Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Abinex Forte 1 % w/v Pour On Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substances:	**Quantity:**
Abamectin	1% w/v

Excipients:

Benzyl Alcohol	25% w/v

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Pour-on solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle (Beef and non-lactating dairy cattle).

4.2 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 spp. (adults only)
Dictyocaulus spp.

Also for the treatment and control of sucking and biting lice (*Linognathus vituli* and *Damalinia bovis* respectively).

4.3 Contraindications

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.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals:

Assess body weight 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.

Special precautions to be taken by the person administering the veterinary medicinal 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.
Do not use in other species.
If the drug is taken by mistake immediately seek medical treatment. Emetine or ephedrine may be useful.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Do not use in cattle producing milk for human consumption.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

Shake well before use.

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

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

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

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

4.11 Withdrawal period(s)

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 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Abamectin or Avermectin B_1 is the natural fermentation product from *Streptomyces avermitilis* containing not less than 90% of 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. This was reflected by the persistent (35 days) blood levels of abamectin.

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl Alcohol
Soya bean oil

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months

6.4 Special precautions for storage

Do not store above 25°C.
Protect from light.

6.5 Nature and composition of immediate packaging

1 L and 2.5 L back pack flat bottomed HDPE containers provided with a cap on which normal pour-on equipment can be fitted. Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Abamectin should not enter watercourses as it is extremely dangerous to fish and aquatic life. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
2, 3 & 4 Airton Close
Airton Road
Tallaght
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22033/035/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26 January 2001
Date of last renewal: 26 January 2006

10 DATE OF REVISION OF THE TEXT

March 2021