

Jan7Merck Animal Health Receives FDA Approval of BRAVECTO® (fluralaner topical solution) for Cats and Dogs

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Topical Treatment for Fleas and Ticks Effective for up to 12 Weeks

Merck Animal Health, known as MSD Animal Health outside of the United States and Canada, today announced the U.S. Food and Drug Administration's approval of BRAVECTO® (fluralaner topical solution) for both cats and dogs, a topical treatment for fleas and ticks effective for up to 12 weeks^{1,2} following a single dose.

"The approval of a second BRAVECTO product builds on the strong foundation and body of scientific evidence that we have established with our chewable tablet for dogs, our oral flea and tick product," said KJ Varma, senior vice president, research and development, Merck Animal Health. "With BRAVECTO Topical, we have expanded our portfolio in the fight against parasites, as well as provided cats flea and tick protection that delivers immediate and persistent killing activity for 12 weeks – another first in the industry."

BRAVECTO Topical is available in a convenient, single-dose spot-on, and is applied topically using the new "Twist'n'Use"™ pipette design for ease of application. BRAVECTO Topical for dogs kills adult fleas and is indicated for the treatment and prevention of flea infestations (*Ctenocephalides felis*) and the treatment and control of tick infestations [*Ixodes scapularis* (black-legged tick), *Dermacentor variabilis* (American dog tick), and *Rhipicephalus sanguineus* (brown dog tick)] for 12 weeks in dogs and puppies six months of age and older, and weighing 4.4 pounds or greater. It is also indicated for the treatment and control of *Amblyomma americanum* (lone star tick) infestations for eight weeks in dogs and puppies six months of age and older, and weighing 4.4 pounds or greater.

BRAVECTO Topical for cats kills adult fleas and is indicated for the treatment and prevention of flea infestations (*Ctenocephalides felis*) and the treatment and control of *Ixodes scapularis* (black-legged tick) infestations for 12 weeks in cats and kittens six months of age and older, and weighing 2.6 pounds or greater. It is also indicated for the treatment and control of *Dermacentor variabilis* (American dog tick) infestations for eight weeks in cats and kittens six months of age and older and weighing 2.6 pounds or greater.

"Fleas and ticks are not simply a nuisance, but can also cause significant irritation to our pets and even ourselves, and can transmit disease. So, effective protection against these parasites is truly essential to the health and well-being of our pets, as well as our homes," said Kathleen Heaney, D.V.M., executive director of technical services, Merck Animal Health. "The convenience of BRAVECTO's extended duration flea and tick protection is now available for cats and dogs in a topical formulation that is fast-acting and lasts nearly three times longer than conventional, monthly flea and tick products."^{1,2}

Fleas and ticks must attach to the treated animal and commence feeding in order to be exposed to the active substance. The active substance of BRAVECTO, fluralaner, an ectoparasiticide belonging to the isoxazoline group, is systemically active against fleas and ticks. The product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD) as a direct result of eliminating flea infestations.

BRAVECTO products are only available through licensed veterinarians. BRAVECTO Topical for cats is expected to be available later in 2016. The dog topical product is expected to be available in the first quarter of 2017.

Important Safety Information (Cats):

The most common adverse reactions recorded in clinical trials were vomiting, itching, diarrhea, hair loss, decreased appetite, lethargy, and scabs/ulcerated lesions. Bravecto has not been shown to be effective for 12-weeks' duration in kittens less than 6 months of age. Bravecto is not effective against American dog ticks beyond 8 weeks of dosing. For topical use only. Avoid oral ingestion. The safety of Bravecto has not been established in breeding, pregnant and lactating cats. Use with caution in cats with a history of neurologic abnormalities. Neurologic abnormalities have been reported in cats receiving Bravecto, even in cats without a history of neurologic abnormalities.

Important Safety Information (Dogs):

The most common adverse reactions recorded in clinical trials were vomiting, hair loss, diarrhea, lethargy, decreased appetite, and moist dermatitis/rash. Bravecto has not been shown to be effective for 12-weeks' duration in puppies less than 6 months of age. Bravecto is not effective against lone star ticks beyond 8 weeks of dosing. For

topical use only. Avoid oral ingestion. Use with caution in dogs with a history of seizures. Seizures have been reported in dogs receiving fluralaner, even in dogs without a history of seizures.

Click to view the U.S. Prescribing Information for BRAVECTO Topical Solution for **cats** and BRAVECTO Topical Solution for **dogs**.

About Merck Animal Health

For 125 years, Merck has been a global health care leader working to help the world be well. Merck Animal Health, known as MSD Animal Health outside the United States and Canada, is the global animal health business unit of Merck (NYSE:MRK). Through its commitment to the Science of Healthier Animals™, Merck Animal Health offers veterinarians, farmers, pet owners and governments one of the widest range of veterinary pharmaceuticals, vaccines and health management solutions and services. Merck Animal Health is dedicated to preserving and improving the health, well-being and performance of animals. It invests extensively in dynamic and comprehensive R&D resources and a modern, global supply chain. Merck Animal Health is present in more than 50 countries, while its products are available in some 150 markets. For more information, visit www.merck-animal-health.com or connect with us on [LinkedIn](#) and Twitter at @MerckAH.

Forward-Looking Statement of Merck & Co., Inc., Kenilworth, N.J., USA

This news release of Merck & Co., Inc., Kenilworth, N.J., USA (the “company”) includes “forward-looking statements” within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company’s management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company’s ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company’s patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company's 2015 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).

1 BRAVECTO Topical for cats is not effective against *Dermacentor variabilis* ticks beyond 8 weeks after dosing.

2 BRAVECTO Topical for dogs is not effective against *Amblyomma americanum* ticks beyond 8 weeks after dosing.

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