

MEDICATION GUIDE
LEQEMBI® (leh-kem'-bee)
(lecanemab-irmb)

injection, for intravenous or subcutaneous use

What is the most important information I should know about LEQEMBI?

LEQEMBI can cause serious side effects including:

- **Amyloid Related Imaging Abnormalities or “ARIA”.** ARIA is a side effect that does not usually cause any symptoms but serious symptoms can occur. ARIA can be fatal. It is most commonly seen as temporary swelling in areas of the brain that usually resolves over time. Some people may also have small spots of bleeding in or on the surface of the brain, and infrequently, larger areas of bleeding in the brain can occur. Most people who develop ARIA do not get symptoms; however, some people may have symptoms, such as:

- | | | |
|-------------|----------------------|-----------------------|
| ○ headache | ○ vision changes | ○ seizures |
| ○ confusion | ○ nausea | ○ difficulty speaking |
| ○ dizziness | ○ difficulty walking | ○ muscle weakness |

Some people have a genetic risk factor (homozygous apolipoprotein E gene carriers) that may cause an increased risk for ARIA. Talk to your healthcare provider about testing to see if you have this risk factor.

You may be at a higher risk of developing bleeding in the brain if you take medicines to reduce blood clots from forming (antithrombotic medicines) while receiving LEQEMBI.

Your healthcare provider will do magnetic resonance imaging (MRI) scans before and during your treatment with LEQEMBI to check you for ARIA.

You should carry information that you are receiving LEQEMBI which can cause ARIA and that ARIA symptoms can look like stroke symptoms.

Call your healthcare provider or go to the nearest hospital emergency room right away if you have any of the symptoms listed above.

There are registries that collect information on treatments for Alzheimer’s disease. Your healthcare provider can help you become enrolled in these registries. For more information, call Eisai at 888-274-2378.

What is LEQEMBI?

LEQEMBI is a prescription medicine used to treat people with Alzheimer’s disease. It is not known if LEQEMBI is safe and effective in children.

Do not receive LEQEMBI if you:

- have serious allergic reactions to lecanemab-irmb or to any of the ingredients in LEQEMBI or LEQEMBI IQLIK. See the end of this Medication Guide for a complete list of ingredients in LEQEMBI or LEQEMBI IQLIK.

Before receiving LEQEMBI, tell your healthcare provider about all of your medical conditions, including if you:

- are pregnant or plan to become pregnant. It is not known if LEQEMBI will harm your unborn baby. Tell your healthcare provider if you become pregnant during your treatment with LEQEMBI.
- are breastfeeding or plan to breastfeed. It is not known if lecanemab-irmb (the active ingredient in LEQEMBI) passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby while receiving LEQEMBI.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Especially tell your healthcare provider if you take medicines to reduce blood clots from forming (antithrombotic medicines, including aspirin). Ask your healthcare provider for a list of these medicines if you are not sure.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How will I receive LEQEMBI?

When given in a vein (intravenously)

- LEQEMBI is given by a healthcare provider through a needle placed in your vein (intravenous (IV) infusion) in your arm.
- Your healthcare provider will tell you how often you should receive LEQEMBI. Each infusion will last about 1 hour.
- If you miss an infusion of LEQEMBI, you should receive your next dose as soon as possible.

When given under the skin (subcutaneously)

Read the detailed Instructions for Use that comes with your LEQEMBI IQLIK for information about the right way to prepare and give your LEQEMBI IQLIK injections at home.

- Your healthcare provider will show you how to use LEQEMBI IQLIK and tell you how often you should use it. Use LEQEMBI IQLIK exactly as your healthcare provider tells you to.

- LEQEMBI IQLIK is given as an injection under your skin (subcutaneous injection), into the front of your thighs or stomach-area (abdomen) by you or a caregiver. A caregiver may also give you an injection of LEQEMBI IQLIK in the back of your upper arm.
- Do not inject into moles, scars, bruises, tattoos, or into areas where the skin is red, hard, tender, or injured.
- Use a different injection site the next time you use LEQEMBI IQLIK.
- If you miss a dose of LEQEMBI IQLIK, inject the missed dose as soon as possible up to 6 days after the missed dose. Continue (resume) your next injection on your regular dosing schedule.

