

IN CASE YOU MISSED THIS

On August 17, 2022, the IACUC voted to increase the frequency of dosing of meloxicam to twice a day as reasonably as possible to 12 hours apart at the same dose (5mg/kg) in mice to provide better pain coverage.

Please ensure that all members of your research team are aware of this change.

How will this affect you and your protocol?

- The standard procedures for meloxicam in mice (oral and injectable) will be updated to say “twice a day as reasonably as possible to 12 hours apart at the same dose (5mg/kg)” instead of “every 24 hours”.
- If you have meloxicam in your current protocol(s), the current standard procedure for Meloxicam will show as ## ARCHIVED##.
- If you have meloxicam in your current protocol(s), you can keep using it at the 24-hour interval until the next time your protocol is renewed or amended.
- As protocols are renewed, Meloxicam usage will be reviewed by the veterinarian and recommendations for changes in dosing interval might be made based on type of procedures/surgeries being performed.

Standard Library

Search

Create Procedure

Create Substance

Procedures In-Review	Procedures	Substances	History	Archived Procedures	Archived Substances		
Filter by ?		Name	%MELOX		Q	+ Add Filter	✕ Clear All
Name	SmartForm	Execute Activity	Date Modified	State	Version	Species	Procedure Type
Analgesia: Meloxicam twice a day (Oral)	[Edit or View] ▼	▶ Actions ▼	9/6/2022 6:03 PM	Active	2	Rodent: Mouse	Substance Administration
Analgesia: Meloxicam twice a day (subcutaneous)	[Edit or View] ▼	▶ Actions ▼	9/6/2022 6:01 PM	Active	3	Rodent: Mouse	Substance Administration



FAQs related to the Injectable Agents Policy



EMORY
UNIVERSITY

Research Compliance and Regulatory Affairs
Research Administration
Institutional Animal Care and Use Committee



Technology Check

Polls

-Pop up window and you check the answer

Annotate feature

-Upper right corner of your Zoom window

How to annotate if you are viewing shared content

While viewing a shared screen or shared whiteboard, click **View Options** then **Annotate** at the top.

Available annotation tools

You will see these annotation tools:



Poll 1

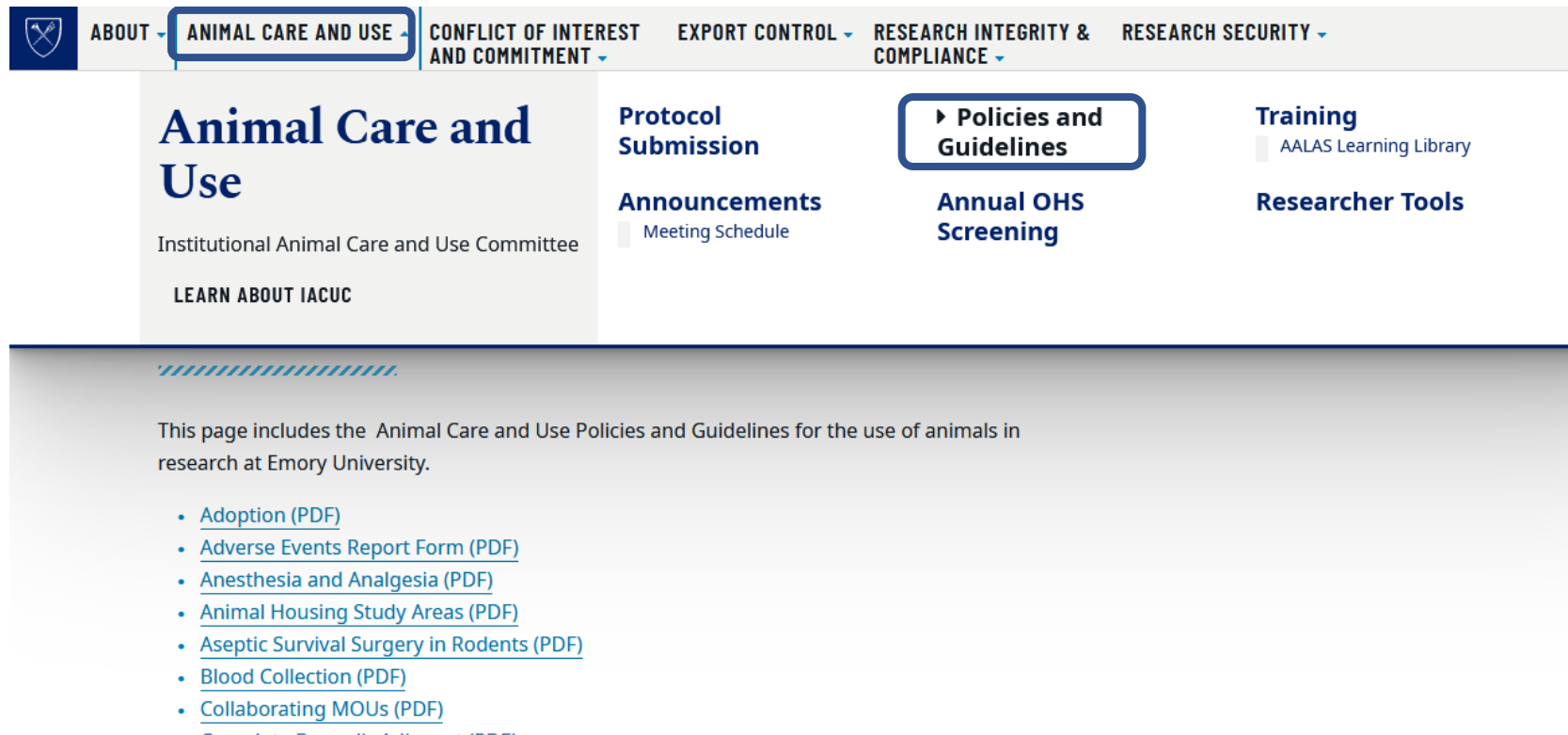
Note: The **Select**, **Spotlight**, and **Save** options are only available if you started the **shared screen** or **whiteboard**.

