

EXUBrion[®]
THERAPEUTICS



making it easy

to integrate Synovetin OA[®]
into everyday practice

Welcome to the **RAM NAVIGATOR**

We are at your service to take care of every step in:

- Amending an existing RAM* license
- Obtaining a new RAM license
- Equipping your practice to use Synovetin OA®

*Radioactive materials



We're here to make the licensing process **as SMOOTH as POSSIBLE**

The Exubrion Therapeutics® RAM Navigator program provides comprehensive support for adding Synovetin OA® to your practice

We've teamed up with F.X. Massé Associates, Inc., a medical physics group that provides a multitude of consulting services related to radiation safety, shielding design, and regulatory compliance. Their extensive experience in the medical and health physics fields ensures the highest standard of service.



Provide training and resources for everything related to licensing for Synovetin OA®



Minimize regulatory hurdles and address any issues associated with licensing



Deliver a high level of personal support and answer licensing questions you may have through RAM Navigator

Everything you need, concisely collated, from our experienced team

Here is an overview of the process we've put together to take the legwork out of amending an existing RAM license or obtaining an initial RAM license:

The Synovetin OA® Starter Kit contains:

- Model 26-1 Frisker GM Survey Meter (with DOSE filter)
 - SPL-VSK Spill Kit (for small hot lab)
 - 100 smears with folders (or 3 boxes of pre-numbered smears)
 - Protec II Syringe Shield (3cc)
 - Unit Dose Carrier (with 0.125 Pb 4 pi shielding)
 - Shielded Sharps Container (1/8" with lock and key)
 - L-Shield at 15 degree angle (9" x 12")
 - Lead brick (4" x 8")
- Easy-to-use online training is available at www.synovetin.com/licensing
 - Once training is completed, all the equipment needed for a veterinary hospital to implement patient treatment with Synovetin OA® can be purchased as a single Synovetin OA® Starter Kit
 - F.X. Massé will complete a new or amended license application for a practice's home state to be submitted by the practice

Specially developed online course streamlines training for your personnel

We've developed a turnkey, web-based course to satisfy most regulatory training requirements:

- Authorized user (AU) training for new licensees consists of 8 training modules, each with an accompanying quiz. Once each quiz is complete, the user will be able to move to the next module
- When all 8 modules are completed, the veterinarian will receive a certificate of completion. This certificate can then be used in obtaining the RAM license
- Supplemental reading material and regulatory templates are also provided and available to download for future reference

Module #	Subject	Time (h)
1	Regulatory Overview	02:00
2	Radioactivity	02:00
3	Interaction of Radiation with Matter	02:00
4	Radiation Detection and Measurement	02:00
5	Radiation Biology	02:00
6	Shielding and Dosimetry	02:00
7	Radiation Safety Surveys and Statistics	02:00
8	Waste, Decay in Storage, and Disposal	02:00

A second training course (Module 9) is also available which addresses the practical use and radiation safety aspects specific to Synovetin OA[®]. This course is streamlined and designed for existing AUs who are already familiar with the handling and use of unsealed radioactive materials.

Module #	Subject	Time (h)
9	Synovetin OA [®]	02:00

On the next pages, please review the easy, step-by-step process for amending an existing RAM license or obtaining a new RAM license.

IF YOU ALREADY HAVE A RAM LICENSE— **Amend your existing RAM license in 5 simple steps**

STEP 1 ▶ Identify your Authorized User (AU)



This is the veterinarian listed on the granted RAM license who has specific training in the safe handling and use of unsealed and sealed radioactive materials.

- Training can be found at www.synovetin.com/licensing. Existing AUs only need to complete Module 9: Synovetin OA®

STEP 2 ▶ Identify the location (space) within your facility where you will perform the Synovetin OA® procedure



- Synovetin OA® can be used in any area suitable for IA-injections

STEP 3 ▶ Acquire the recommended materials and instrumentation for the safe use of Synovetin OA®



- See inside back cover for full list and contact FX Massé Associates with any questions

STEP 4 ▶ Send current RAM license, practice floor plan, physical address, and contact name to F.X. Massé Associates



- Email info@fxmasse.com or call 978-283-4888 (9 am to 5 pm ET), and they will draft the license amendment request on your behalf

STEP 5 ▶ F.X. Massé Associates will send you the completed license amendment request†



- Your practice just needs to submit the request to the appropriate regulatory authority for your state as specified by F.X. Massé

†The license is only a few pages, but the renewal content will be approximately 20 pages, including the ALARA, waste, dosimetry, radiation protection program policies, etc.

