

INSTRUCTIONS FOR USE

REDITREX® (re-dee-treks)

(methotrexate injection, for subcutaneous use)

Important: Do not share your syringes with other people, even if the needle has been changed. You may give other people a serious infection or get a serious infection from them.

Use these instructions with all doses of REDITREX. Make sure that you have the right dose that has been prescribed for you.

REDITREX Prefilled Syringe Parts (See Figure A)

Note: The plunger rod for your dose may be a different color than shown in the figures in this Instructions for Use.

Supplies needed to give your injection (See Figure B)

Only the prefilled syringe is included in the package

- A clean flat well-lit surface, such as a table
- 1 dose tray containing a REDITREX prefilled syringe with a fixed needle
- 1 alcohol prep (swab)
- 1 cotton ball or gauze pad
- 1 puncture-resistant sharps container for safe disposal of used needles and syringes. (See Step 8, “How should I dispose of used prefilled syringes and needles?”)

Make sure you have all of the items you need to give yourself an injection.

Step 1. Prepare to use REDITREX

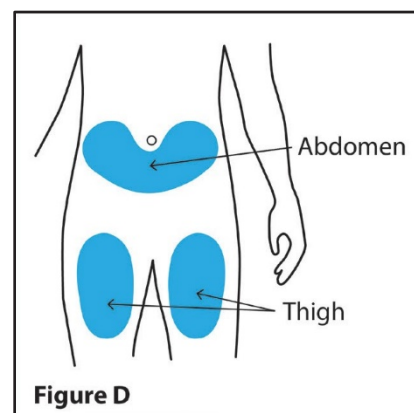
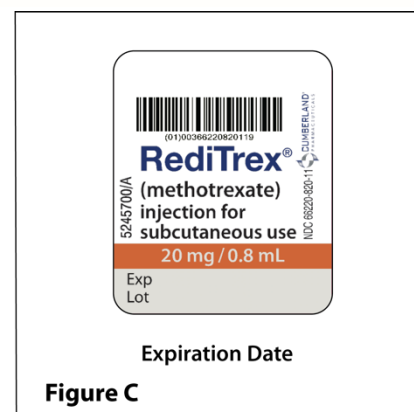
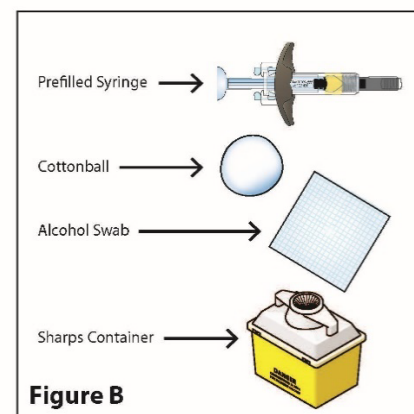
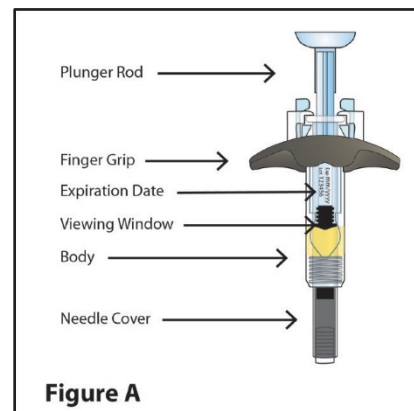
- **Do not** remove needle cover until you are ready to inject REDITREX.
- Check the expiration date on the label of prefilled syringe. (See Figure C)
- **Do not** use if expired. (See Step 8)
- Wash your hands well with soap and warm water.

Step 2. Check the liquid

- The liquid in the syringe should be yellow in color and should not have any lumps or particles in it.
- You may see air bubbles. This is normal.

Step 3. Choose an injection site

- REDITREX should be injected into the stomach (abdomen) or thigh. (See Figure D)
- **Do not** inject REDITREX within 2 inches of the belly button (navel).
- **Do not** inject REDITREX in the arms or any other areas of the body.
- **Do not** inject REDITREX in areas where the skin is tender, bruised, red, scaly, hard, or has scars or stretch marks.