Goals of this L&L

- Review the key messages from the Injectable Agents Policy
- Recent exemption to single-dose preservative-free saline and water
- Recent Drug alert
- ❖ Number of punctures in injectables such as Meloxicam
- ❖ Drug labeling
- ❖ Mix of preservative-free (diluent or drug) with preservative (diluent or drugs) solutions
- ❖ Bup HCl and Bup SR
- ❖ Use of the multi-adaptor to facilitate multiple draws

Emory IACUC - Injectable Agents Policy

<https://rcra.emory.edu/iacuc/forms.html>



The screenshot shows the Emory IACUC website. The top navigation bar includes links for ABOUT, ANIMAL CARE AND USE (highlighted with a blue box), CONFLICT OF INTEREST AND COMMITMENT, EXPORT CONTROL, RESEARCH INTEGRITY & COMPLIANCE, and RESEARCH SECURITY. Below this, the main content area features a large section for 'Animal Care and Use' with the text 'Institutional Animal Care and Use Committee' and a link 'LEARN ABOUT IACUC'. To the right, there are links for 'Protocol Submission', 'Announcements' (with a sub-link 'Meeting Schedule'), 'Policies and Guidelines' (highlighted with a blue box and a sub-link 'Annual OHS Screening'), and 'Training' (with a sub-link 'AALAS Learning Library'). Below these, there is a section for 'Researcher Tools'. The bottom part of the page shows a list of links for various documents, including 'Adoption (PDF)', 'Adverse Events Report Form (PDF)', 'Anesthesia and Analgesia (PDF)', 'Animal Housing Study Areas (PDF)', 'Aseptic Survival Surgery in Rodents (PDF)', 'Blood Collection (PDF)', and 'Collaborating MOUs (PDF)'.

Animal Care and Use
Institutional Animal Care and Use Committee
[LEARN ABOUT IACUC](#)

Protocol Submission
Announcements
Meeting Schedule

Policies and Guidelines
Annual OHS Screening

Training
AALAS Learning Library

Researcher Tools

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This page includes the Animal Care and Use Policies and Guidelines for the use of animals in research at Emory University.

- [Adoption \(PDF\)](#)
- [Adverse Events Report Form \(PDF\)](#)
- [Anesthesia and Analgesia \(PDF\)](#)
- [Animal Housing Study Areas \(PDF\)](#)
- [Aseptic Survival Surgery in Rodents \(PDF\)](#)
- [Blood Collection \(PDF\)](#)
- [Collaborating MOUs \(PDF\)](#)

