North America Region Animal Health Group Pfizer Inc 812 Springdale Drive Exton, PA 19341

Animal Health



March 9, 2000

Dear Doctor.

The purpose of this letter is to inform you of several changes Pfizer will implement in 2000 regarding Rimadyl® (carprofen). Similar to trends observed in human medicine, the veterinary community is finding that their clients are becoming more educated on medical conditions. These educated consumers are demanding more detailed explanations and comprehensive product information than they have in the past. The following outlines several ways Pfizer Animal Health will take the lead to help you facilitate appropriate risk benefit communication with your clients when prescribing Rimadyl. This letter also contains important medical/safety information and is part of an ongoing commitment of Pfizer Animal Health and the FDA-CVM to provide updated information about veterinary products.

In 2000, Pfizer will begin including an updated Rimadyl Owner Information Sheet which will be provided along with the prescribing information (product insert) written for veterinarians. Similar to Patient Prescribing Information (PPI), which is commonly distributed with pharmacy prescriptions for people, this owner information sheet is written in "consumer-friendly" language and provides information about the benefits and side effects associated with NSAIDs and Rimadyl. Like the product insert, this Owner Information Sheet will be attached to each bottle of Rimadyl Caplets and Rimadyl Chewable Tablets. Pfizer also plans to add this feature to other major veterinary pharmaceuticals.

Pfizer Animal Health and the FDA-CVM encourage the dispensing of prescription products in manufacturer's approved packaging to help ensure child resistance, to provide complete prescribing and owner information, and maintain quality assurance. To better enable veterinarians to dispense full bottles, Rimadyl Caplets will be available in 60-count and 180-count bottles like packaging currently available for Rimadyl Chewable Tablets. (The 100 and 250 count bottles will be discontinued as inventories are depleted.) These new bottle counts will provide a convenient 1-month and a 3-month supply. Additionally, in 2000, Pfizer will introduce a new 14-count trial size for Rimadyl Caplets and Rimadyl Chewable Tablets, which contains a 7-day supply. The trial size bottles are designed to offer a 7-day supply for new patients to help you and your clients determine if Rimadyl is the appropriate medicine for their dog. Eventually, all bottles will have both the prescribing information (product insert) written for veterinarians and the new Owner Information Sheet attached as an outsert on the outside of the bottles. Pfizer will still provide dispensing sheets if you choose to repackage Rimadyl in some situations.

As I am sure you are aware, Pfizer Animal Health introduced Rimadyl Chewable Tablets in June 1999. Since this introduction Pfizer has received reports of accidental overdose in dogs and cats. Dogs, and apparently cats, are attracted to the tablets due to the palatability. Please remind clients that Rimadyl Chewable Tablets should be stored in a **secured** area out of reach of their dogs and cats. This safety measure is outlined on the product insert as well as the product container, and is emphasized in the Owner Information Sheet.

As part of our commitment to communicate with the veterinary community about the safe and effective use of its products, Pfizer Animal Health recently published an updated Technical Bulletin, entitled: *Update: Two-Year (1997-1998) Clinical Experience with Rimadyl (carprofen)*. This update, distributed in August 1999, contains a recent summary of adverse event report information as well as data from contemporary clinical studies. The incidence of reported possible adverse drug events in 1998 was approximately 0.18% or 2/10ths of 1%. Some of these side effects, like those of many other NSAID-class medications, may occur without warning and, in rare situations, may be serious, resulting in hospitalization or even death. Additional copies of this technical bulletin can be requested through Pfizer Technical Services 1(800) 366-5288 or by accessing our websiteⁱ. In December 1999, FDA-CVM published their 1998 adverse drug event report and provided an update that addresses the high number of reports in dogs receiving Rimadyliⁱⁱ. The data in the FDA report is consistent with the information Pfizer previously provided to veterinarians in the August 1999 Technical Bulletin.

In summary this communication is part of Pfizer's continued commitment to provide complete information about the safe and effective use of its products. Pfizer, in conjunction with the FDA-CVM, encourage veterinarians to provide owners with information about both risks and benefits associated with all potential therapeutic options. Pfizer is assisting veterinarians to do this by continually updating prescribing information, providing Owner Information Sheets, and packaging Rimadyl in convenient trial size, 1 and 3 month supply bottles.

Please share this letter with other associates in your practice. If you have questions or comments about the contents of this letter please feel free to contact Pfizer Technical Services at 1(800) 366-5288. Enclosed with this letter is the most current Rimadyl prescribing information and Owner Information Sheets soon to be attached to all Rimadyl bottles.

Sincerely,

Edward W. Kanara, DVM, DABVP Director, Technical Services

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Companion Animal Division

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iwww.pfizer.com/AH

iiwww.FDA.gov