What are the possible side effects of LEQEMBI?

LEQEMBI can cause serious side effects, including:

- **see “What is the most important information I should know about LEQEMBI?”**
- **serious allergic reactions.** Swelling of the face, lips, mouth, or tongue, hives, or difficulty breathing have happened during treatment with LEQEMBI. Tell your healthcare provider if you have any symptoms of a serious allergic reaction during or after LEQEMBI infusion.
- **infusion-related reactions.** Infusion-related reactions are a common side effect with LEQEMBI injection into a vein (intravenously), which can be serious. You will receive your infusion at a healthcare facility. If a serious infusion reaction happens while you are receiving LEQEMBI, your infusion may be stopped. Serious infusion reactions can also occur after completion of the infusion. Tell your healthcare provider right away if you get these symptoms during an infusion or after completion of the LEQEMBI infusion:
 - fever
 - flu-like symptoms (chills, body aches, feeling shaky, and joint pain)
 - nausea
 - vomiting
 - dizziness or lightheadedness
 - changes in your heart rate or feel like your chest is pounding
 - difficulty breathing or shortness of breath
 - changes in blood pressure

If you have an infusion-related reaction, your healthcare provider may give you medicines before your LEQEMBI infusions to decrease your chance of having an infusion-related reaction. These medicines may include antihistamines, anti-inflammatory medicines, or steroids.

- **injection-related reactions. Injection-related reactions may occur with LEQEMBI injection under the skin (subcutaneous injection with LEQEMBI IQLIK).** Redness, swelling, heat, pain, itching, rash, bruising and blood collection under the skin at the injection site may be observed. Headache, fatigue, or fever may also be observed after an injection. Tell your healthcare provider if you experience these symptoms during or after an injection.

The most common side effects of LEQEMBI include:

- infusion-related reactions
- swelling in areas of the brain, with or without small spots of bleeding in or on the surface of the brain (ARIA)
- headache

These are not all the possible side effects of LEQEMBI. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store LEQEMBI IQLIK?

- Store LEQEMBI IQLIK autoinjectors in a refrigerator between 36°F to 46°F (2°C to 8°C).
- Do not freeze.
- Keep LEQEMBI IQLIK autoinjector in the original package until ready to use, to protect from light.
- LEQEMBI IQLIK may be stored at room temperature up to 77°F (25°C) for up to 14 days in the original package. Do not place it back in the refrigerator if it has been brought to room temperature.
- Do not shake LEQEMBI IQLIK.
- Throw away (dispose of) LEQEMBI IQLIK that is out of date, or if it is not stored the right way.

Keep LEQEMBI IQLIK and all medicines out of the reach of children.

General information about the safe and effective use of LEQEMBI.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use LEQEMBI for a condition for which it was not prescribed. Do not give LEQEMBI to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about LEQEMBI that is written for health professionals.

What are the ingredients in LEQEMBI?

Active ingredient: lecanemab-irmb.

Inactive ingredients (intravenous): arginine hydrochloride, histidine, histidine hydrochloride monohydrate, polysorbate 80, and water for injection.

Inactive ingredients (subcutaneous): arginine hydrochloride, histidine, histidine hydrochloride monohydrate, polysorbate 80, and water for injection.

Manufactured by:

Eisai Inc.

Nutley, NJ 07110

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LEQEMBI IQLIK™ is a trademark of Eisai R&D Management Co., Ltd.

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For more information, go to www.LEQEMBI.com or call 1-888-274-2378.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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INSTRUCTIONS FOR USE
LEQEMBI® IQLIK™ (Ie-KEM-bee)
(lecanemab-irmb)
360 mg/1.8 mL
injection, for subcutaneous use
single-dose prefilled autoinjector

This Instructions for Use contains information on how to prepare and use LEQEMBI IQLIK.

Before each use of LEQEMBI IQLIK

Read this Instructions for Use before you start using LEQEMBI IQLIK and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

Your healthcare provider should show you or a caregiver how to use LEQEMBI IQLIK the right way before you use it for the first time. If you have any questions about how to use the autoinjector, contact your healthcare provider.

