



TRANSMITTED VIA FACSIMILE

JUL 28 2000

Robert L. Garnick, Ph.D.
Vice President, Regulatory Affairs
Genentech, Inc.
1 DNA Way
South San Francisco, CA 94080-4990

RE: NDA # 21-075
Nutropin Depot [somatropin (rDNA origin) for injectable suspension]
MACMIS ID# 9082

Dear Dr. Garnick:

This letter refers to Genentech Incorporated's (Genentech) May 16, 2000 submission to the Division of Drug Marketing, Advertising, and Communications (DDMAC) under cover of Form FDA 2253 of a Healthcare Professional In-Service Resource Kit (item number 7223300) for Nutropin Depot. DDMAC, in consultation with the Division of Metabolic and Endocrine Drug Products, has reviewed the Resource Kit and has determined that it is in violation of the Federal Food, Drug, and Cosmetic Act and its implementing regulations. Specifically, we object for the following reasons:

Misleading Claims

Genentech presents the claim "Nutropin Depot represents a significant advance in terms of convenience over other currently available growth hormone replacement therapies." This claim is misleading because it implies comparable efficacy to daily growth hormone therapies along with the increased convenience of a once or twice monthly regimen. This implication is misleading because it does not convey the material information provided in the approved product labeling (PI) that growth rates for the long-acting formulation may not be comparable to those achieved with the daily formulation. Historical studies showed growth rates achieved on daily therapy are higher for treatment-naive patients. Also, according to the PI, patients previously treated with daily growth hormone who were switched to Nutropin Depot experienced a decrease in growth rate. This decrease was of a higher magnitude than could be accounted for by the normal decrease experienced by patients who remain on a daily regimen.

The claim that Nutropin Depot is "the first long-acting dosage form of somatropin" is misleading because it implies a greater usefulness than has been demonstrated by substantial evidence. Nutropin Depot is only indicated for the long-term treatment of growth failure due to a lack of adequate endogenous GH secretion. Because there are other forms of somatropin that are approved for additional indications, this claim misleadingly implies that Nutropin Depot can be used in place of any other somatropin for any other indication.

Lack of Fair Balance

The Resource Kit contains effectiveness claims that are not fairly balanced with information regarding contraindications, warnings, precautions, and adverse reactions. Risk information should appear with a prominence and readability reasonably comparable to the presentation of information relating to the effectiveness of Nutropin Depot. For example, the 30-page handbook for caregivers and patients presents numerous efficacy claims for Nutropin Depot therapy. Risk information is only presented on 3 pages of the booklet and the information is inadequate to fully convey the risks of Nutropin Depot therapy. No information is presented regarding contraindications and warnings. Furthermore, your presentation of information regarding injection-site reactions minimizes the frequency and magnitude of their occurrence.

Requested Action

Genentech should immediately cease dissemination of this violative material and any other promotional materials with the same or similar claims or representations. You should respond to this letter by August 11, 2000. We request that you respond, in writing, with your intent to comply with the above. Your response should also include a list of all identified violative material and the proposed method and date for discontinuing their use.

Genentech should direct the correspondence to the undersigned by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising, and Communications, HFD-42, Rm. 17B-20, 5600 Fishers Lane, Rockville, MD 20857.

Robert Garnick
Genentech
NDA # 21-075
MACMIS #9082

Page 3

DDMAC reminds you that only written communications are considered official. In all future correspondence regarding this matter, please refer to MACMIS #9082 and the NDA number.

Sincerely,

/s/

Margaret M. Kober, R.Ph.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications

Genentech, Inc.
Genentech, Inc.
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1 DNA Way
South San Francisco, CA 94080-4990
(650) 225-1000
FAX: (650) 225-6000

Dear Healthcare Professional:

We are pleased to present you with the Nutropin Depot™ [somatotropin (rDNA origin) for injectable suspension] Healthcare Professional In-Service Resource Kit. This kit has been designed to provide you and your staff with the information you will need regarding this important new growth hormone therapy—the first long-acting dosage form of somatotropin. Nutropin Depot represents a significant advance in terms of convenience over other currently available growth hormone replacement therapies, as it is the only growth hormone formulation to offer patients the option of once- or twice-monthly dosing (which may require more than one injection per dose).

Enclosed you will find the following educational tools and sources of information for you and your patients:

For Healthcare Professionals

- **Technical Information for the Healthcare Professional**—This brochure provides answers to commonly asked questions about Nutropin Depot, including product mechanism of action, dosage and administration information, storage and reconstitution recommendations, and more.
- **Nutropin Depot Dosage Guide**—A weight-based dosage “slide guide” to help simplify dosage calculations. At a glance, the guide provides you with total milligrams per dose, total volume per injection, minimum number of injections per dose, and vial size selection, for both once- and twice-monthly dosing regimens.
- **Prescription Pad Stickers**—Peel-off stickers (with information conveniently color-coded by vial size) that provide you a quick, easy tool to prescribe Nutropin Depot.
- **Patient File Stickers**—A quick reminder, to place on patient files, of the dosage you’ve prescribed for each patient receiving Nutropin Depot. These stickers also provide space for you to customize patient distributor and insurance information—for easy reference.
- **Syringe and Injection Guide**—A simple visual reference to help you instruct your patients and their families on the correct dose and dosing schedule for Nutropin Depot. The information is color-coded by vial size for ease of reference. Once you have customized the guide to your patient’s dose, you can provide it to your patients and their families to take home. You may wish to keep a copy for the patient’s files.

- **Nutropin Depot Full Prescribing Information**—A document providing important information regarding clinical pharmacology, efficacy studies, indications and usage, contraindications, and other information that prescribing healthcare professionals need to know when selecting Nutropin Depot™ [somatotropin (rDNA origin) for injectable suspension] for their growth hormone-deficient patients.

