ROADRUNNER PHARMACY

ROADRUNNER EXPRESS

Roadrunner Pharmacy 711 E. Carefree Hwy. Suite 140, Phoenix, AZ 85085 • 877-518-4589

Fall 2014

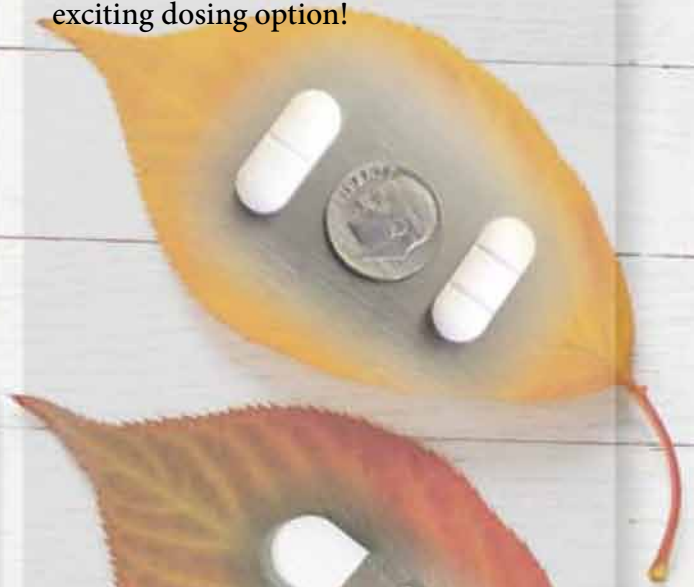
New INNOVATIVE Therapies

Shelter Five

Practitioners from shelters, rescues and humane societies always ask about options for treating their populations with a flexible liquid dosage form that they can use against common GI parasites, heartworm and fleas. With so many weight ranges, it has been difficult for them to dose their diverse populations. At the request of veterinarians, we have compounded an oil-based suspension containing oxantel, praziquantel, pyrantel, ivermectin and lufenuron which can be dosed with a sliding scale based on animal weight for a reasonable price. Call one of our knowledgeable pharmacists for information about what we call SHELTER FIVE.

INTRODUCING FLEX TABS

Flex-Tabs, Roadrunner Pharmacy's newest flexible dosing tablets, provide clinics and pet owners with remarkable versatility and value. Scored in half on one side and thirds on the other, this dosage form facilitates titration with new therapies as well as having the intrinsic value of four different strengths in a single tablet. Call one of our friendly pharmacists for more information on this exciting dosing option!



BitterRx Topical Spray

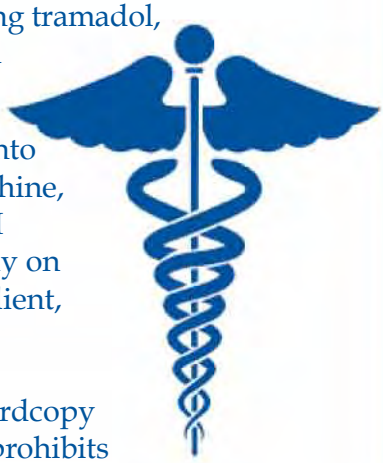
Hot spots? Biting? Acral Lick Dermatitis? Lick Granuloma?

While there are a few 'bitterants' or bad tasting deterrents in the veterinary community, many practitioners continue to ask first about diphemanil availability. The active ingredient in no-longer-available products like Bandguard® and Variton®. Diphemanil is a classic anticholinergic agent with a characteristic foul taste.

Practitioners have asked us to compound a 3% aqueous spray for topical administration on bandages and dressings used for wound protection. Additionally, this non-staining formulation can be applied to the fur as a deterrent against licking and self-mutilation. Call and speak to one of our pharmacists for more information!

FOCUS ON CONTROLLED SUBSTANCES

On August 18, 2014, tramadol became a Schedule IV Federally Controlled Substance. Not only does this mean that clinics will have to review security issues and record keeping, but the drug itself is likely to become difficult to find as many vendors pull back from the new heightened requirements. Under the auspices of our special DEA license, we are able to compound select controlled substances, including tramadol, for office stock in states that permit office use. Please refer to the special insert for a complete listing of available controlled substances included with this newsletter.



Beginning October 6, 2014, **all** products containing hydrocodone will be moved into the Schedule II class of controlled substances, sharing space with items like morphine, fentanyl and meperidine. Under the 21-page final rule from the DEA, Schedule II requirements will apply to "all pharmaceuticals containing hydrocodone currently on the market in the United States, including those combining it with another ingredient, such as homatropine." These requirements include, but are not limited to, requirements related to security protocols, labeling and packaging, inventory, recordkeeping and reporting. New prescriptions will now require an original hardcopy with an ink signature, and must be mailed to the pharmacy. Also, as federal law prohibits refills on schedule II drugs, a new prescription will be required for each fill.