Important information

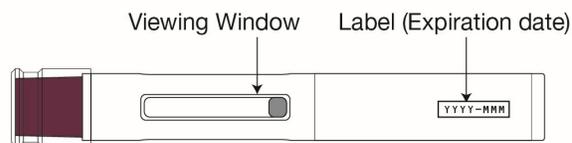
- LEQEMBI IQLIK is only given as an injection under the skin (subcutaneous).
- **Do not** remove the clear cap until you are ready to inject.
- **Do not** try to take apart the autoinjector at any time.
- **Do not** reuse the autoinjector.
- **Do not** inject through clothing.
- **Do not** shake the autoinjector.
- **Do not** use the autoinjector if the carton or any parts look damaged or has been dropped.
- **Do not** hold the autoinjector by the magenta needle cover.

Storing LEQEMBI IQLIK

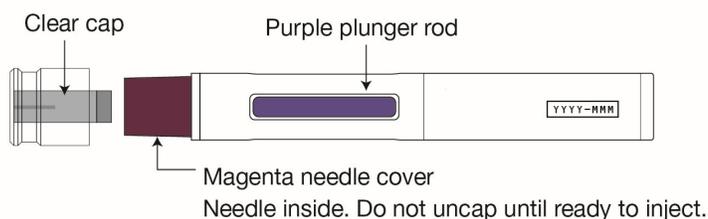
- Store the LEQEMBI IQLIK autoinjector in a refrigerator between 36°F to 46°F (2°C to 8°C).
- **Do not** freeze.
- Keep the LEQEMBI IQLIK autoinjector in the original package until ready to use, to protect it from light.
- LEQEMBI IQLIK may be stored at room temperature up to 77°F (25°C) for up to 14 days in the original package. **Do not** place it back in the refrigerator if it has been brought to room temperature.
- **Do not** shake LEQEMBI IQLIK.
- Throw away (dispose of) LEQEMBI IQLIK that is out of date, or if it is not stored the right way.
- Keep your LEQEMBI IQLIK autoinjector and all medicines out of the reach of children.

The LEQEMBI IQLIK autoinjector

Before use



After use



Gather Supplies

Included supplies

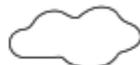


1 LEQEMBI IQLIK
autoinjector

Supplies not included



Alcohol wipe



Cotton ball or gauze



Sharps container



Adhesive bandage

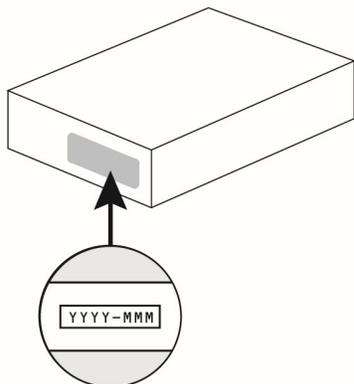
Preparing to Inject LEQEMBI IQLIK

Step 1

Remove carton from the refrigerator and **wait 20 minutes** for the autoinjector to reach room temperature. **Do not** try to speed up the warming process in any way because the product may be damaged.

Check the carton.

- **Do not** use if the expiration date on the carton has passed.
- **Do not** use if the seal on the carton is broken.



Step 2

Check the autoinjector.

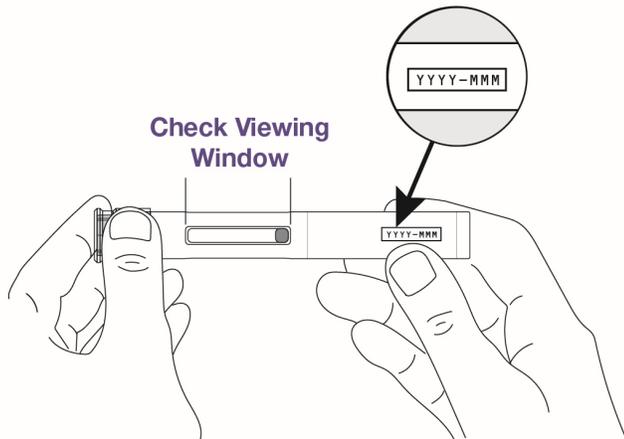
- **Do not** use if the autoinjector is damaged or has been dropped.

