

What should I expect if my child joins the study? (con't.)

- Your child will receive the investigational study medication. You will know the name of the medication being tested. The investigational medication will be given by injection.
- You must tell the study doctor about all prescription and over-the-counter drugs your child takes. This includes vitamins, herbs, topical medicines, and other kinds of therapies. Some medications that your child takes now may not be allowed to be used during the study.

What if I, or my child, decide my child should not participate in this clinical research study?

You and/or your child may decide at any time during the study that your child should no longer participate. Your child may leave the study at any time. Neither you, nor your child, have to give a reason.

**To learn more about the
CADMUS Jr. clinical research study,
please contact:**



Virginia Clinical Research, Inc.
6160 Kempsville Circle, Suite 200A
Norfolk, VA 23502
757-625-0151



The CADMUS Jr.
Clinical Research
Study for Children
with Moderate-to-Severe

PLAQUE PSORIASIS



What is a clinical research study?

A clinical research study is a scientific evaluation conducted by researchers and doctors in human volunteers. Clinical research studies answer important medical questions about how an investigational medication works in the body, how it affects certain conditions, and how safe it is to use. Safety of the study volunteers is always the main concern of the researchers, doctors and sponsors conducting a clinical research study.

Participating in this clinical research study may help your child's plaque psoriasis skin condition, but it is not guaranteed. Your child may be exposed to side effects, which range from unpleasant to serious and life-threatening while participating in this clinical research study. Your child's participation in this clinical research study is voluntary and he or she can stop participating at any time.

In order to develop reliable information, well-controlled clinical research studies need volunteers to participate. Before you and your child decide if your child wants to volunteer for this clinical research study, you should talk with your family and your doctor.

What is the purpose of this clinical research study?

The purpose of the CADMUS Jr. clinical research study is to determine the safety and effectiveness of an investigational medication and to find out how it works in children. The study drug being tested in this clinical trial is being developed to possibly treat moderate-to-severe plaque psoriasis.

Who may participate?






Your child may be eligible to participate in this study if he or she:

- Is between the ages of 6 to 11 years
- Has a diagnosis of plaque psoriasis for at least 6 months

Additional criteria will apply. The study physician will tell you about other eligibility requirements.

What is informed consent?

Before you decide to volunteer for a clinical research study, you should talk with your family and your physician. If you decide that you want your child to participate in this clinical research study, the study doctor or other study professional is required by law to review a very detailed document about the study with the child's parent/guardian. This is called an informed consent. The purpose of the informed consent is to make sure that:

-  **You understand the study thoroughly, including all the study procedures and the potential side effects and other risks associated with the study or the study procedures**
-  **You understand your responsibilities as the parent/guardian of a study participant**
-  **All your questions about the study have been answered**
-  **You want your child to be in the study**
-  **You know that your child can leave the study at any time, for any reason**

What is assent?

Before your child can volunteer for this clinical research study, he or she may be asked to sign an assent form to agree to participation. The assent form explains to your child how and why the clinical research study is being conducted. Your child can withdraw his or her assent at any time, even if you still want them to participate. A child may not continue in a clinical research study against his or her will.

What should I expect if my child joins the study?

- After you sign the informed consent form and your child signs the assent form (if applicable), your child will undergo tests and evaluations at a screening visit to determine if he or she is a good candidate for the study.
- If your child is a good candidate to participate in the study, the study doctor will enroll your child in the study. His or her participation will last for 56 weeks. Your child will need to visit the clinical study site 8 times during the study, not including the screening visit.