Poll 2

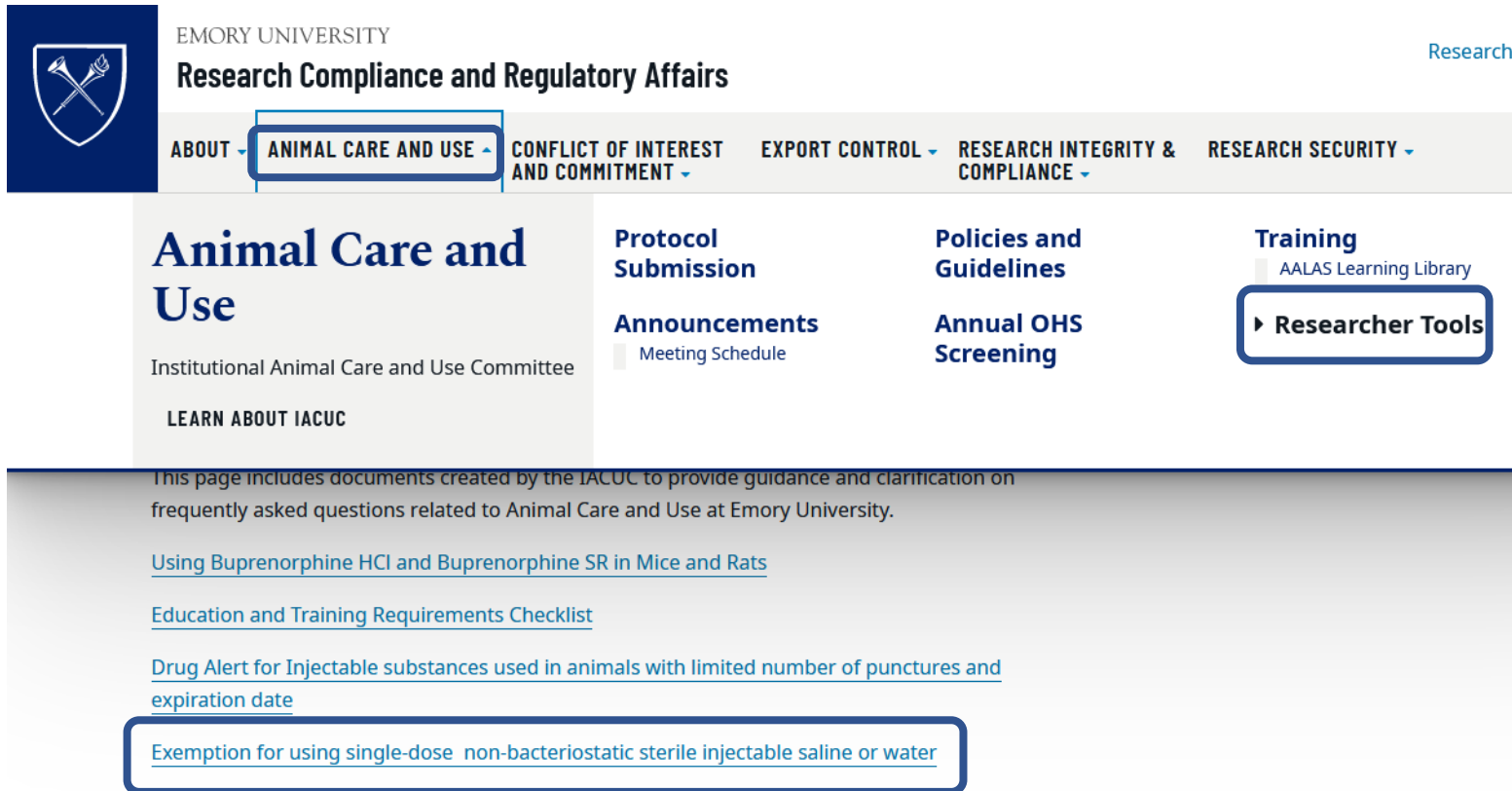
https://rcra.emory.edu/_includes/documents/sections/iacuc/forms/366_injectable_agents.pdf

Key messages from the Injectable Agents Policy

1. Reconstitution, storage and use of pharmaceutical and non-pharmaceutical drugs
2. Inspect bags/bottles for evidence of contamination
3. Leave refrigerated drugs to come to RT before use in animals
4. Transferring drugs to a secondary container
5. Labelling drugs
6. Conditions for drugs that may be used up to 30 days after date of first use
7. Use of single-use drugs (without preservative or bacteriostatic)
8. Additional requirements for controlled or dangerous substances

Emory IACUC – Exemption to the Injectable Agents Policy

https://rcra.emory.edu/iacuc/researcher_tools.html



EMORY UNIVERSITY
Research Compliance and Regulatory Affairs

Research

ABOUT ▾ **ANIMAL CARE AND USE ▾** CONFLICT OF INTEREST AND COMMITMENT ▾ EXPORT CONTROL ▾ RESEARCH INTEGRITY & COMPLIANCE ▾ RESEARCH SECURITY ▾

Animal Care and Use
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LEARN ABOUT IACUC

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► **Researcher Tools**

This page includes documents created by the IACUC to provide guidance and clarification on frequently asked questions related to Animal Care and Use at Emory University.

