

Attachment #12



YOUR FAMILY'S GUIDE TO PREPARING AND ADMINISTERING

***Nutropin* DEPOT**

[somatotropin (rDNA origin) for injectable suspension]

for Pediatric Growth Hormone Deficient Patients

ESCAPE FROM THE EVERYDAY

An Instruction
Handbook for
Caregivers and
Patients

Injection Site Reactions

As with many injected medications, Nutropin Depot™ [somatropin (rDNA origin) for injectable suspension] can cause temporary reactions at the injection site. Following an injection, you may notice a change in the skin around the injection site. Reactions at the injection site are frequent but usually do not last long, and should not be a cause for alarm. Other reactions, however, may indicate that something more serious is going on—which may require the attention of your child's doctor.

In clinical trials, the most frequently reported adverse reactions were injection-site reactions, which occurred in nearly all patients. On average, 2 to 3 injection-site reactions were reported per injection.

A small nodule, or lump, the size of a pea (61%): This is the area where the dose of Nutropin Depot stays as it is released. The nodule will shrink over the next couple of weeks as the medication is absorbed into the body.

Redness at the site (53%): This usually lasts just a few days.

Pain and tenderness at the injection site: This may occur during (43%) or after (47%) an injection. However, it shouldn't interfere with your child's daily activities. Mild, over-the-counter pain relievers may ease the discomfort. Or, soak the area in a warm bath or apply a warm, moist compress.

Bruising (20%): This may last several days to a week.

Itching (13%): Although it may be annoying if it occurs, this reaction should go away fairly quickly.

Skin depression, or "dimple" (13%) (referred to by doctors as "lipoatrophy"): This will take a few weeks to disappear. Until it does, you should avoid using this area as an injection site.

Swelling or puffiness at the site (8%): This usually does not last very long.

These reactions usually go away over time with little or no treatment.

Other Reported Reactions

In clinical studies of Nutropin Depot, other less frequent reactions were observed. These included headache, nausea, lower extremity pain, fever, and vomiting. These symptoms were generally well tolerated and went away on their own.

Severe Reactions

It is possible that in rare cases a more severe reaction to the injections may develop. If you notice any of the following signs or symptoms, call your child's doctor immediately:

- Swelling or lump at the injection site that doesn't go away over time
- Rash at the injection site
- Any signs of infection or inflammation at an injection site (pus, persistent redness of surrounding skin that is hot to the touch, persistent pain after the injection)
- Difficulty breathing
- Body rash

Discuss the potential risks and benefits of growth hormone treatment with your child's doctor so you are familiar with any possible side effects. Your child's doctor, nurse, and pharmacist are there to help answer any questions you may have about treatment with Nutropin Depot™ [somatropin (rDNA origin) for injectable suspension].

Nutropin Depot should not be used for growth promotion in pediatric patients whose bone growth is completed. Nutropin Depot should not be used in patients with active cancer. GH therapy should be discontinued if evidence of cancer develops.

Seek prompt medical attention if your child experiences allergic reactions or complains of severe headache, changes in vision, or nausea and/or vomiting. In addition, notify your doctor if your child develops a limp or complains of hip or knee pain. If your child is admitted to the hospital for any reason, notify his or her endocrinologist immediately.

