

Instructions For Use of AMLITELIMAB PFS for clinical study LTS17789

☒ Transport

☒ Storage

☒ Preparation/Administration

You will receive AMLITELIMAB pre-filled syringes (PFS) which you will transport, store and administer at your home.

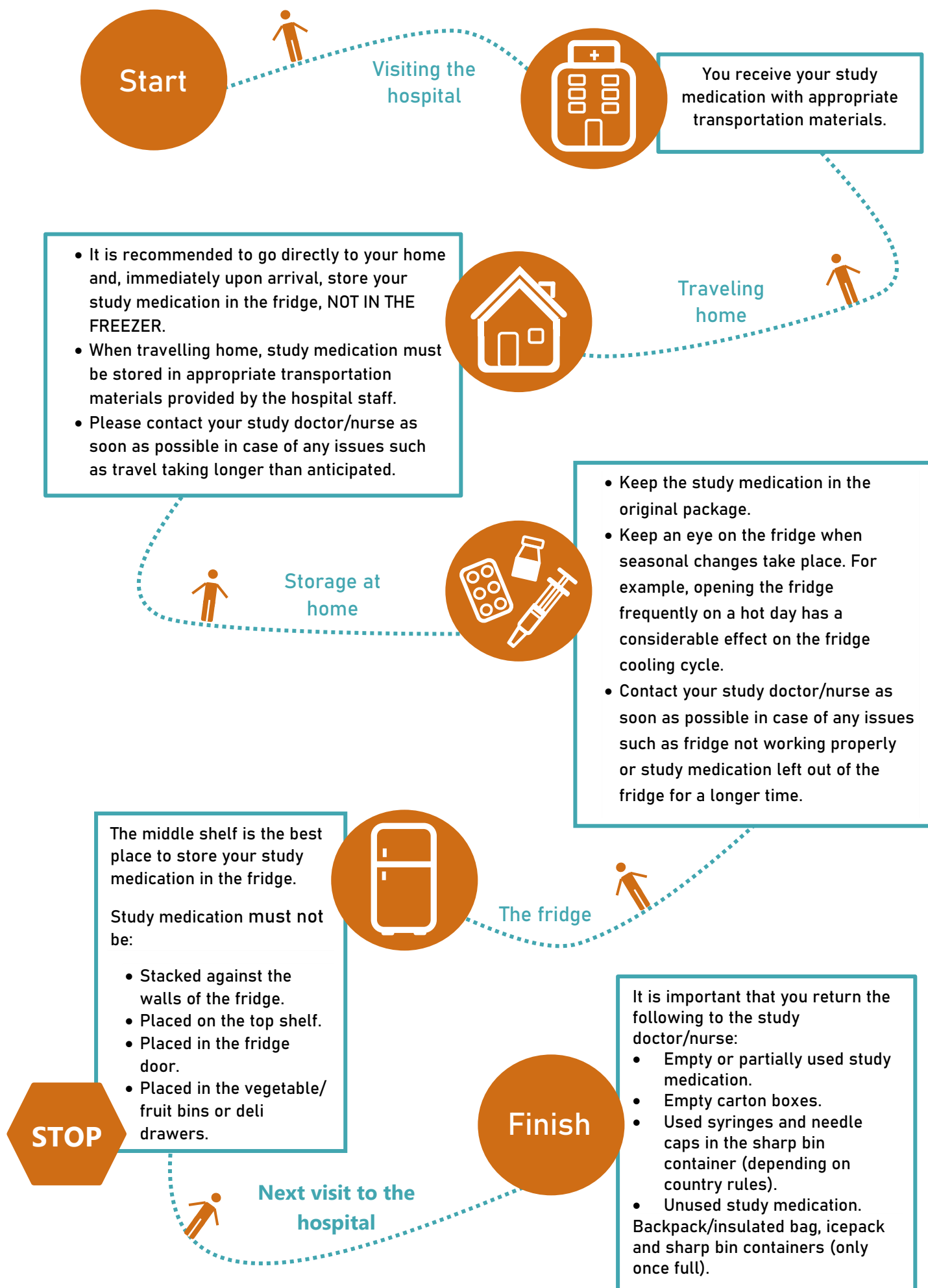
This flyer provides guidance to help you to understand how to prepare and administer your study medication during the study, as well as how to transport, store and return your study medication.

