

PART III

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the veterinary medicinal product

Abinex Forte Pour On

2. Qualitative and quantitative composition

2.1 Active Substances

Abamectin	1% w/v
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2.2 Excipients

Benzyl Alcohol	20% w/v
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3. Pharmaceutical form

Pour-on solution.

4. Pharmacological properties

Abamectin or Avermectin B₁ is the natural fermentation product from *Streptomyces avermitilis* containing not less than 90% for the B_{1a} component and not more than 10% of the B_{1b} component.

The action of avermectins is on nematode and arthropod parasites by paralysing them through potentiating the presynaptic release of gamma amino butyric acid (GABA).

The pharmacokinetic profile of avermectins may be influenced by the formulation used.

Abinex Forte Pour-on is formulated in a carrier vegetable oil base. Vegetable oils are preferred to effectively cause permeation through the skin. The persistent (35 days) blood levels of Abamectin reflected this.

Avermectins are widely dispersed in all tissues with the liver and fat levels being the highest. Excretion is mainly intra intestinal, through bile, and the drug is eliminated via the faeces.

5. CLINICAL PARTICULARS

5.0 Target Species

Cattle (Beef and non-lactating dairy cattle).

5.1 Indications for Use, Specifying the Target Species

A broad-spectrum endectocide of the avermectin family, effective against internal and external parasites sensitive to this family. For the treatment and control of the following mature and immature roundworms and lungworms in cattle:

Haemonchus spp., *Ostertagia* spp., *Cooperia* spp., *Trichostrongylus* spp., *Oesophagostomum* spp., *Nematodirus* spp., *Trichuris* adults and *Dictyocaulus* spp. Also for the treatment and control of sucking and biting lice (*Linognathus vituli* and *Damalinia bovis* respectively).

5.2 Contra-indications

Do not concurrently treat animals with drugs which can increase GABA activity such as barbital.

Do not treat animals with a known hypersensitivity to the active ingredient.

5.3 Undesirable Effects (Frequency and Seriousness)

None.

5.4 Special precautions for use

Assess bodyweight as accurately as possible before calculating dosage. Intensive use or misuse of anthelmintics may give rise to drug resistance. To reduce this risk, dosing programs should be discussed with your veterinary surgeon.

5.5 Use During Pregnancy and Lactation

Do not use in cattle producing milk for human consumption.

5.6 Interaction with other Medicaments and other Forms of Interaction

None known.

5.7 Posology and Method of Administration

Shake well before use.

Abinex Forte Pour-on is ready to use through standard pour-on equipment.

Cattle: 1 ml/20 kg bodyweight (based on the recommended dose of 500 micrograms of Abamectin per kg bodyweight) poured on the mid-back of the animal if using the 200 ml pump pack, the measuring cup on the 400 ml pack or if using a pour-on gun attached to the specially made container cap. Using the 200 ml pump pack, 1 stroke per 44 kg bodyweight.

To obtain maximum benefit from the persistent activity of Abinex Forte Pour-on calves which are set-stocked in their first grazing season should be treated at turn-out and at 8 week intervals.

Rain Resistance

Clinical trials have shown that the efficacy of Abinex Forte Pour-on is not affected by simulated rainfall 1 hour after treatment, based on faecal egg counts 3 weeks after treatment. It is advised not to treat cattle when the hide or hair is wet.

5.8 Overdose (Symptoms, Emergency Procedures, Antidotes) (if Necessary)

Trials showed that a dose of 1000 µg/kg single or repeated after 21 days caused no ADRs, however several fold overdose of the injectable formulation of Abinex Forte can cause toxicity; animals will become recumbent within 24 hours and may not recover; there is no antidote.

5.9 Special Warnings for each Target Species

None.

5.10 Withdrawal Periods

Cattle must not be treated within 35 days of slaughter for human consumption.

Do not use in cows producing milk for human consumption.

Do not use in non-lactating dairy cows, including pregnant heifers within 60 days of calving.

5.11 Special Precautions to be taken by the Person Administering the Product to Animals

Avoid contact with the skin.

Do not smoke or eat while handling the product.

The use of plastic gloves is advised.

Wash hands after use.

For animal treatment only.

Do not use in other species.

If the drug is taken by mistake immediately seek medical treatment. Emetine or ephedrine may be useful.

6. PHARMACEUTICAL PARTICULARS

6.1 Incompatibilities

None known.

6.2 Shelf-life

Two years.

6.3 Special Precautions for Storage

Do not store above 25°C.

Protect from light.

6.4 Nature and Contents of Container

Clear, straw coloured oily solution packed in 200 ml pump pack, 400 ml pack and 1L and 2.5 L fluorinated HDPE, black, jerry cans provided with a cap on which normal pour-on gun could be fitted.

6.5 Name and Address of Veterinary Product Authorisation Holder

Bimeda Chemicals Ltd.,
Broomhill Road,
Tallaght
Dublin 24

6.6 Special Precautions for the Disposal of Unused Product or Waste Materials, if any

Abamectin should not enter watercourses as it is extremely dangerous to fish and aquatic life. Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7. FINAL INFORMATION

7.1 Marketing Authorisation Number

VPA 10126/66/1

7.2.1 Date of Approval of SPC

26th January, 2001

7.2.2 Date of Revision of SPC