IF YOU DO NOT ALREADY HAVE A RAM LICENSE— **Apply for an initial RAM license in 6 simple steps**

STEP 1 ▶ Identify your Authorized User (AU)



This is the veterinarian to be listed on the RAM license who has specific training in the safe handling and use of unsealed and sealed radioactive materials.

- New AU training for Synovetin OA® can be found at www.synovetin.com/licensing

STEP 2 ▶ Identify your Radiation Safety Officer (RSO)



- F.X. Massé Associates will provide a list of local consultants who can meet the requirements for a local consulting RSO

STEP 3 ▶ Identify the location (space) within your facility where you will perform the Synovetin OA® procedure and where you will store the RAM



- Synovetin OA® can be used in any area suitable for IA-injections

STEP 4 ▶ Acquire the recommended equipment and instrumentation for the safe use of Synovetin OA®



- See next page. All the equipment needed can be purchased as a single Synovetin OA® Starter Kit through an FX Massé Associates affiliate. For more information, contact FX Massé Associates

STEP 5 ▶ F.X. Massé Associates will draft a RAM license application on your behalf



- This will use key information you provide to F.X. Massé Associates at info@fxmasse.com
- If you have any questions, feel free to email or call 978-283-4888 (9 am to 5 pm ET)

STEP 6 ▶ Once you receive your completed application from F.X. Massé:



- Review the draft application for accuracy
- Copy the application cover sheet onto your letterhead and sign. Send your completed application packet to your state regulatory body to initiate the RAM licensing process, which may take 3–9 months

Staff, space, and equipment needed for use of Synovetin OA®



Staffing Requirements

- Radiation Safety Officer (RSO): Responsible for all radiation safety aspects of the license
- Authorized User (AU): Responsible for administration of medical isotopes
- Veterinary Nurses and Technicians: Any other staff can be trained internally (optional)



Physical Space Requirements

- A designated storage space/cabinet where radioactive materials are stored and prepared for therapy
- Delivery location for arriving radioactive product(s)



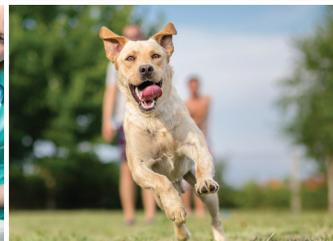
Instruments

- Ludlum 26-1 DOSE Geiger Counter
- Dosimetry badges: Required for trained personnel



Radiation Safety Supplies

- Spill kit
- Syringe shield(s)
- Unit dose carrier
- Signage
- Shielded sharps container
- Solid waste bin
- Wipes for wipe tests
- L-shield for unit dose preparation
- Templates for regulatory records
- Lead brick(s)



To streamline your practice setup process, F.X. Massé will direct you to one of their distributor partners who has assembled an all-inclusive Synovetin OA® Starter Kit.

RAM Navigator from Exubrion **IS HERE TO SUPPORT YOU**

*Together with F.X. Massé, we are dedicated to making
the licensure process simple and seamless*



Meet your F.X. Massé Concierge Staff: www.fxmasse.com/staff

F.X. Massé Associates is here to personally assist you through the entire process of licensing for Synovetin OA[®]. We have 65 years of experience licensing radioactive materials and are staffed with board-certified medical and health physicists.

**Contact F.X. Massé Associates with any questions,
9 am to 5 pm ET**

Phone: 978-283-4888; email: info@fxmasse.com

Key support resources:

Training program: www.synovetin.com/licensing

F.X. Massé Associates:

info@fxmasse.com

978-283-4888 (9 am to 5 pm ET)

www.fxmasse.com/contact



Synovetin OA

Synovetin OA[®] is marketed by:

EXUBRION
THERAPEUTICS

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