Check viewing window.

- **Do not** use if the medicine looks cloudy, discolored, or contains particles. The medicine should be clear and colorless to pale yellow. It is normal to see air bubbles in the window.

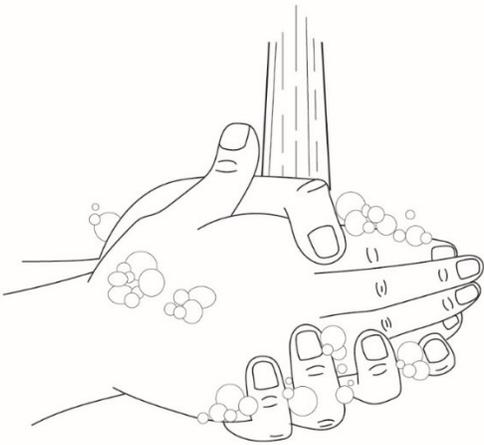
Check the expiration date.

- **Do not** use if the expiration date on the autoinjector has passed.



Step 3

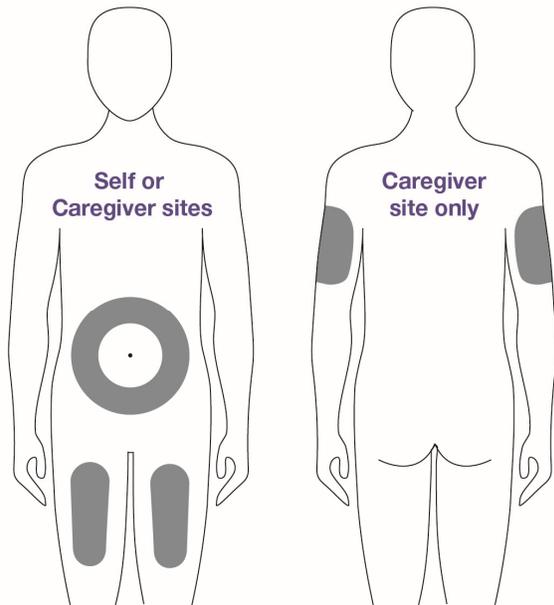
Wash your hands with soap and water or use hand sanitizer.



Step 4

You can inject into the front of your thighs or stomach area (abdomen). If a caregiver gives you the injection, they may also do it in the back of your upper arm.

- **Do not** inject into moles, scars, bruises, tattoos or into areas where the skin is red, hard, tender or injured.
- **Do not** inject into the 2-inch area around the belly button.

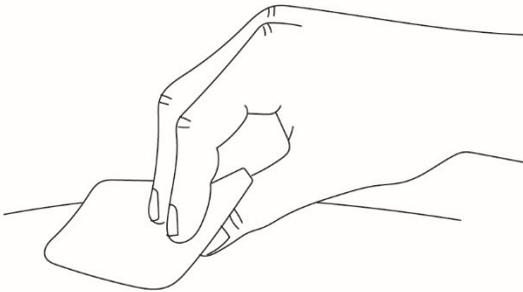


Injecting LEQEMBI IQLIK

Step 5

Clean the injection site with an alcohol wipe and allow the skin to air dry.

- **Do not** touch the injection site after it is cleaned.
- **Do not** fan or blow on the cleaned area.

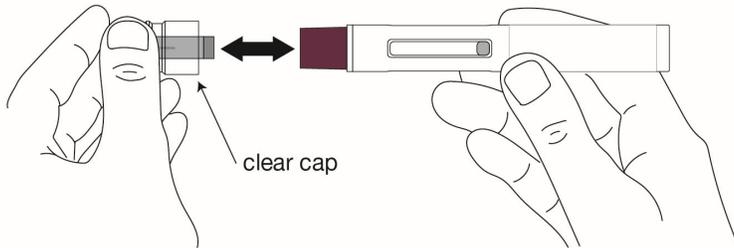


Step 6

Remove the clear cap when you are ready to inject.

