



Elanco Animal Health

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**FOR IMMEDIATE RELEASE**

**Elanco Launches ITRAFUNGOL (itraconazole oral solution),  
FDA-Approved Feline Treatment for Ringworm**

**GREENFIELD, Ind.** (January 10, 2016) – Elanco Animal Health, a division of Eli Lilly and Company, has launched Itrafungol™ (itraconazole oral solution), the only marketed FDA-approved\* systemic treatment for dermatophytosis (ringworm) caused by *Microsporum canis* in cats.

Itrafungol is a cost-effective<sup>1</sup>, cherry caramel-flavored<sup>2</sup> liquid that is easy to dose and easy to administer. It requires a short course of pulse therapy oral dosing on alternate weeks for three treatment cycles.

“Our research indicated veterinarians were searching for a safe, effective and easy-to-administer feline ringworm treatment option<sup>3</sup>,” according to Cathy Martin, Sr. Director, Companion Animal Marketing, Elanco Animal Health. “Itrafungol’s goal is to meet those needs in a flavored systemic oral solution.”

It is estimated 1.3 million cats<sup>4</sup> are treated for ringworm each year, yet limited options exist that are approved by the U.S. Food and Drug Administration (FDA) for the treatment of ringworm in cats. Many currently available options are not FDA approved and treatment can be expensive<sup>1</sup> and lengthy in duration. Because topical treatments can be licked off, and bathing a cat can be difficult, many veterinarians consider resolution of ringworm to be a lengthy and trying process.<sup>5</sup> This resolution can range from six weeks to six months<sup>5</sup> depending on the severity and challenges to treatment. Itrafungol has not been shown to be sporicidal; therefore in order to reduce zoonotic potential, environmental contamination, and to decrease course of the disease, topical and environmental treatment should also be utilized.

Any cat can develop a dermatophyte (ringworm) infection. However, weak or immunosuppressed animals can be more susceptible to the development of the condition. Consequently, infection is seen most commonly in:

- Juvenile or geriatric cats<sup>6</sup>
- Cats with poor body condition<sup>6</sup>
- Cats with concurrent/debilitating disease<sup>6</sup>
- High density populations, such as shelters<sup>7</sup>

Dermatophytosis is a superficial fungal skin disease of cats. While it is highly contagious, it is not life-threatening and is treatable and curable. Cats can easily contract ringworm by direct contact. Additionally, ringworm is of zoonotic importance.<sup>6</sup>

While dermatophytosis can vary in presentation, typical clinical signs include hair loss, may be singular or multiple circular or irregular shaped patches, scaling/crusting and erythema. Lesions may affect the whole body, but mainly occur on the head, ears, tail and front paws.

Itrafungol is approved by the FDA and available only through veterinarians. The product is available in one 52mL SKU with an itraconazole concentration of 10 mg/mL.

### **IMPORTANT SAFETY INFORMATION**

Do not administer to cats with hypersensitivity to itraconazole. ITRAFUNGOL has not been shown to be safe in pregnant cats and should only be used in pregnant or lactating cats when the benefits outweigh the potential risks. Not for use in humans. Keep this and all medications out of reach of children. Wash hands and exposed skin after use. Use with caution in cats with renal dysfunction or impaired liver function. If clinical signs suggestive of liver dysfunction develop, treatment should be discontinued. ITRAFUNGOL is a cytochrome p-450 inhibitor and may increase or prolong plasma concentrations of other drugs metabolized by this pathway. Cats suffering from heart disease should be carefully monitored during treatment. The most common adverse reactions reported in clinical trials include vomiting, diarrhea, decreased appetite and elevated hepatic enzymes. For full prescribing information, please call 1-888-545-5973.

### **ABOUT ELANCO PRODUCTS**

ITRAFUNGOL joins Elanco's broad portfolio of products including OSURNIA (florfenicol/terbinafine/betamethasone acetate), ATOPICA (cyclosporine capsules) USP MODIFIED, ATOPICA for Cats (cyclosporine oral solution) USP MODIFIED, SUROLAN (miconazole nitrate, polymyxin B sulfate, prednisolone acetate) and ZOBUXA (enrofloxacin).

### **ABOUT ELANCO**

Elanco provides comprehensive products and knowledge services to improve animal health and food-animal production in more than 70 countries around the world. We value innovation, both in scientific research and daily operations, and strive to cultivate a collaborative work environment for more than 6,500 employees worldwide. Together with our customers, we are committed to raising awareness about global food security and celebrating and supporting the human-animal bond. Founded in 1954, Elanco is a division of Eli Lilly and Company. Our worldwide headquarters and research facilities are located in Greenfield, Indiana. Visit us at [elanco.com](http://elanco.com).

*This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about Itrafungol as a systemic treatment for dermatophytosis (ringworm) caused by *Microsporium canis* in cats, and reflects Lilly's and Elanco's current belief. However, as with any animal health product, there are substantial risks and uncertainties in the process of development and commercialization. Among other things, there can be no guarantee that Itrafungol will receive additional regulatory approvals or be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's most recent Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly and Elanco undertake no duty to update forward-looking statements to reflect events after the date of this release.*

\*NADA 141-474

### **SOURCES**

<sup>1</sup>Elanco Data on File

<sup>2</sup>Elanco Data on File

<sup>3</sup>Itraconazole Research, Market Vibes, 2013

<sup>4</sup>Market estimation based on disease incidence from itraconazole Research, Market Vibes, 2013

<sup>5</sup>Dermatology Platform Study, Ipsos, December 2014

<sup>6</sup>Moriello KA. Journal of Feline Medicine and Surgery (2014) 16: pp. 419-431.

<sup>7</sup>van der Leij, R. (2012), "The other side of ringworm," Proceedings of the European Veterinary Conference Voorjaarsdagen, Amsterdam, 5-7 April. Available at:  
[http://www.voorjaarsdagen.org/index.php?option=com\\_phocadownload&view=category&download=1588:vdleij-othersideringworm&id=60:companion-animal-scientific-proceedings-2012&Itemid=97&start=20](http://www.voorjaarsdagen.org/index.php?option=com_phocadownload&view=category&download=1588:vdleij-othersideringworm&id=60:companion-animal-scientific-proceedings-2012&Itemid=97&start=20) (Accessed: November 2, 2016).

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