Please follow this guidance as study medication can lose its effectiveness & could let to undesirable effects when exposed to wrong temperature.

Of your study medication

Study name	LTS17789/ATLANTIS
Study medication	AMLITELIMAB PRE-FILLED SYRINGES (PFS)
Storage conditions	BETWEEN +2°C & +8°C (+36°F & +46°F), PROTECTED FROM LIGHT
Route of administration	SUBCUTANEOUS
Dosage	250 MG OR 125 MG IN PFS FILLED WITH 2 ML OF SOLUTION







Backpack /
insulated bags for
the transport of
your study
medication will
be provided to
you by the study
site staff

There are three options of transportation materials



- 1.** Backpack with 4 small ice packs If your travel is no longer than 90 minutes



- 2.** Insulated bag with 4 ice packs If your travel is no longer than 6 hours

- 3.** Insulated bag with 6 ice packs If your travel is no longer than 20 hours

Planning a trip?

With the following steps you can easily keep your study medication properly stored while traveling



- 1 Minimum 48 hours before using bag, put ice packs in your freezer (-18°C / -0.4°F).
- 2 After these 48 hours, take the ice packs out of the freezer and place them at room temperature for 5 minutes (Between $+15^{\circ}\text{C}$ & $+25^{\circ}\text{C}$ / $+59^{\circ}\text{F}$ & $+77^{\circ}\text{F}$).
- 3 Insert ice packs in designated compartments of the bag.
- 4 Take the study drug out of your refrigerator and place them in the centre of the bag.
- 5 Close the bag.



General information

PURPOSE: The following instructions for use are to help the participant/caregiver/legally authorized representative to prepare and administer the study medication injections. Do not try to inject with the study medication until you have been trained how to do it by a designated study site staff. Study site staff can also assist you with the injections until you are comfortable doing these without assistance. The study doctor or study site team can discuss this with you.

HOW TO STORE YOUR STUDY MEDICATION (AT HOME):

- Your study medication should always be stored in a refrigerator at +2°C to +8°C (+36°F to +46°F) until use.
- Do not freeze your study medication.
- Always keep the pre-filled syringe in its original packaging to protect it from light and direct sunlight.

CALL THE STUDY DOCTOR OR STUDY SITE STAFF BEFORE/AFTER USING A PRE-FILLED SYRINGE IF:

- You lost power to your refrigerator.
- Any items in the main part of your refrigerator have frost or are partially frozen.
- You have left the pre-filled syringe outside of the refrigerator for more than 4 hours.
- The pre-filled syringe is cracked or broken.

In all cases the pre-filled syringe cannot be used.

WHEN: The study medication should be injected subcutaneously (under the skin) once every 4 weeks (at the planned dates indicated by your study doctor). If you are unable to perform the injection as scheduled, please call the study doctor or the site team.

In children 12 years of age and older, it is recommended that Amltelimab be administered by or under supervision of an adult.

NEED HELP? Please call the study doctor or study site team.

Description of your study medication and associated supplies

All representations in this flyer are for illustrative purposes only. The shape, color, appearance, etc. may differ.

Study medication

- Study medication is provided as a kit (carton box) containing one pre-filled syringe (called syringe in these instructions) with a deliverable volume of 2.0 mL.



Note : Pictures/photos are for illustration only, it may differ a little

Before administrating your study medication

HOW SHOULD I STORE THE SYRINGE?

