

# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Chan Broad Spec Oral Suspension

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

### Active Substances

Rafoxanide 22.5 mg

Levamisole Hydrochloride 15 mg

### Excipients

Patent Blue V (E131) 0.005 mg

Sodium metabisulphite 1.0 mg

For a full list of excipients see section 6.1.

## 3 PHARMACEUTICAL FORM

Oral suspension.

## 4 CLINICAL PARTICULARS

### 4.1 Target Species

Cattle, sheep.

### 4.2 Indications for use, specifying the target species

Chan Broad Spec is effective in the treatment and control of roundworm, lungworm and fluke infections in cattle and sheep. It is highly effective against mature and developing immature stages of levamisole-susceptible major nematode species: *Haemonchus* spp, *Ostertagia* spp (except inhibited *Ostertagia* larvae in cattle), *Nematodirus* spp, *Trichostrongylus* spp, *Cooperia* spp, *Oesophagostomum* spp, *Chabertia* spp and *Bunostomum* spp and lungworms causing hoose (husk) in cattle and sheep. Chan Broad Spec is highly effective against mature fluke in cattle and sheep and 83% effective against 4-week old immature fluke in sheep. Chan Broad Spec is also effective against *Oestrus ovis* in sheep.

### 4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredients.

Do not use in animals less than 6 months of age.

#### 4.4 Special warnings for each target species

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 bodyweight, misadministration of the product, or lack of calibration of the dosing device.

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 tests strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

#### 4.5 Special precautions for use

##### Special precaution(s) for use in animals

When a dosing gun is used to administer the product, care must be taken to avoid damage to the pharyngeal region.

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

When using do not eat, drink or smoke. Wash hands and exposed skin before meals and after work. Remove immediately any contaminated clothing. Wash splashes from eyes and skin immediately. Levamisole can cause idiosyncratic reactions and serious blood disorders in a very small number of people. If symptoms such as dizziness, nausea, vomiting or abdominal discomfort are experienced when using the product, or sore mouth/throat or fever occur shortly afterwards, then medical advice should be sought immediately.

#### 4.6 Adverse reactions (frequency and seriousness)

Occasionally at the recommended dose cattle may show signs of lip-licking and slight muscle tremors.

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

Chan Broad Spec is safe for use during pregnancy (see section 4.11).

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

Animals should not be treated simultaneously with products containing organophosphorous compounds or diethyl carbamazine citrate. Any such treatment should not take place within 14 days before or after the use of Chan Broad Spec. Not to be diluted or mixed with other products.

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

For oral administration only using properly calibrated dosing equipment.

Estimate bodyweight accurately.

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.

One ml of Chan Broad Spec contains 22.5 mg of Rafoxanide and 15 mg of Levamisole HCL.

The dose rate for cattle and sheep is 7.5 mg levamisole HCL and 11.25 mg rafoxanide per kg bodyweight, equivalent to 5 ml Chan Broad Spec per 10 kg bodyweight in sheep and 25 ml per 50 kg bodyweight in cattle.

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

Clinical signs of toxicity include lip-licking, increased salivation, muscle tremors and head-shaking.

#### **4.11 Withdrawal Period(s)**

Cattle and sheep may be slaughtered for human consumption only after 60 days from the last treatment.

Cattle:

Not authorised for use in cattle producing milk for human consumption, including pregnant cattle intended to produce milk for human consumption.

Sheep:

Not authorised for use in ewes producing milk for human consumption including during the dry period. Do not use within 1 year prior to the first lambing in ewes intended to produce milk for human consumption.

### **5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES**

Pharmacotherapeutic group: Fasciolicide, rafoxanide.

ATCvet code: QP52AG05

Pharmacotherapeutic group: Anthelmintic, levamisole.

ATCvet code: QP52AE01

#### **5.1 Pharmacodynamic properties**

Chan Broad Spec contains both rafoxanide, a fasciolicide and levamisole HCL an anthelmintic in fixed combination.

Rafoxanide is a salicylanide derivative and has been used as a fasciolicide for several years. It acts by uncoupling oxidative phosphorylation in the parasitic cells, gradually depriving them of energy. Because it is highly protein bound it is only activated when released from the plasma proteins by the action of blood sucking organisms, it therefore is selective for fasciola and blood sucking organisms.

Levamisole is the l-isomer of the anthelmintic tetramisole. It acts as a cholinergic agonist causing depolarising ganglionic blockade of the parasite's neuromuscular junction.

#### **5.2 Pharmacokinetic properties**

Rafoxanide is absorbed slowly, binds to plasma proteins and is slowly eliminated from the body.

Levamisole is quickly and extensively absorbed from the gastrointestinal tract and is also quickly eliminated.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Disodium Hydrogen Phosphate Dodecahydrate  
Citric Acid Monohydrate  
Disodium Edetate  
Sodium Metabisulphite  
Patent Blue V (E131)  
Colloidal silicone dioxide  
Polysorbate 20  
Propylene Glycol  
Simethicone emulsion  
Xanthan Gum  
Purified Water

### **6.2 Incompatibilities**

None known.

### **6.3 Shelf-life**

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

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

Do not store above 25°C.

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

1 litre, 2.5 litre and 5 litre high density polyethylene containers with polyethylene closures.

Not all pack sizes may be marketed.

### **6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials**

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

## **7 MARKETING AUTHORISATION HOLDER**

Chanelle Pharmaceuticals Manufacturing Ltd.,  
Loughrea,  
Co. Galway,  
Ireland.

## **8 MARKETING AUTHORISATION NUMBER(S)**

VPA: 10987/010/001

## **9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

30<sup>th</sup> September 2009

**10 DATE OF REVISION OF THE TEXT**

January 2014