

Proposed Labeling

“Tradenname to be selected” (IVERMECTIN)

PALATABLE “SOFT-CHEW” FOR ORAL USE IN HORSES

Items in quotes are descriptive and may be changed in the final labeling.

NADA NO. (To be determined), Approved by FDA

WARNING

Do not use in horses intended for food purposes.

Not for use in humans. Keep this and all drugs out of reach of children. Refrain from smoking and eating when handling. Wash hands after use. Avoid contact with eyes. The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse reactions in users, to obtain more information, or to obtain a MSDS, contact Intervet Inc. at 1-800-441-8272

PRECAUTIONS

“Brand Name” has been formulated specifically for use in horses **only**. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

Environmental Safety: Ivermectin and excreted residues may adversely affect aquatic organisms. Do not contaminate ground or surface water. Dispose of container in an approved landfill or by incineration.

Note to User: Swelling and itching reactions after treatment with ivermectin have occurred in horses carrying heavy infections of neck threadworm (*Onchocerca* sp.) microfilariae. These reactions were most likely the result of microfilariae dying in large numbers. Symptomatic treatment may be advisable. Consult your veterinarian should any such reactions occur. Healing of summer sores involving extensive tissue changes may require other appropriate therapy in conjunction with treatment with “Brand Name”. Reinfection, and measures for its prevention, should also be considered. Consult your veterinarian if the condition does not improve.

INDICATIONS

Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. “Brand Name” provides effective control of the following parasites in horses:

Large strongyles (adults): *Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*.

Small strongyles including those resistant to some benzimidazole class compounds
Triodontophorus spp., (adults and fourth-stage larvae): *Cyathostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp., *Cylicodontophorus* spp.

Pinworms (adults and fourth-stage larvae): *Oxyuris equi*.

Ascarids (adults and third- and fourth-stage larvae): *Parascaris equorum*.

Hairworms (adults): *Trichostrongylus axei*.

Large-mouth stomach worms (adults): *Habronema muscae*.

Bots (oral and gastric stages): *Gastrophilus* spp.

Lungworms (adults and fourth-stage larvae): *Dictyocaulus arnfieldi*.

Intestinal threadworms (adults): *Strongyloides westeri*.

Summer sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae:
Dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

DOSAGE AND ADMINISTRATION

This package contains a sufficient number of "soft-chews" to treat one 1,250 lb. horse at the recommended dose rate of 91 mcg ivermectin per lb. (200 mcg/kg) of body weight. Administer one "soft-chew" per 250 pounds of body weight of the horse. The "soft-chews" may be offered from your hand as the "soft-chews" have a flavor that horses commonly find pleasing. If you do not wish to offer the "soft-chews" from your hand the alternative method of administration would be to place the appropriate number of "soft-chews" on the horses feed so that they will be consumed.

PARASITE CONTROL PROGRAM

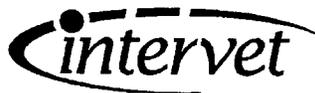
All horses should be included in a regular parasite control program with particular attention being paid to mares, foals and yearlings. "Dosing directions for various ages of animals will be determined during the consumption study and the method of dosing, or other recommendations, will be reflected in this section of the labeling." Consult your veterinarian for a control program to meet your specific needs. "Brand Name" effectively controls gastrointestinal nematodes and bots of horses. Regular treatment will reduce the chances of verminous arteritis caused by *Strongylus vulgaris*.

PRODUCT ADVANTAGES

Broad-spectrum Control – "Brand Name" kills important internal parasites, including bots and arterial stages of *S. vulgaris*, with a single dose. "Brand Name" is a potent antiparasitic agent that is neither a benzimidazole nor an organophosphate.

ANIMAL SAFETY

"Brand Name" may be used in horses of all ages including mares at any stage of pregnancy. Stallions may be treated without adversely affecting their fertility.



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