

To the research community,

We have a very important announcement regarding the use of Buprenorphine SR in rodents.

Buprenorphine SR

The FDA recently ruled that off-label and compounded drugs can only be used without a veterinary prescription if an FDA-approved alternative is not available. The new [FDA guidance](#) requires that a labeled product is used when one is available. As of now, there are two labeled extended-release buprenorphine veterinary products: Ethiqā labeled for mice and rats, and Simbadol for cats. Buprenorphine SR ("Bup SR) has commonly been used for rodent analgesia, especially for surgical pain. However, an on-label, FDA-approved, extended release, veterinary, buprenorphine product is available, Ethiqā XR[®] (<https://ethiqaxr.com>).

Effectively immediately, UAC Veterinary Services can no longer prescribe Buprenorphine SR for use in rodents (mice and rats). Buprenorphine SR can still be used in other species as there is no FDA-labeled alternative (large animals, rabbits, ferrets, etc.).

Some key points:

1. Investigators can use existing supply of Buprenorphine SR.
2. Any mouse and rat protocols currently approved to use Buprenorphine SR will need to transition to Ethiqā XR[®] or, for short-term analgesia, Buprenorphine HCl. This change will be accomplished using the amendment and deNovo processes. Instructions to change products will occur during administrative and veterinary review.
3. Once supply of Buprenorphine SR is exhausted, no further activity can take place until an amendment has been approved to change to another product.

Dosing for the two drugs are as follows, and these are now available in eSirius in the veterinary drug list:

Mice:

- Buprenorphine HCl 0.1-0.5mg/kg SC q4-6hrs
- Ethiqā XR[®] 3.25mg/kg SC, 48-72hrs of analgesia

Rats:

- Buprenorphine HCl 0.05-0.1mg/kg SC q6-8hrs
- Ethiqā XR[®] 1.3mg/kg SC, 72-96hrs of analgesia

If you have any questions, please contact your UAC veterinarian or the Animal Welfare Program office, and thank you for your patience while we transition to the new requirements.