Hold the autoinjector with 1 hand and firmly pull the clear cap straight off with your other hand.

- **Do not** bend or twist the clear cap while pulling it off.
- **Do not** put your fingers or hand over the needle. Doing this may cause a needle injury.
- **Do not** put back the clear cap on after it has been removed from the autoinjector.

**Step 7**

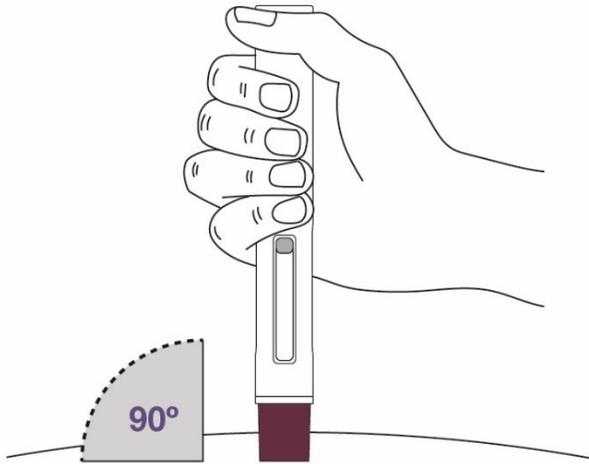
Throw away (dispose of) the cap in the household trash or sharps disposal container.



Step 8

Place the magenta needle cover at a 90-degree angle flat against the skin. Make sure you can see the viewing window.

- **Do not** inject through clothing.

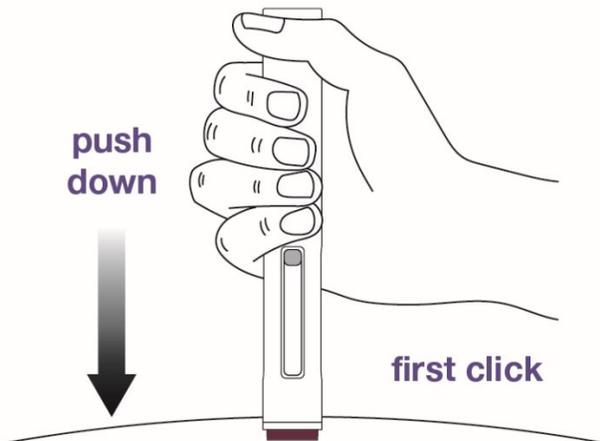
**Step 9**

Push the autoinjector firmly against the skin to start the injection.

The injection will start automatically.

- You may hear a first “click” which indicates the start of the injection.
- The purple plunger rod will move down in the viewing window during the injection.

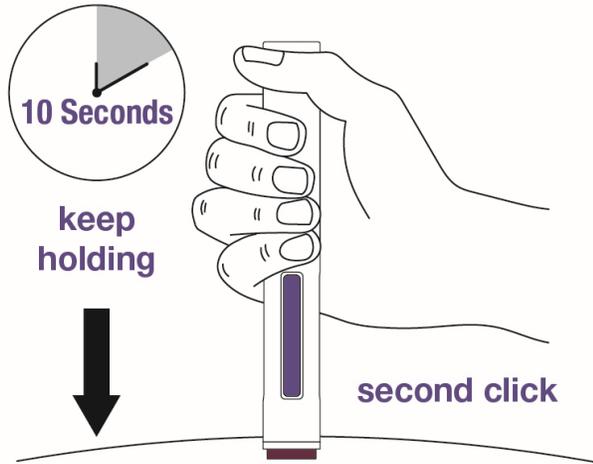
If you have trouble hearing the click, watch the purple plunger rod as it moves down.