[Using Buprenorphine HCl and Buprenorphine SR in Mice and Rats](#)

[Education and Training Requirements Checklist](#)

[Drug Alert for Injectable substances used in animals with limited number of punctures and expiration date](#)

[Exemption for using single-dose non-bacteriostatic sterile injectable saline or water](#)

Poll 3

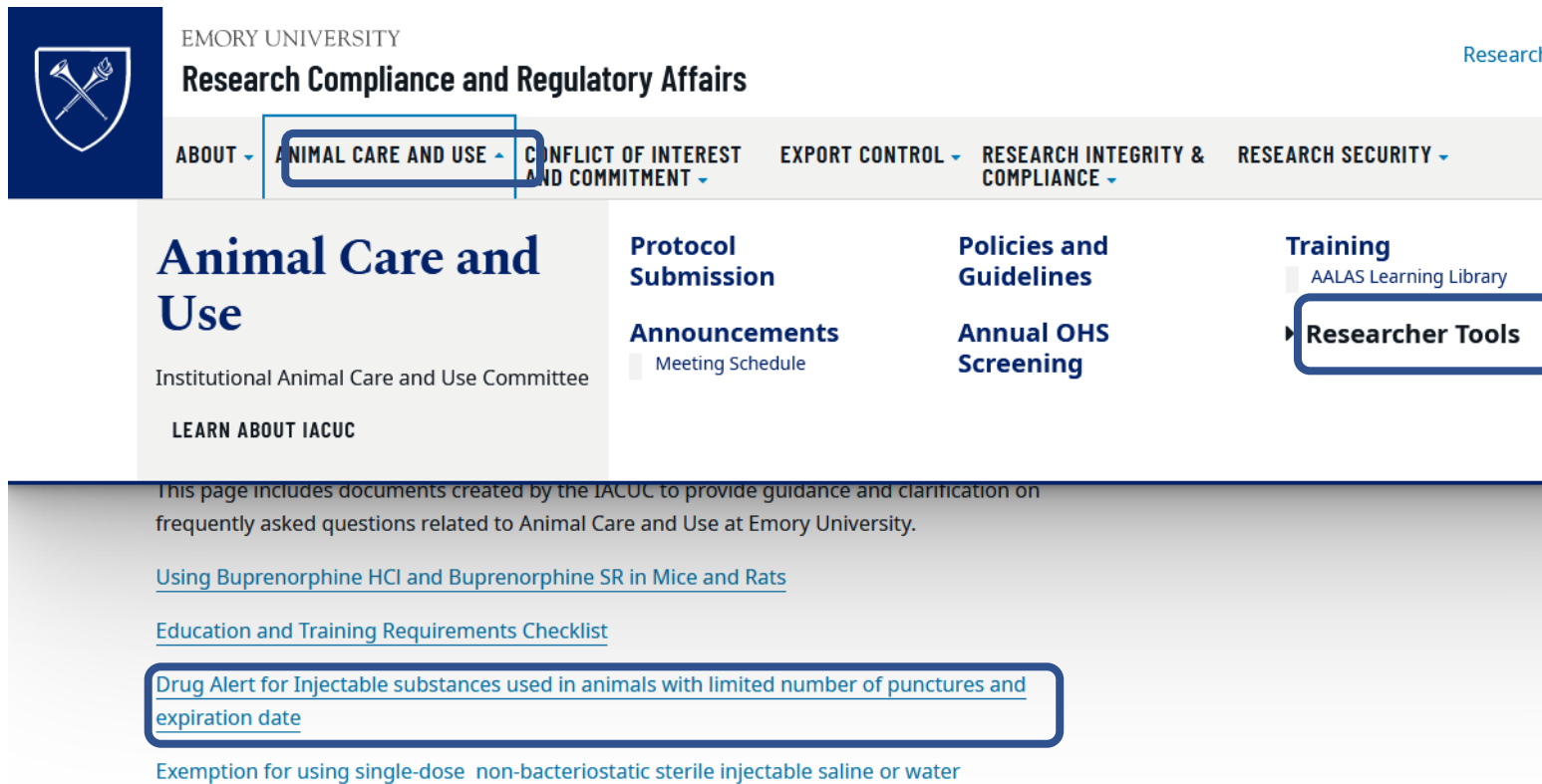
https://rcra.emory.edu/_includes/documents/sections/iacuc/forms/exemption-single-dose-non-bacteriostatic-sterile-diluent.pdf

