



News Release

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U.S. Food and Drug Administration Approves *Profender*[®] Topical Solution (emodepside/praziquantel)

The first and only topical feline dewormer that treats and controls ascarids, hookworms, and tapeworms

SHAWNEE, KAN. (August 1, 2007) — The Animal Health Division of Bayer HealthCare LLC has introduced *Profender*[®] *Topical Solution* (emodepside/praziquantel), the first and only topical feline dewormer that treats and controls ascarids, hookworms, and tapeworms. *Profender* is a new, prescription only, topical solution for cats that provides stress-free administration for the cat, cat owner, and the veterinarian.

Profender features the time-tested active ingredient praziquantel, for the treatment of tapeworms, combined with the new unique compound emodepside which treats and controls larval and adult ascarids and hookworms. A single dose of *Profender* is effective, and a second dose should not be necessary to cover prepatent emergence.

Along with effective control of intestinal parasites, convenience of medication administration is a major issue among cat owners. Nearly 99 percent of veterinarians report that cat owners have a difficult time giving pills to their cats, according to a recent survey of small animal practitioners.¹

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“Orally administering a dewormer to a cat can be stressful for both the animal and the owner,” says Craig Reinemeyer, DVM, Ph.D, president of East Tennessee Clinical Research. “*Profender* provides stress-free treatment for cats and easy-to-use administration for owners, ultimately improving owner compliance and their pet’s health.”

A topical application of *Profender* is absorbed through the skin and enters the circulation, allowing both active ingredients, emodepside and praziquantel, to exert their effects directly on target parasites in the gastrointestinal tract. This new formulation is the first topical dewormer for cats with efficacy against most common intestinal parasites — ascarids, hookworms, and tapeworms. *Profender* is available in three convenient dose sizes — Small (.35ml for 2.2 lbs to 5.5 lbs) Medium (.70ml for >5.5 lbs to 11 lbs), and Large (1.12ml for >11 lbs to 17.6 lbs).

The Centers for Disease Control and Prevention (CDC), Companion Animal Parasite Council (CAPC), and American Association of Veterinary Parasitologists all recommend a strategic deworming program to help reduce the risk of transmission to pet owners. Leading parasitologists (CAPC) recommend year-round anthelmintics for cats.² Strategic deworming is a planned parasite control program that involves targeted deworming of pets to treat and control clinical disease and limit environmental contamination.

“Ideally, cat owners will apply *Profender* to treat and control intestinal parasites in a strategic deworming program based on risk factors and their veterinarian’s recommendation to ensure their cats are free of intestinal parasites,” says Joe Hostetler, DVM, Bayer Veterinary Services manager.

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In addition to strategic deworming, *Profender* is also a gap deworming tool. Gap deworming is the practice of deworming to fill the gaps in intestinal parasite treatment and control left by monthly heartworm preventatives/intestinal parasite combination products. Heartworm preventatives are administered at treatment intervals based on the lifecycle of heartworms, not intestinal parasites, and most do not kill immature and/or migrating stages. Heartworm preventatives don't prevent pets from acquiring new infections between doses and they have a varied parasitic spectrum. This creates a situation where a pet may shed potentially zoonotic eggs into the environment, as often as monthly, even if they are on a fully compliant heartworm regimen. When gaps and infection occur, *Profender* makes deworming easier for the cat.

In addition to affecting a cat's health, intestinal parasites pose a risk to owners and their families.

Zoonotic diseases can be transmitted via intestinal parasites, and children, pregnant women, and immunocompromised people are especially vulnerable. Backyards, sandboxes, public parks, and beaches accessible to dogs, cats, and wildlife often are contaminated with parasite eggs from an infected animal's feces.

According to the CDC, three to six million people in the United States are infected with *Toxocara larva migrans* each year, and the overall seroprevalence ranges from an average of 3.5 percent to more than 23 percent in some areas.³

“The public's exposure to zoonotic parasites is of a magnitude not generally recognized by some in the veterinary and medical communities,” said Byron Blagburn, M.S., Ph.D, Department of Pathobiology, Auburn University and president of CAPC. “The general public, particularly families with young children, need to be aware of the risk and take the appropriate steps to limit their exposure.”

Cat owners can limit their risk of exposure by practicing good personal hygiene and having children wash their hands after playing with pets and playing in potentially infected environments.

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Federal law (U.S.A.) restricts this drug to use by or on the order of a licensed veterinarian. Not for human use. Keep out of the reach of children. To prevent accidental ingestion of the product, children should not come in contact with the application site for up to twenty-four (24) hours while the product is being absorbed. Pregnant women, or women who may become pregnant, should avoid direct contact with, or wear disposable gloves when applying, this product.

Safe use of this product has not been evaluated in cats less than 8 weeks of age or weighing less than 2.2 lbs (1 kg), in cats used for breeding, during pregnancy or in lactating queens. The effectiveness of this product when used before bathing has not been evaluated. Use with caution in sick or debilitated cats. Oral ingestion or exposure should be avoided. Use with caution in heartworm positive cats. The cats enrolled in the field study were antigen and antibody negative prior to entering the study. In a laboratory study, cats artificially infected with adult heartworms and treated with *Profender* Topical Solution had fewer worms recovered than the placebo control group.

About Bayer Animal Health

Bayer HealthCare's Animal Health Division is the maker of Advantage® flea control for cats and dogs and K9 Advantix®, a flea, tick, and mosquito control product for dogs. Advantage, K9 Advantix, and Profender are trademarks of Bayer. The division is a worldwide leader in parasite control and prescription pharmaceuticals for dogs, cats, horses, and cattle. North American operations for the Animal Health Division are headquartered in Shawnee, Kan. Bayer Animal Health is a division of Bayer HealthCare LLC, one of the world's leading healthcare companies.

About Bayer HealthCare AG

Bayer HealthCare, a subsidiary of Bayer AG, is one of the world's leading, innovative companies in the healthcare and medical products industry and is based in Leverkusen, Germany. Bayer HealthCare generated sales amounting to some 9.4 billion euros and employed 33,800 people worldwide in 2005.

The company combines the global activities of the Animal Health, Consumer Care, Diabetes Care, Diagnostics and Pharmaceuticals divisions. The new Pharmaceuticals division was established on January 1, 2006, and comprises the former Biological Products and Pharmaceutical divisions. Pharmaceuticals now has three business units: Hematology/Cardiology, Oncology, and Primary Care.

Bayer HealthCare's aim is to discover and manufacture products that will improve human and animal health worldwide. The products enhance well-being and quality of life by diagnosing, preventing and treating diseases.

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¹ Results of a survey with a 401 small animal veterinarians, 2007

² Capcvet.org

³ CDC.gov