Step 10

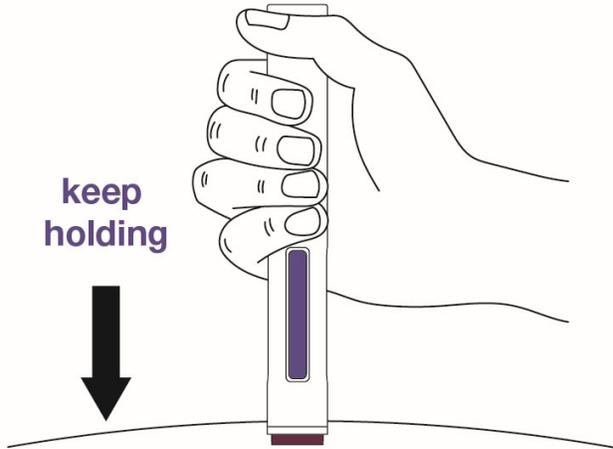
Continue holding the autoinjector down against the skin for about **10 seconds**. You will hear a second click. The purple plunger rod will fill the viewing window.

Your injection is complete, but continue holding the autoinjector.



Step 11

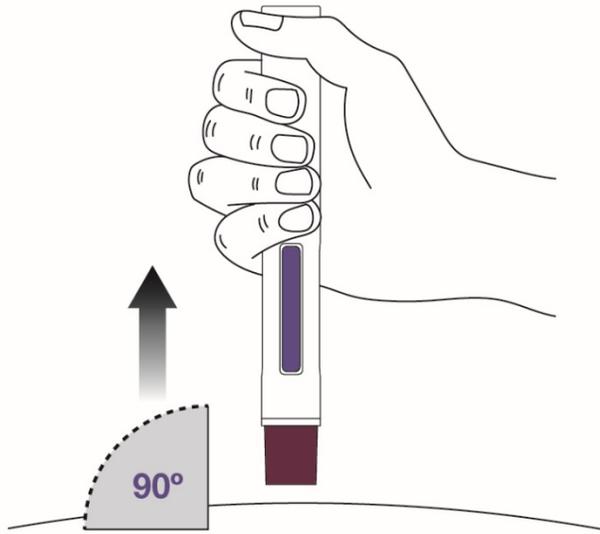
Keep holding the autoinjector in place **for at least 5 more seconds** after the injection is complete.



Step 12

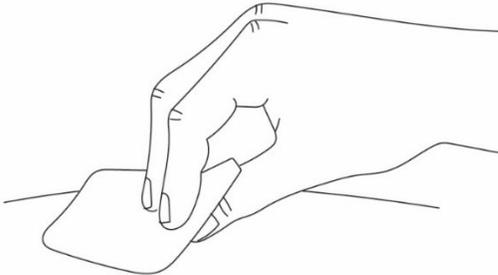
Remove the autoinjector by pulling it straight up from the injection site.

- The magenta needle cover will automatically move into place to cover the needle.

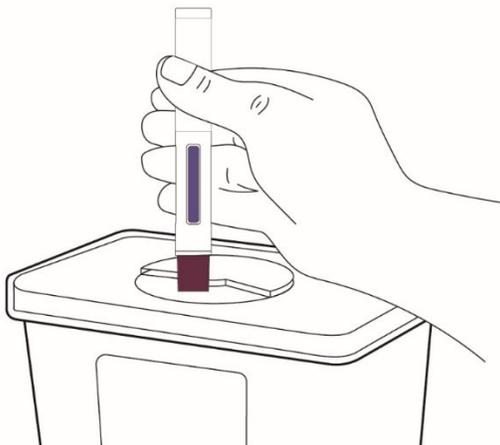
**Step 13**

You may notice a small drop of blood at the injection site. This is normal. Press a cotton ball or gauze on the area.

- If needed, cover the injection site with an adhesive bandage.
- **Do not** rub the injection site.

**Step 14**

Throw away (dispose of) the autoinjector in an FDA-cleared sharps disposal container.



Disposing of LEQEMBI IQLIK

Do not throw away (dispose of) the autoinjector in the household trash.

If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:

- made of heavy-duty plastic,
- can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
- upright and stable during use,
- leak-resistant, and
- properly labeled to warn of hazardous waste inside the container.

When your sharps disposal container is almost full, follow your community guidelines for the right way to throw away (dispose of) your sharps container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>.

Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this.

Do not recycle your used sharps disposal container.

Manufactured by:
Eisai Inc.
Nutley, NJ 07110
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