Step 4. Clean the injection site

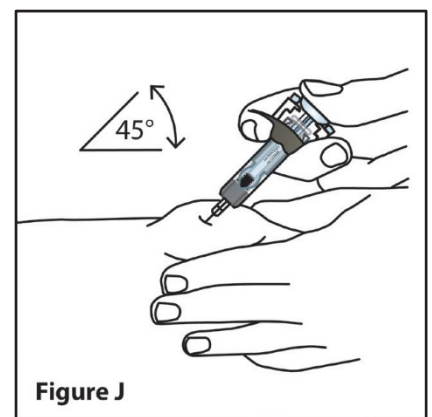
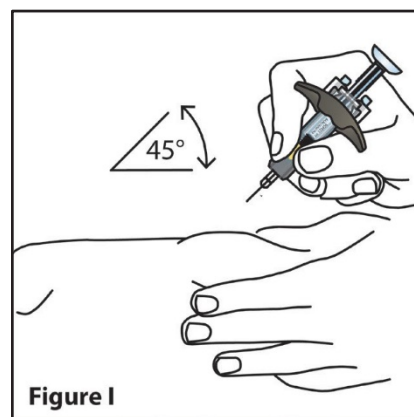
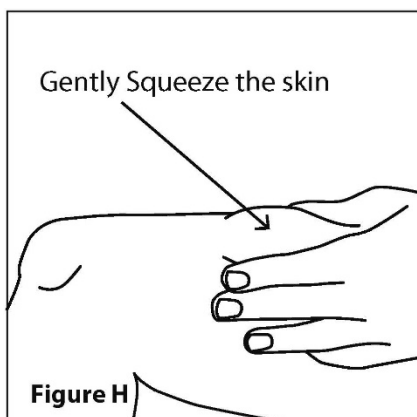
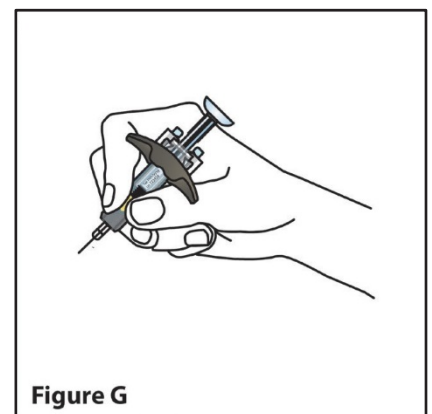
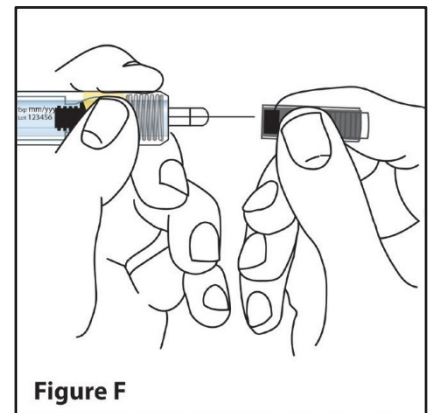
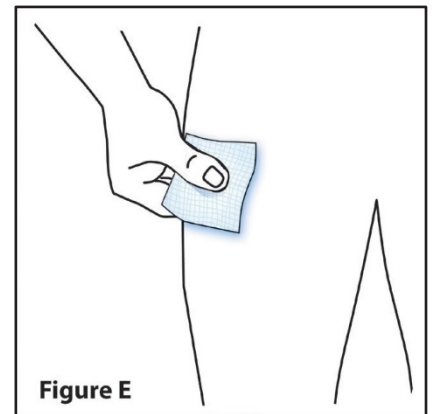
- Wipe the area with an alcohol (prep) swab. **(See Figure E)**
- Let the skin dry. **Do not** touch this area again before giving REDITREX.
- **Do not** fan or blow on the clean area.

Step 5. Prepare the syringe and needle

- Always hold the prefilled syringe by the body of the syringe.
- Remove needle cover.
- Hold the syringe in 1 hand. With the other hand gently remove the needle cover by pulling it straight off. **(See Figure F). Do not** hold or touch the plunger while you remove the needle cover.
- Throw away the needle cover in a puncture-resistant sharps container right away. **(See Step 8)**
- **Do not** touch the needle with your fingers or let the needle touch anything.
- You may see a drop of liquid at the end of the needle. This is normal.

Step 6. Inject REDITREX

- Hold the body of the prefilled syringe in 1 hand between the thumb and index finger. Hold the syringe in your hand like a pencil. **(See Figure G)**
- **Do not** pull back on the plunger at any time.
- With your other hand, gently squeeze the area of the cleaned skin and hold it firmly. **(See Figure H)**
- Using a quick, dart-like motion, insert the needle into the squeezed skin at about a **45-degree angle**. **(See Figure I)**
- Slowly push the plunger all the way in until all of the liquid is injected and the syringe is empty. **(See Figure J)**
- When the plunger is pushed all the way in, the needle withdraws automatically into the body of the syringe and the needle will be automatically covered.

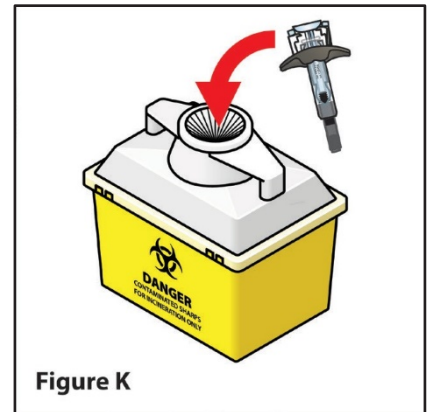


Step 7. After the injection

- Press a cotton ball or gauze pad over the injection site and hold it for 10 seconds. **Do not** rub the injection site. You may have a small amount of bleeding. This is normal.
- Throw away the used prefilled syringe and needle. **(See Step 8 “How should I dispose of used prefilled syringes and needles?”)**
- Keep a record of the dates and location of your injection sites. To help you remember when to take REDITREX, you can mark your calendar ahead of time.

Step 8. How should I dispose of used needle and syringe?

- **Put your used needle and syringe in a FDA-cleared sharps disposal container right away after use (See Figure K). Do not throw away (dispose of) loose needles and syringes in your household trash.**
- **Do not** try to touch the needle.
- If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:
 - made of a 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, you will need to follow your community guidelines for the right way to dispose of your sharps disposal 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>.
- For the safety and health of you and others, needles and used syringes **must never** be re-used.
- The used alcohol pads, cotton balls, dose trays and packaging may be placed in your household trash.
- **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.**
- **Always keep the sharps container out of the reach of children.**



How should I store REDITREX?

- Store REDITREX at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep REDITREX in the carton until ready to use to protect from light.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.
Manufactured for: Cumberland Pharmaceuticals Inc., Nashville TN 37203

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