 **Keep the syringe and all medicines out of reach of children.**

- Store unused syringe in the refrigerator between +2°C (+36°F) and +8°C (+46°F).
- Store the syringe in the original carton box to protect them from light and direct sunlight.

 **Do not** shake the syringe at any time.

 **Do not** heat the syringe.

 **Do not** freeze the syringe.

 **Do not** use the syringe if dropped.

BEFORE YOU BEGIN

RECOMMENDED

Read the Instructions For Use before using the syringe.

Do not inject yourself or someone else until you have been trained how to inject.

Gather Supplies

Ensure you have the following:

- 1 alcohol wipe
- 1 cotton ball or gauze
- A sharps bin container

The alcohol wipe, cotton ball or gauze, and the sharps bin container are not included in the carton box.

Only the single-dose syringe is included in the carton box.

STEP 1: RETRIEVE CARTON BOX FROM REFRIGERATOR

Look at the Label on the carton to ensure you have the correct study medication and dose.

Step 1.1 : Inspection



- Inspect the carton for any external damage.
- Check you have the correct study medication, dose and the expiration date on the carton label.

 **Do not** use the study medication if the expiration date has passed.

- Open the carton by opening the tamper evident seal.

Preparing your study medication

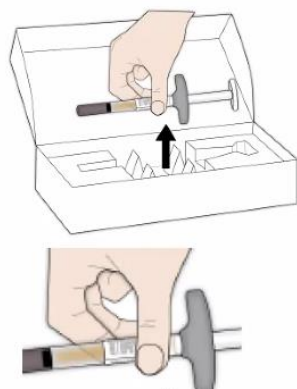
STEP 2: PREPARE SYRINGE

Step 2.1: Remove

Remove the syringe from the carton box by holding the middle of the syringe body.



Do not touch the plunger rod.



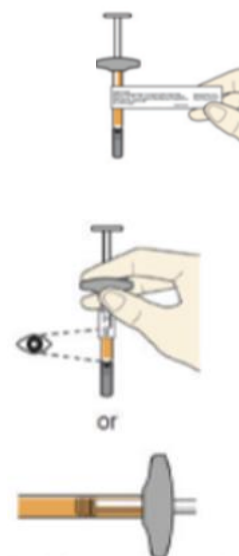
Check the syringe for damages and do not use the syringe if it has been dropped on a hard surface or damaged.



Do not remove the needle cap until you are ready to inject.

Step 2.2: Look at the study medication

- Unwrap (not unstick) the syringe label and look at the study medication through the glass of the syringe to ensure that the liquid is clear.



Do not use the syringe if the liquid appears cloudy or contains visible flakes or particles.

Note Do not remove any air bubbles you may see in the syringe, this is normal.

Step 2.3: Wait

Lay the syringe on a flat surface to allow it to naturally warm to room temperature (less than +77°F or less than +25°C ideally) for at least **30 minutes** before proceeding with the injection.



The study medication must be administered within 4 hours after being removed from the refrigerator.



Do not heat the syringe.



Do not place the syringe in the direct sunlight.

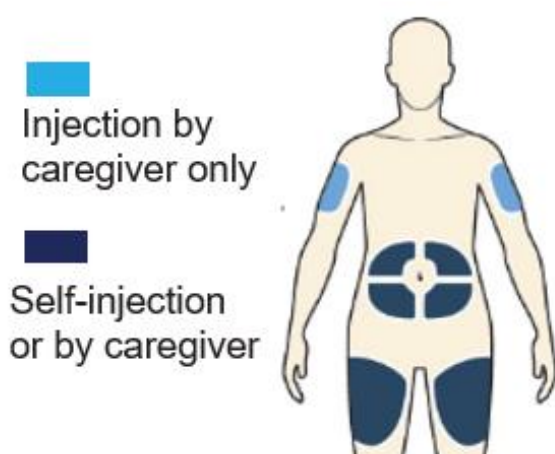
Administering your study medication

STEP 3: PREPARE INJECTION SITE

Step 3.1 Choose the Injection Site and remove appropriate clothing

You can Inject in the abdomen, the outer thighs or the upper arms. To be noted that the upper arm site can only be injected by a trained caregiver/legally authorized representative or health care professional (do not self-inject in the upper arms).

