

BRAVECTO®: JUST THE FACTS FOR PET OWNERS

August 2017



Many of us at MSD Animal Health are veterinarians and/or pet owners and do what we do because of our love for animals. Their health and well-being is our top priority. We know that veterinarians and pet owners look to us to provide accurate and balanced information about our products, which is why it is so important that we share the **FACTS** about Bravecto®.

THE IMPORTANCE OF FLEA AND TICK PREVENTION

As you may be aware, fleas and ticks are not just a nuisance, but also pose animal and human health risks, as they can transmit disease (including *Babesia* (Biliary), *Ehrlichia*, *bartonellosis* and others).

That's why it's critical to protect pets from these parasites and keep them out of homes. Bravecto® is the first and only treatment that has been shown to quickly and effectively kill fleas and multiple tick species, as well as demodectic mites, for 12 weeks in a single dose.

More than 45 million doses of Bravecto® have been dispensed since its approval in 2014 and Bravecto is distributed in more than 60 countries around the world. We are pleased with the overwhelmingly positive responses we've had from veterinarians and pet owners from throughout the world about the benefits of Bravecto®.

EXTENSIVE SAFETY RESEARCH

- We are confident in the safety of Bravecto®.
- Prior to its first approval by a regulatory agency, the **safety of Bravecto® was established** through **comprehensive clinical research [studies](#)**.

As part of the product approval process, **regulatory agencies throughout the world** have reviewed the Bravecto® research data and have **deemed it safe for sale in their countries**, when used according to the product label. **Global safety surveillance** of Bravecto® use has provided **additional compelling evidence of the safety** of the product.

- In a well-controlled field study Bravecto® was used concurrently with other medications, such as vaccines, anthelmintics, antibiotics and steroids. **No adverse reactions were observed** when Bravecto® was used at the same time as other medications.^{1,2}
- The **rate of all adverse event reports is classified as RARE** (0,01-0,1 % of dogs treated). The most common reported events are mild and transient gastro-intestinal upset. The rate of **serious adverse events**, for example seizures, reported is classified as **VERY RARE** (less than 0,01 %)
- MSD Animal Health's research scientists have thoroughly reviewed the safety data for Bravecto® from **more than 55 controlled clinical trials**. These clinical trials were the basis for the approval of Bravecto® by 72 regulatory agencies around the world. Each of these regulators have affirmed, and continue to affirm, that Bravecto® is safe and effective for use as indicated in the label. Bravecto® is one of the few veterinary



treatments that regulators have approved for use in breeding, pregnant and lactating dogs, which is another indicator of its strong safety profile.

- Clinical research data and analysis of adverse events **do not demonstrate a causal relationship between Bravecto® and liver or kidney issues or cancer.**

COMMITMENT TO ETHICS AND TRANSPARENCY

- As a responsible animal health company, **we take every single report of a potential adverse event seriously.**
- Whenever possible, we work with the pet owner and attending veterinarian to assemble as much clinical information as we can, to try to **help determine the cause of a pet's health issue**, and whether or not the product may have been involved.
- **It is important to critically examine the facts relating to adverse events** vs. anecdotes that are not substantiated by science and medical evidence. **A report does not mean causation.**
- **We report findings to governing regulatory agencies** around the world (based on a country's respective laws and policies), so that they can make a fully informed, scientific assessment about the safety of the product.
- We do this so that **accurate safety and efficacy information is available for veterinarians prescribing our products.**
- **We are confident in the safety of Bravecto®.**

To reiterate, as a responsible animal health company, we take every report of a potential adverse event seriously and investigate thoroughly. We work with the pet owner and attending veterinarian to assemble all the information necessary to gain a complete picture of every case to help determine the cause of a pet's health issue. It is important to note that a pet may be on multiple medications or have other illnesses or pre-existing conditions. The adverse event may be related to these other factors and not to Bravecto®. However, we report all findings to the governing regulatory agency whether they were linked to the product or not. We do this so that accurate safety and efficacy information is always up-to-date and readily available for veterinarians prescribing our products.

**For more information, please visit www.bravecto.co.za.
Always consult with your own veterinarian about the
health and well-being of your pet, and when making
a decision about flea and tick control products.**

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¹ Röhlich et al. *Parasites & Vectors*, 2014, 7: 83.

² Walther et al. Plasma pharmacokinetic profile of fluralaner (Bravecto™) and ivermectin following concurrent administration to dogs. *Parasites & Vectors* (2015) 8:508.

BRAVECTO® Reg. No. G4083 (Act 36/1947) each chew contains 25 mg Fluralaner per kg body weight.

Intervet South Africa (Pty) Ltd., Reg. No. 1991/006580/07

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