Key message from the Exemption to the Injectable Agents Policy

- The exemption allows the use of the single-dose saline and water for all routes, **up to 30 days**.
- The solution must be filtered with a sterile 0.22 μm or smaller porosity filter.
- The filtration process must be done **every time** for all routes of administration past 24 hours, except for SC administration which is allowed, without filtration, for up to 30 days.
- Use in immunocompromised animals is still limited to the first 24 hours.
- This exemption is only applicable to mice, rats, hamsters, voles, spiny mice, gerbils.

Emory IACUC – Drug Alert for some injectables

https://rcra.emory.edu/iacuc/researcher_tools.html



EMORY UNIVERSITY
Research Compliance and Regulatory Affairs

Research

ABOUT ▾ ANIMAL CARE AND USE ▾ CONFLICT OF INTEREST AND COMMITMENT ▾ EXPORT CONTROL ▾ RESEARCH INTEGRITY & COMPLIANCE ▾ RESEARCH SECURITY ▾

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[Drug Alert for Injectable substances used in animals with limited number of punctures and expiration date](#)

[Exemption for using single-dose non-bacteriostatic sterile injectable saline or water](#)

Poll 4

https://rcra.emory.edu/_includes/documents/sections/iacuc/forms/drug-alert_injectables-with-puncture-date.pdf

Key message from the Drug Alert for drug expiration

- Some injectable analgesics include the expiration date and the maximum number of vial punctures as a set point for expiration.
- Meloxicam: Alloxate, Loxicom and Eloxiject
- These conditions apply to both the stock bottle and to working containers (for example dilutions produced by the laboratory)
- What to write on the bottle
 - Date of first puncture
 - Determine how the number of punctures will be tracked
- Optional: use a multi-dose adaptor to maintain sterility

<https://www.shopmedvet.com/product/jorvet-needle-free-multi-dose-vial-adaptor>



Why to inspect the drug?

Use the annotation tool to write why you think inspecting the bottle or bag before administering to your laboratory animal is important




Why to inspect the drug?

1. To detect particulate in the solution
2. To detect precipitates
3. Observe integrity of bottle or bag, is it still sterile?



Why to read the label?

Use the annotation tool to write why you think reading the label before administering the drug to your laboratory animal is important

<p>WARNING</p> <p>Repeated use of meloxicam in cats has been associated with acute renal failure and death. Do not administer additional injectable or oral meloxicam to cats. See Contraindications, Warnings and Precautions for detailed information.</p> <p>Warning: Not for use in humans. Keep this and all medications out of reach of children.</p> <p>Store at controlled room temperature, 68-77°F (20-25°C). Use within 180 days of first puncture and puncture a maximum of 51 times.</p> <p>Made in the UK. Norbrook Laboratories Limited Newry, BT 35 6PU, Co. Down, Northern Ireland</p>	<p>NDC 55529-040-11</p> <p>Loxicom[®] (meloxicam)</p> <p>5 mg/mL Solution for Injection</p> <p>Net Contents: 20 mL</p> <p>CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian. Approved by FDA under ANADA # 200-491</p> <p> Norbrook</p>	<p>Indications: Dogs: For the control of pain and inflammation associated with osteoarthritis. Cats: For the control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy and castration when administered prior to surgery. Refer to package insert for complete dosage and administration information.</p> <p>Lot No.: Exp. Date:</p> <p>105670L03 Rev. 10/2018</p>
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Why to read the label?

1. Expiration date
2. Warnings
3. Puncture number limit and use by date

WARNING
Repeated use of meloxicam in cats has been associated with acute renal failure and death. Do not administer additional injectable or oral meloxicam to cats. See Contraindications, Warnings and Precautions for detailed information.

Warning: Not for use in humans. Keep this and all medications out of reach of children.