Syringe should not be administered at the exact site of a recent injection or in areas which are not suitable: e.g. tender, bruised, red or hard, presence of Atopic Dermatitis lesions, areas with visible veins or scars.

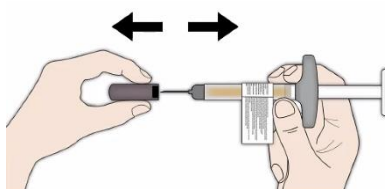


 **Do not** inject through clothes.

STEP 4: GIVE INJECTION

Step 4.1 Remove the Needle cap

Hold the syringe in the middle of the syringe body with the needle pointing away from you and pull the needle cap straight off. Inject the study medication right away after removing the needle cap.



 **Do not** twist or bend the needle cap.

 **Do not** hold the syringe from the plunger rod while removing the cap.

 **Do not** touch the needle.

 **Do not** put the needle cap back on to avoid needle stick or damage the needle.

Step 3.2 Prepare the injection Site

Wash your hands with soap.



Clean the injection site with an alcohol wipe.
Allow skin to dry.



 **Do not** touch the site again or blow on it before the injection.

Administering your study medication

Step 4.2 : Pinch

Pinch a fold of skin at the injection site. The figure below shows an example of pinching a fold of skin on your abdomen.



Step 4.3 : Insert

Insert the needle completely into the skin at a 45° angle.



⚠ Do not touch the plunger rod until you are ready to inject.

⚠ Do not inject through your clothes.

⚠ Do not twist plunger rod.

Step 4.4 : Push

Slightly relax the pinch of the fold of skin.

Push the plunger rod down slowly and steadily as far as it will go until the syringe is empty.

The injection must be administered at a constant pressure.



Note: You may feel some resistance, this is normal.

Step 4.5 : Remove

Remove the needle from the skin at the same angle it was inserted.



Lightly press a cotton ball or gauze on the injection site if you see any blood.

⚠ Do not put the needle cap back on.

⚠ Do not rub the skin at the injection site.

After administrating your study medication

STEP 5: DISPOSE

Place the used syringe and needle caps in a sharps bin container right away after use.



 **Do not** put the needle cap back on.

 **Do not** put the needles, syringe and needle caps in your household trash.

For more or specific information about safe sharps bin container in the country / state that you live in, go to the health authority website of your country.

 **Do not** dispose of your used sharps bin container in your household trash, return it to study site.

 **Do not** recycle your used sharps bin container.

 Always keep the sharps bin container out of the reach of children.

Confirmation of training & Planning for home administration

- Confirmation (appendix A) that you or a caregiver/legally authorized representative have been trained by the study site staff on the preparation and injection of the study medication.
- For dose administered at your home, please complete the paper "Participant Injection Diary" provided by your study doctor and return it to the site at the next on-site visit.

Missed dose

Please inform as soon as possible your Study Doctor/Nurse if you have missed your dose.

Appendix A

Confirmation of training

Patient Number | _ . _ . _ | _ . _ . _ . _ | _ . _ . _ . _ . _ |

The below signatures confirm that a patient/non-professional caregiver/legally authorized representative has been trained on the preparation and injection of the study medication using this Instruction For Use for Clinical Study LTS17789 and that she/he feels comfortable to prepare and perform the injections.

Person responsible for the training:

Investigator or delegate's Name

Date

Signature

Person trained:

Patient / non-professional caregiver
/legally authorized representative's Name

Date

Signature

Please file the original in the patient's file and provide the patient / non-professional caregiver /legally authorized representatives with a copy.