important organelles involved in the motility, the division and the secretion processes of cells in all living organisms. In the worms the blocking of microtubules perturbs the uptake of glucose, which eventually empties the glycogen reserves. This blocks the whole energy management mechanism of the worms that are paralyzed and die or are expelled.

Since cell division is also disturbed, worm egg production and development is also blocked by benzimidazoles, i.e. most of them also have an ovicidal effect.

Albendazole also inhibits a helminth-specific fumarate reductase, an enzyme involved in the energy management of the worm cells as well.

#### **Pharmacokinetics of albendazole:**

After oral administration of albendazole, up to 45% of the administered dose is absorbed into the bloodstream. In ruminants, the slow passage through the complex stomach prolongs the time it can be absorbed. Direct administration into the abomasum (e.g. due to the "oesophageal groove reflex") strongly diminishes the



absorption and consequently its efficacy.

Absorbed albendazole is very quickly metabolized in the liver to its sulfoxide derivative, which has also anthelmintic efficacy and is exactly ricobendazole, another commercial anthelmintic active ingredient. In fact, in most species the parent molecule remains almost undetectable in blood after administration. In a second much slower step the sulfoxide is further metabolized in the liver to the sulfone metabolite that has no anthelmintic efficacy. The high plasma levels of albendazole sulfoxide make it effective against adult worms and immature stages in various host tissues and organs outside the gastrointestinal tract.

Interestingly, part of the sulfoxide produced through metabolism is released back to the rumen, where the bacterial flora reduces it back to albendazole. This increases the bioavailability of albendazole in ruminants.

Excretion occurs through bile and feces, as well as through urine. In ruminants 60-70% of the administered dose is excreted through urine in the form of various metabolites, the major one being the sulfoxide. In sheep about 14% of the administered dose is excreted through the bile, partly in the form of various active metabolites, which enables reaching effective anthelmintic concentrations in the bile ducts.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Sucrose;

Dextrin;

Corn starch;

Magnesium stearate;

Purified talc

Green colorant

### **6.2 Incompatibilities**

Not known.

### **6.3 Shelf life**



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3 years.

#### **6.4 Special precautions for storage**

Store in a cool dry place below 30 °C. protect from light.

#### **6.5 Nature and content of immediate packaging**

PVC plate and Aluminum foil;

Albendazole bolus 250mg, 5 boli per blister, 22 blisters per paper box.

#### **6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Dangerous to fish and aquatic life.

### **7. MARKETING AUTHORIZATION HOLDER**

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