

ELRiSE MDS RETACRIT® Self-Administration Instructions to Patients – Version 1

RETACRIT® Storage

1. Your study coordinator (SC) will give you the study drug RETACRIT® (vials or prefilled syringes), self-administration supplies (syringes, needles, alcohol swabs, cotton gauze, red sharps container) and Self-Administration Diary Card(s), one for each planned dose.
2. Transport the RETACRIT® home in the provided study cooler bag with an ice pack.
Store the RETACRIT® in the **refrigerator** between 36 °F and 46 °F (2 °C to 8 °C).
Keep the RETACRIT® away from light (keep in the package).
Record on the Self-Administration Diary Card the date and time you placed the RETACRIT® in your refrigerator.
Do not shake or freeze RETACRIT®; Do not use if RETACRIT® has been frozen.
Do not use vials if the **green** area on the freezer strip indicator inside the RETACRIT® carton looks **white or cloudy**.
3. The RETACRIT® liquid is **clear** and **colourless**. Do not use RETACRIT® if the liquid looks discoloured or cloudy, or if the liquid has lumps, flakes or particles.

RETACRIT® Preparation on Day of Administration

4. Review the Self-Administration Diary Card you received and identify the RETACRIT® planned dose date, planned total dose amount in millilitres (mL), and number of vials or prefilled syringes required.
If you have questions, contact your study doctor immediately.
5. Gather the supplies provided including syringes, needle, alcohol swabs (at least 2), cotton gauze and the red sharps container.
Remove only the required amount of the RETACRIT® from the refrigerator. Record the time removed from the refrigerator. During this time, protect the RETACRIT® vial from light.
6. Wash your hands with soap and water.

FOLLOW STEPS 7 to 13 IF PROVIDED RETACRIT® VIALS (FOR PREFILLED SYRINGES then go to STEP 12)

7. The RETACRIT® vial has a coloured cap on the top of the vial. Remove the cap and wipe the rubber stopper on top of the vial with the alcohol wipe provided. Once the alcohol has dried, it is ready for use. (Discard the wipe).
8. Prepare the syringe with a needle as instructed by the study staff. Pull back on the plunger and add air into the syringe; the amount of air should equal the amount of RETACRIT® liquid needed. Inject all the air into the bottle.
9. Keep the needle inside the vial. Turn the vial and syringe upside down with the tip of the needle in the RETACRIT liquid. Slowly pull the plunger back to fill the syringe with RETACRIT® liquid to the dose provided on the Diary Card.
10. Double-check that you have the correct dose in the syringe. Lay the vial down on its side with the needle still in it until ready to inject. Repeat steps 7-9 if more than one syringe and vial is needed to prepare the total planned dose amount.
11. Keep and return all used and unused vials to clinic on your next visit.

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12. ***Follow the directions to prepare the syringes and self-injection instructions as taught to you by your study doctor and SC.***
13. Identify the skin location for injection on your abdomen (or if needed your upper thighs or upper arms) for your injection. Using a new alcohol wipe, wipe alcohol on your skin in a circular motion starting in the centre bullseye and circling out. Allow skin to dry. Discard wipe.

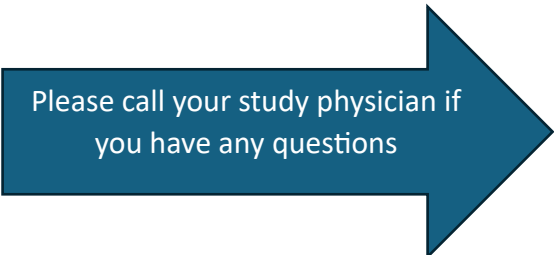
RETACRIT Injection on Day of Administration

14. Hold the prepared syringe in the hand that you will use to inject. Use your other hand to pinch a fold of the skin and insert the needle into that area (as instructed by the site). NOTE: If blood has entered the syringe, pull the needle out and discard. Restart with new syringe.
15. Slowly push the plunger until all the RETACRIT® liquid in the syringe is injected below the skin. Remove the needle and press a cotton gauze on the site and use a bandage if needed.
16. Do not recap the needle; immediately discard the syringe and needle into the red sharps box provided by the SC.
17. Repeat Steps 12-16 if more than one syringe is required for the total dose amount.
18. Record on the Self-Administration Diary Card
 - a. Date and time RETACRIT® vial(s) removed from fridge
 - b. Injection date
 - c. Injection time
 - d. Number of injection sites
 - e. Total amount of RETACRIT® injected (mL)
 - f. Indicate the injection site location(s) by marking a small x on the figures on the card
 - g. If the injection was on a different day than planned date or a different amount than planned, please provide reason
 - h. Write the name of the person who prepared and performed the injection:
19. Keep the used RETACRIT® vials. Return all the used vials and all the completed Self-Administration Diary Cards to the clinic at your next onsite study visit.

You may refer to the commercial RETACRIT® Prescribing Information and complete FDA-approved Instructions for Use for RETACRIT®:

US-sourced vials: <https://labeling.pfizer.com/ShowLabeling.aspx?id=10738>

EU-sourced prefilled syringes: www.ema.europa.eu/en/documents/product-information/retacrit-epar-product-information_en.pdf



Please call your study physician if
you have any questions

