

MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET (5 kg and 25 kg labels)

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing Authorisation Holder:
Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ivomec Premix for pigs 0.6% premix for medicated feed

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

Containing Ivermectin 0.6% w/w.

4. PHARMACEUTICAL FORM

Premix for medicated feed.

5. PACKAGE SIZE

5 kg

25 kg

6. INDICATIONS

The highly effective in-feed programme for the treatment and control of mange, lice and roundworms in adult and growing pigs.

The following parasites will be controlled by IVOMECC medicated Premix for Pigs when it is incorporated in the finished feed at the recommended rate.

External parasites

Treatment and control of:

Mange Mites: *Sarcoptes scabiei* var. *suis*

Lice: *Haematopinus suis*

Internal parasites

Treatment and control of:

Gastro - intestinal roundworms:

Ascaris suum - Adults and fourth-stage larvae

Hyostromylus rubidus - Adults and fourth-stage larvae

Oesophagostomum spp. - Adults and fourth-stage larvae

Strongyloides ransomi - Adults*

Lungworms:

Metastrongylus spp. - Adults

*IVOMEK Premix, when given to pregnant sows before farrowing, will control the transmission of *Strongylus ransomi* to piglets through the milk.

7. CONTRAINDICATIONS

Do not use for any other animal species as severe adverse reactions, including fatalities in dogs, may occur.

8. ADVERSE REACTIONS

9. TARGET SPECIES

Pigs.

10. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

To ensure thorough dispersion of the product, it should first be mixed with a suitable quantity of feed ingredients before incorporation in the final mix.

DOSAGE AND ADMINISTRATION

The recommended dose level is 100 mcg ivermectin/kg bodyweight fed daily for seven consecutive days. The inclusion rate of IVOMEK Premix, in kilograms per tonne of finished feed, can be calculated as follows:

$$\text{IVOMEK Premix inclusion rate} = \frac{0.1 \times \text{average bodyweight (kg)}}{6 \times \text{average daily feed intake (kg)}} \\ \text{(kg/tonne feed)}$$

Growing Pigs: The recommended dose level of 100 mcg of ivermectin per kg of bodyweight is obtained under most circumstances, for pigs up to 40 kg bodyweight, by including 333 g of IVOMEK Premix in each tonne of final feed. The IVOMEK Premix must be thoroughly mixed in the finished feed and fed continuously as the only ration for seven consecutive days.

In pigs weighing 40 kg and over, average daily feed consumption may fall below 5% of bodyweight, particularly if they are on a restricted feeding programme or where pigs are fed a high protein ration. Therefore, for pigs weighing 40 kg to 100 kg, include 400 g of IVOMEK Premix per tonne of feed.

Adult Pigs: The recommended dose level for adult pigs weighing over 100 kg is achieved in most circumstances by thoroughly mixing 1.67 kg of IVOMEK Premix with 1 tonne of pig feed. The resultant medicated feed is to be fed at the rate of 1 kg per 100 kg of bodyweight each day for seven consecutive days, as part of the individual ration. Where medicated feed is fed as part of the ration, it is recommended that the IVOMEK medicated feed is fed first. After this is consumed,

any remainder daily feed allocation should be given. This should be repeated for seven consecutive days.

Alternatively, where dry feed intake can be accurately measured and all the animals to be treated have a similar bodyweight, the inclusion rate can be calculated using the previous formula. This assumes the total ration is to be medicated.

11. ADVICE ON CORRECT ADMINISTRATION

RECOMMENDED TREATMENT PROGRAMME

Growing Pigs: Groups of growing pigs should be treated by feeding medicated feed for seven consecutive days on transfer to clean quarters.

Where an all-in all-out system is not possible, it is recommended that the parasite control programme should begin with treatment of all the growing pigs already in the house.

Breeding Animals: Breeding animals are treated by feeding medicated feed for seven consecutive days. At the time of initiating the parasite control programme, it is important to treat all the animals in the herd. After the initial treatment, use IVOMEC Premix regularly as follows:

Sows: Treat, preferably 14-21 days before farrowing, to minimize infection of the piglets.

Gilts: Treat 14-21 days prior to service. Treat 14-21 days prior to farrowing.

Boars: Treat at least 2 times per year. Frequency of and need for treatment are dependent on parasite exposure.

Note (1): Exposure of treated pigs to infected animals, contaminated premises, soil or pasture may result in reinfestation and retreatment may be necessary.

Note (2): Since the effect of ivermectin on mange mites is not immediate, avoid direct contact between treated and untreated pigs for at least one week after completion of treatment.

Note (3): Since louse eggs are unaffected by ivermectin and may take up to three weeks to hatch, retreatment may be necessary.

Category A manufacturers only. When used as recommended, this product should only be incorporated by Category A manufacturers.

The product can be incorporated in pelleted feed preconditioned with steam for up to 10 seconds at a temperature not exceeding 85° C.

12. WITHDRAWAL PERIOD

Animals must not be slaughtered for human consumption during treatment.

Adult pigs weighing more than 100 kg may be slaughtered for human consumption only after 12 days from the last treatment.

Pigs weighing less than 100 kg may be slaughtered for human consumption only after 3 days from the last treatment.

13. SPECIAL STORAGE PRECAUTIONS

PHARMACEUTICAL WARNINGS

Do not store above 25 °C.

Store in a dry place.

The product will remain stable in the finished feed for three months when stored below 25° C in a dry place.

14. SPECIAL WARNINGS

Do not smoke, drink or eat while handling the product.

Wash hands after use.

Mixing of the product with feed must take place in a well ventilated area.

Avoid contact with skin and eyes. In case of accidental contact, wash the affected areas thoroughly with clean running water. If eye irritation persists, seek medical advice.

15. EXPIRY DATE

Expiry Date:

16. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

ENVIRONMENTAL SAFETY

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE.

Do not contaminate surface water or ditches with the product or used containers.

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

18. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

POM-VPS

19. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of reach of children.

20. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/4168

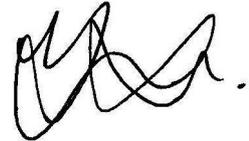
21. MANUFACTURER'S BATCH NUMBER

Batch No.:

22. FURTHER INFORMATION

Further information is available on request.

To be supplied only on veterinary prescription.

A handwritten signature in black ink, consisting of several loops and a final flourish.

Approved: 28 May 2020