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Made in the UK.
Norbrook Laboratories Limited
Newry, BT 35 6PU, Co. Down, Northern Ireland


NDC 55529-040-11

Loxicom[®]
(meloxicam)

5 mg/mL
Solution for
Injection

Net
Contents:
20 mL

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.
Approved by FDA under
ANADA # 200-491


Norbrook

Indications: **Dogs:** For the control of pain and inflammation associated with osteoarthritis.
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Lot No.:
Exp. Date:

105670L03 Rev. 10/2018

Labelling drugs

using the annotation tool, indicate
what information should be
written on the bottle after first
use



Labelling drugs

Labelling of the bottle

Researcher Tool

Using Buprenorphine HCl and
Buprenorphine SR in Mice and Rats:
https://rcra.emory.edu/_includes/documents/sections/iacuc/forms/buphcl_bupsr.pdf



Date of puncture

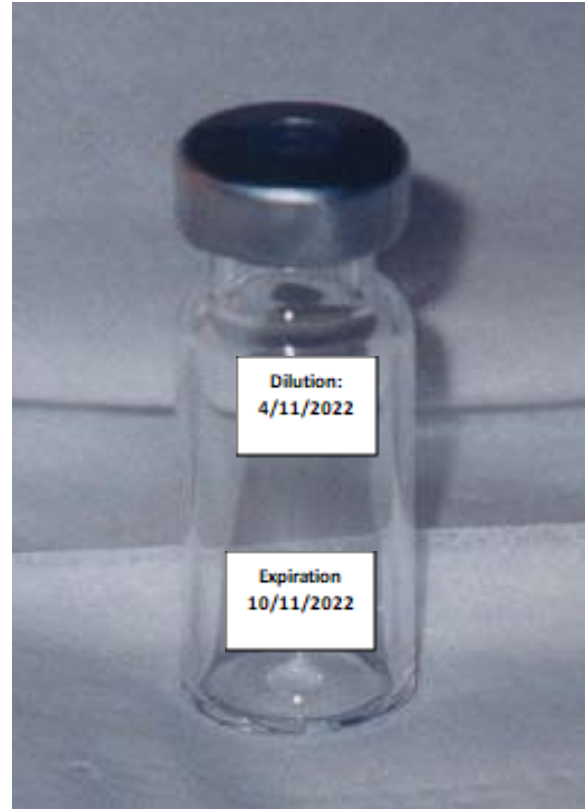


Expiration date is 6 months
later after puncture -unless
the expiration date on the
bottle is earlier than 6-mo
after first puncture



Labelling drugs – secondary container

Type I Borosilicate vials for sterile dilution



Name of the drug

Date that the dilution was made

Earliest expiration date for either drug or diluent

Labelling drugs



https://www.amazon.com/PHARMEX-1-370-Permanent-Opened-Yellow/dp/B00U2H522C/ref=pd_lpo_3?pd_rd_i=B00U2H522C&psc=1

Single Use Drug – assess the use of this drug

- ☐ Drug name: Bupivacaine
- ☐ Preservative free
- ☐ Use by date 6/17/2022
- ☐ Need to use it on 3/5/2022
- ☐ To be used IM in immunocompetent mice
- ☐ Can you use the exemption?
- ☐ What type of diluent would you use?

Provide the information to be written on the label



Assessment for using Bupivacaine

- ☐ Drug name: Bupivacaine
- ☐ Preservative free
- ☐ Use by date 6/17/2022
- ☐ Need to use it on 3/5/2022
- ☐ To be used IM in immunocompetent mice
- ☐ Can you use the exemption?- **YES**
- ☐ What type of diluent would you use? **Saline**

DATE OPENED	EXP. DATE	INITIAL
3/5/2022	4/5/2022	EM

©1988



Pharmaceutical Grade



Assess the use of this drug

Drug: Bupivacaine, 50 ml bottle

Expiration: February 2024.

Number of punctures: one time on 8/10/22.