Legal News: Collaboration Leads to Better Understanding

Despite the exclusion for veterinary compounding in the recently enacted federal law, virtually every state has enacted legislation that affects the way veterinarians provide care. As a result of the NECC tragedy, states are reigning in compounders with legislation that often impairs the quality of pet care. The practice of veterinary medicine is rarely a consideration when states consider compounding regulations. Instead, the utilization of compounds in human medicine are addressed with little to no thought to animal care. In this era of back-ordered, shorted and deleted drugs, compounded medication for office use and acute dispensing is an increasingly popular concept. As is the case in many states, in the great state of Virginia veterinarians found themselves at odds with their restrictive state regulations. In a huge collaborative effort, their VMA championed an amendment that now allows for stocking and dispensing small quantities of compounded medications. They have put together an impressive review to help others understand the process leading to the amendment; we have their permission to FAX it to others who are interested. Of note in this thorough review is this sentence that describes their first meeting: "…the most notable observation…is the contrast between human physicians and veterinarians relative to office stocks of compounded products."

Every state can do what this robust team did. We are delighted to FAX this document; please call one of our pharmacists if interested.

How a Drug Becomes a Sterilized Compound

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Sterile compounding is a very complex and exacting process that begins long before medications are involved. The United States Pharmacopeia (USP) provides the framework for sterile compounding facilities and procedures. Each room within our sterile facility is continuously monitored for temperature, humidity, pressure differentials and environmental contaminants. In addition to this monitoring, the cleanroom facility is certified by an independent company, every 6 months, who dynamically tests for proper air flow, particulate counts, surface contaminants, and air contaminants. In order to keep particle counts and contaminants to a minimum, access to the cleanroom is limited to sterile compounders and select pharmacists. Our sterile compounders must obtain a national certification and complete an intensive in-house training program based on principles found in USP chapter 797. Only after these are complete can we begin actual compounding. This infographic illustrates the path from beginning to end:

1. First, sterile compounders create a compound log where lot number and a Beyond-Use Date (B.U.D) are assigned. Documented on this log are:

- formula/recipe
- ingredients
- quantities
- calculations
- equipment used

2. Once ingredient selection and accurate quantity measurements have been verified by a pharmacist, they will then be combined in the mixing room (isolated clean room preparation area) according to the formula.

3. Next, the unsterile compound is taken to the buffer room (clean room) to be sterilized.

4. Sterilized depyrogenated glass vials and/or sterile ophthalmic containers are then filled with the appropriate aliquot of medication.

5. Samples of each lot, quantities based upon batch size and type, are then tested for sterility which includes a 14 day quarantine time.

6. During the quarantine period, certain additional tests including endotoxin and potency, are performed based on batch type. In addition to these tests, the sterility samples are monitored daily for turbidity.

7. If at any point turbidity is seen, the sterility test sample is sent to a 3rd party laboratory for gram staining and isolation and identification if necessary. If, after 14 days, all tests have favorable results, the batch will be released from quarantine and available for purchase.

8. If any applicable test were to come back out of specification, the entire batch would be discarded.

A Good Base Makes All the Difference!

Over the years, tacrolimus has become a popular option for the treatment of keratoconjunctivitis sicca (KCS) in dogs. As compounders, we regularly have requests to put medications, including tacrolimus, into specific vehicles or bases. These requests are usually based on veterinarian preference, a new study or due to allergy restrictions in the patient. Whatever the case may be, we do our best to accommodate the request. Aqueous tacrolimus is commonly requested for various reasons, including possible allergies to proteins found in corn, olive and coconut oil. There are proprietary formulations for aqueous tacrolimus available, but unfortunately the dating is relatively short because tacrolimus is not soluble in water. Components of the formulations for aqueous tacrolimus help suspend the drug in water but do not truly solubilize it into a solution. Independent laboratory testing shows that tacrolimus in an aqueous base degrades much more rapidly than in oil formulations. A process called sonication, the use of sound waves to agitate particles, can be used when testing aqueous tacrolimus which will show improved results. While this appears to be great news for pharmacies selling aqueous tacrolimus with extended dating, unfortunately clients will not be able to sonicate their medication prior to administration to their pets bringing the potency into question.

Tacrolite tube shown approximate actual size

Knowledge of this information has led us to the newly formulated non-aqueous tacrolimus compound we refer to as Tacrolite™. This formulation is protein free and clear in color alleviating most concerns with allergies or tear staining. This mineral oil formulation has testing to support dating beyond the 6 months we assign at room temperature.

If you would like more information or copies of test results for aqueous and non-aqueous formulations feel free to contact us at 877-518-4589 or e-mail QA@roadrunnerpharmacy.com.

Please Join Us: Veterinarian Dinner Talks

October 20: White Marsh, MD - *Parker's*
October 21: Wilkes-Barre, PA - *Isabella Restaurant & Bar*
October 22: Sommerville, NJ - *Alfonso's Family Trattoria*
October 23: Paramus, NJ - *Joe's American Bar & Grill*

Call for more information or to R.S.V.P
call 877-518-4589 ext. 513

Winning Big with Roadrunner!

Congratulations to Dr. Dan Kerins of Alibaster Animal Clinic who won a flat-screen television at the Southern Veterinary Conference in August.

Pictured left to right: Michael Weber, Dr. Dan Kerins, Scott Chapman, Ryan Koenig.