

Oral Medications Used in Clinical Studies

Medications used in clinical studies include:

- Medications that have not yet been approved by the U.S. Food and Drug Administration (FDA).
- Medications that have been approved by the FDA for certain health conditions and now being tested for safety and effectiveness to treat new or different health conditions.

You are participating in a clinical study and are taking a study medication by mouth. The name of the medication that you are taking is:

_____ and the study number is:_____.

Here is some important information on participating in a study and how to safely take, handle, and store the study medication:

What do I need to know about being in a clinical study?

- Your study medication may be available to patients with other diseases and information on its use may be available in ads and on websites. However, because you are taking this medication as part of your participation in a clinical study, you must follow the instructions that the study team gave you.
- Some clinical studies use a “control group” to determine if the investigational treatment is effective. This means that you may receive the standard treatment or a placebo instead of the investigational medication.
- A placebo is an inactive tablet, capsule, or other treatment. In clinical studies with control groups or placebos, you and your doctor may not

know which medication you are taking. Even if you may be taking a placebo, it is important to take your study medication exactly as directed.

- The “Informed Consent” document you signed at the beginning of the clinical study has more information about your study medication and how to contact the study team.

How should I take the study medication?

- Take your study medication exactly as instructed. This will ensure your safety and allows the study team to receive accurate information from your participation.
- If you are taking medications by mouth, it is important that you swallow each tablet or capsule whole. Do not chew, crush, or open the medication unless the study team tells you that you can do that.
- If you cannot swallow the study medication, contact your study team about other ways to take your medication.
- If you miss a dose or vomit up a dose, check the instructions that the study team gave you or contact the study team as soon as you can to find out what you should do.
- If you receive a medication diary or a study log, fill it out completely and accurately. In the medication diary, be sure to list any doses that you missed or vomited and any side effects that you felt.
- Bring the medication diary or your log with you to the next hospital or clinic visit.

How do I store the medication?

- Keep the study medication in its original container. Do not transfer the medication to another container or medication box.

- Store your medication in a safe place, away from other family medications or food, and out of the reach of children and pets.
- Check the medication label to see if it requires special storage, such as refrigeration or protection from light.
- If your medication needs to be stored at room temperature, store it away from excessive heat and moisture and out of direct sunlight. Do not store your medication in the bathroom.
- If your medication needs to be stored in the refrigerator, use a zip-top bag to keep it away from food.
- If the medication needs to be protected from light, place it in a brown paper bag or a dark cabinet or closet.
- When you travel, do not store the medication in the car to avoid exposure to extreme temperatures.
- When you fly, take the medication in your carry-on luggage to ensure that the temperature is controlled and to avoid losing the medication.

What are some important tips to study participants?

Be sure to bring **all** bottle(s) or container(s) (including empty containers) to each clinic visit or if you are admitted to the hospital.

Do not dispose of any study medication yourself.

Study medications may interact with other medications, supplements, or herbal products. Include your study medication in the list of medications you take at home. Tell your pharmacist and primary care doctor about your study medication so that they will have an accurate list of all your medications.

How should I protect myself if the medication is considered hazardous?

- Wash your hands before and after handling study medications.
- Check with the study team to determine if it is necessary to wear gloves while handling the medication.
- If you spilled the medication on your skin, remove contaminated clothing, wash the area with soap and a large amount of water, and contact the study team. Do not wash soiled clothes with your other laundry.
- If the medication got into the eyes, flush with water for at least 15 minutes and contact the study team.
- If you are instructed to dissolve the study medication in liquid or mix it with food, check with the study team to see if you need to cover the work area to protect from contamination and to use disposable dishes and utensils.
- If you have a low-flush or high-efficiency toilet, close the lid and flush twice to ensure all body waste is removed.

When do I need to contact the study team?

- If you accidentally spilled the study medication on your skin or the medication got into your eye.
- If you dropped a pill or misplaced the medication bottle.
- Before starting a new medication (including over-the-counter medications and herbal supplements).
- If you feel that you are having side effects from taking the study medication.
- If you have any questions or concerns about the study or study medication.

- If you are not sure how to take the study medication.

Whom can I contact?

During office hours contact:

Name Phone

After hours contact:

Where can I find more information on clinical studies or study medications?

- <https://www.cancer.gov/about-cancer/treatment/clinical-trials>
- <http://www.fda.gov/forpatients/clinicaltrials/default.htm>

Notes: _____

Disclaimer: This document is for informational purposes only and is not intended to take the place of the care and attention of your personal physician or other professional medical services. Talk with your doctor if you have questions about individual health concerns or specific treatment options.

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