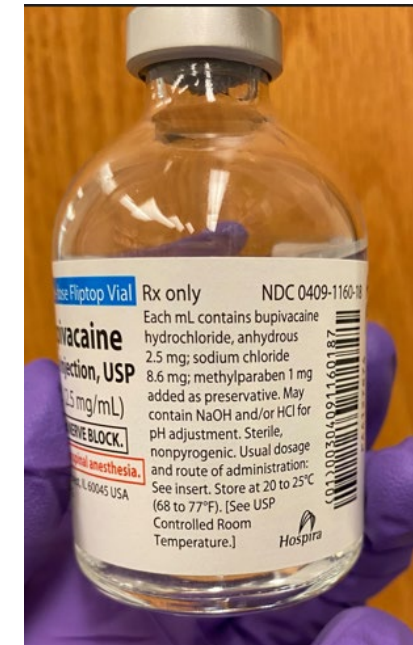
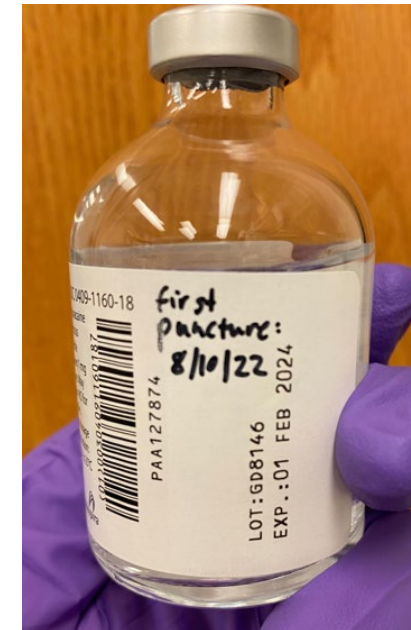
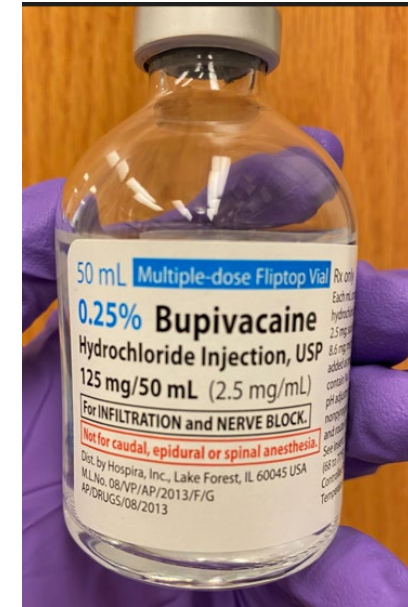
Drug label does not specify how many punctures or how long after first puncture it expires

Species: Mice

Immunity status: immune-competent

Bupivacaine is currently on backorder from multiple vendors.

Do you have a recommendation as to where to order a replacement bottle? Or can we get approval to use the stock bottle past 30 days as long as we log the punctures and do not go past 180 days from the first one or a certain number of punctures?



Single-dose or Multiple-dose

Drug: Bupivacaine, 50 ml bottle

Expiration: February 2024.

Number of punctures: one time on 8/10/22.

Drug **label does not specify how many punctures** or how long after first puncture it expires

Species: Mice

Immunity status: immune-competent

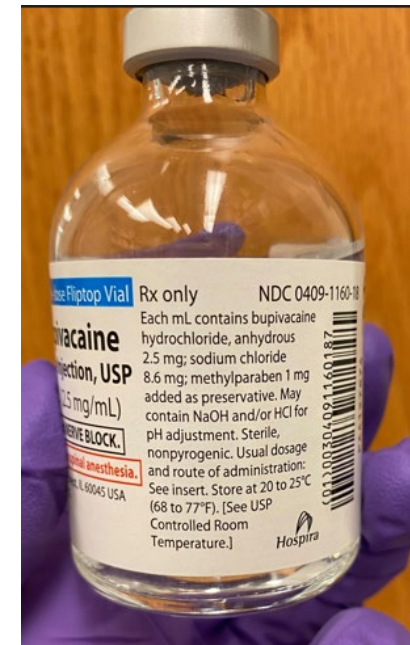
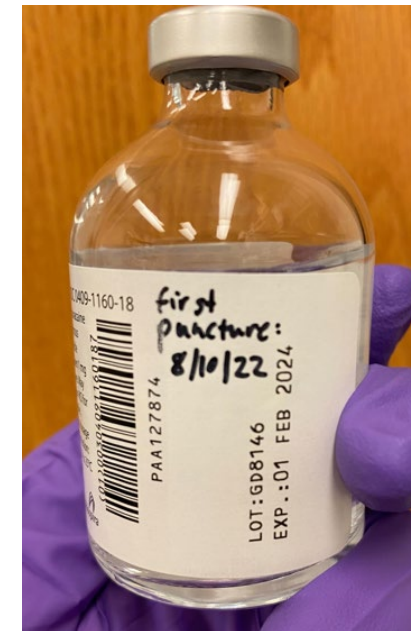
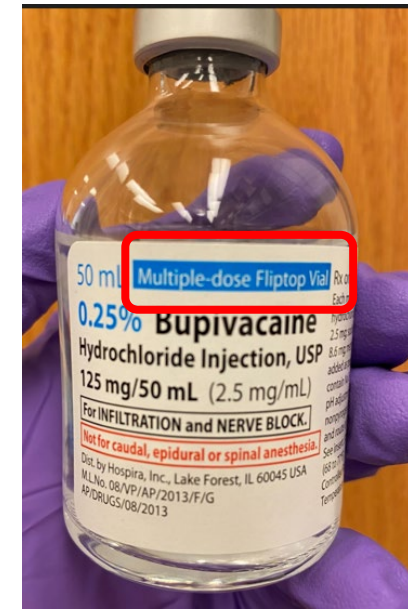
Does the single-use exemption apply?

Do we need to log the # of punctures ?

ANSWER:

This stock bottle of Bupivacaine is multi-dose vial as stated in blue on the label. **Thus, the alert about single dose use vial does not apply here.**

Regarding the number of punctures, **this applies only applies to bottles which have that particular labelling on them.** This bottle does not have the labelling, so that also does not apply here. This stock bottle of Bupivacaine can be used until it expires.



Single Use Drugs and Buprenorphine

- ❑ Drugs marked Preservative Free or Single Use may be given for up to 24 hours after opening for any of the approved routes of administration of the drug - i.e. IV, IP, SC, IC or IM
- ❑ Read the label, if there is a puncture limit, you need to write the **date of first puncture** and 6-month expiration date (check expiration date)
- ❑ If drug may be diluted, it must be diluted with a preservative containing diluent like bacteriostatic saline into septum topped vials, or apply the Emory IACUC exemption



Use of Buprenorphine HCl and Buprenorphine ER (SR)

Buprenorphine HCl

Administer every
8-12 hours

Storage in double
locked safe box

Does not require
prescription by DAR
veterinarian

May be diluted using
bacteriostatic saline or
water

Buprenorphine Extended Release (SR)

Administer every
72 hours

Storage in double
locked safe box

Requires prescription
provided by DAR
veterinarian

Cannot be diluted

Important notice from ZooPharm

In order to remain compliant with the most current regulatory guidelines, we are updating the labeling on our SR formulations from Buprenorphine and Meloxicam SR to Buprenorphine and Meloxicam ER. The extended release formulations are designed to release the medications for up to 72 hours post a single subcutaneous injection.

Rest assured, there are no changes to the formulations, the only change is to the name on the label. The label change will take effect on July 1, 2022.

We know that any change, no matter how small, can be difficult. If you have any questions, please call our Customer Service Team at (866) 823-9314.



Other Links

<https://rcra.emory.edu/oric/controlled-substances/index.html>

CONTROLLED SUBSTANCES



Controlled Substances are drugs for which there is a potential for abuse/addiction. Controlled Substances are divided into Schedules I-V depending on their medicinal value and potential for abuse. A [general list of Controlled Substances \(PDF\)](#) as defined by the Drug Enforcement Agency (DEA) is available. Individual states can include additional substances as Controlled Substances over and above substances on the DEA list. Here are links to the lists of Georgia Code [Schedule I](#), [Schedule II](#), [Schedule III](#), [Schedule IV](#), and [Schedule V](#) Controlled Substances.

Different legal and policy requirements apply to investigators performing research using controlled substances and to health care and veterinary practitioners using controlled substances to provide care to patients/clients.

The [Policy for Research Use of Controlled Substances at Emory University](#) governs investigators who are performing research using Controlled Substances, while practitioner licensing requirements and health care facility policies govern medical/veterinary practice use of Controlled Substances.

[Review our FAQs page](#) for a review of State and Federal Requirements regarding the applicable laws/regulations and Controlled Substances Policy.

Use [this template SOP](#) for the management of controlled substances schedule I.

DANGEROUS DRUGS



Thank You!



Thank you for your attendance

Questions?

We are here to help:

Office number: 404-712-0734

Office email: IACUC@emory.edu



Winners of a \$20.00
Amazon Gift Card

Rachel Jang
Micah Chrenek



IACUC Voluntary Self-paced Continuing Education

The IACUC Office is sponsoring a VOLUNTARY Continuous Education opportunity for personnel handling animals or who are related to animal care and use (researchers, animal care staff, faculty, administrators, members of the IACUC). Individuals who receive a completion certificate for at least one course from the list provided below will be invited to a luncheon with the Institutional Official, Dr. Robert Nobles. The first luncheon will be held early in December.

The list of courses from the AALAS Learning Library to complete at your own pace and voluntary

- Common Health Conditions of Mice (multiple modules)
- Maintaining Animal Procedure Areas
- Common Compliance Issues
- Refresher working with the IACUC
- AVMA Guidelines for Euthanasia of Animals 2020
- Transgenic Animals (multiple modules)

Again, this is a VOLUNTARY self-paced continuing education initiative and will not influence your IACUC protocol.

At least **one** of the courses will need to be completed in the AALAS Learning Library between September and November 30, 2022.

Submit your certificate of completion to iacuc@emory.edu.