For Patients and Caregivers

- **Your Family's Guide to Preparing and Administering Nutropin Depot**—A booklet and video offering complete, step-by-step instructions for resuspending and injecting Nutropin Depot. Includes tips to ease the injection process, as well as safety and side effects information. A "Q&A" section addresses commonly asked questions about Nutropin Depot and growth hormone therapy.
- **Preparation and Administration Quick Reference**—A laminated brochure that provides an abridged reminder for patients and caregivers on how to prepare and administer Nutropin Depot, as well as tips to ease the injection process.
- **Nutropin Depot Patient Package Insert**—A two-sided sheet providing illustrated, step-by-step instructions for preparing and administering Nutropin Depot. It also covers injection-site selection, proper storage, and potential reactions to the medication.
- **Injection-Site Stickers**—Colorful calendar stickers that serve the dual purpose of reminding patients of injection days and helping them keep track of injection-site rotations. These stickers will be provided with each caregiver instruction booklet and video kit (titled *Your Family's Guide to Preparing and Administering Nutropin Depot*).
- **Growth Hormone Encouragement Stickers**—Cheerful motivational stickers that offer patients words of encouragement and a fun, post-injection reward. A set of stickers will be provided to each patient in the Starter Kit Backpack.

If we can be of further assistance in answering your questions, providing you with more information, or supplying you with additional quantities of any of the materials in this kit, please contact your Genentech representative or call Customer Service at 1-800-551-2231.

Sincerely,

Genentech, Inc.

Please see enclosed full prescribing information for Nutropin Depot.

Genentech[®]
ENDOCRINOLOGY

Genentech, Inc.

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TECHNICAL INFORMATION

for the
Healthcare Professional

***Nutropin* DEPOT™**

[somatropin (rDNA origin) for injectable suspension]
for subcutaneous administration

ESCAPE FROM THE EVERYDAY

Nutropin DEPOT™

[somatotropin (rDNA origin) for injectable suspension]

Technology

Q: What is Nutropin Depot?

A: Nutropin Depot is the first long-acting dosage form of somatotropin recombinant growth hormone. It is the only growth hormone replacement therapy that offers patients and caregivers the convenience and added freedom of fewer injections. Nutropin Depot is administered by subcutaneous injections given once or twice a month.

Q: How does Nutropin Depot deliver growth hormone?

A: Nutropin Depot delivers growth hormone through the use of microsphere technology. Growth hormone is embedded in microspheres made up of soluble, biodegradable polymers, similar to those used in resorbable sutures and other long-acting drugs. When Nutropin Depot is injected into the subcutaneous space (tissue), growth hormone is released as the microspheres degrade.

Dosing

Q: How often is Nutropin Depot administered?

A: Based on the outcome of clinical trials, it is recommended that Nutropin Depot be administered once monthly (at a dose of 1.5 mg/kg) or twice monthly (at a dose of 0.75 mg/kg). The dose should be administered on the same day or days of each month (for example, on the 1st and/or the 15th). The total monthly dose by weight for both regimens is the same—1.5 mg/kg, given in a standard dilution of 19 mg/mL. Some patients may require more than one injection per dose.

Q: Why are there two different dosing schedules?

A: The two different dosing schedules for Nutropin Depot are designed to provide flexibility in administering the total monthly dose. Both schedules provide weight-based dosing that has been proven effective in clinical trials. Depending on the preference of the physician and patient and the amount of growth hormone prescribed, the dosing schedule can be customized to minimize the number of injections per dose or the number of injections per month. For example, larger children may prefer the twice-monthly schedule in order to reduce the number of injections per dose.

Q: What is the maximum number of injections per dose?

A: Children weighing up to 30 kg (66 lb) will require no more than two injections per dose, once monthly. Children weighing 31 kg to 60 kg (68 lb to 132 lb) will require no more than two injections per dose, twice monthly. Based on the weight distribution of patients on growth hormone therapy in the National Cooperative Growth Study who are currently being treated with Genentech growth hormone products, fewer than 5% of patients would require more than two injections per dose. More than two injections per dose may be administered, if necessary. Please see the Dosage and Administration section of the accompanying full prescribing information. Genentech has created an easy-to-use dosage guide to help simplify dose calculations for your patients.

Q: What is the maximum volume of drug per injection?

A: The recommended maximum volume of Nutropin Depot™ [somatropin (rDNA origin) for injectable suspension] per subcutaneous injection is 1.2 mL.

Q: Must Nutropin Depot be given on the same day(s) every month?

A: Nutropin Depot should be administered as closely as possible to the prescribed dosing schedule in order to achieve maximum benefit.

Q: What if a patient misses an injection or wants to change the injection schedule?

A: Instruct parents and patients that Nutropin Depot may be given one or two days before or after the scheduled injection. The family should notify the physician if a dosing schedule has been altered or if a dose is missed entirely. Be sure the patient and caregivers understand that they should not try to make up for a missed injection by "doubling up" on injections—or they may experience adverse events.

Administration

Q: How is Nutropin Depot administered?

A: Nutropin Depot is administered by subcutaneous—not intramuscular—injection. The needle used to give injections of Nutropin Depot should be held at a 45- to 90-degree angle. Just as with Nutropin® [somatropin (rDNA origin) for injection] or Nutropin AQ® [somatropin (rDNA origin) injection], caregivers and patients can be trained to give injections of Nutropin Depot. However, there may be exceptions, such as when you, the healthcare professional, choose to administer a patient's dose in your office or clinic.

Q: How does administration differ from that of Nutropin or Nutropin AQ?

A: Like Nutropin and Nutropin AQ, Nutropin Depot is administered by subcutaneous injection. However, Nutropin Depot is given less frequently and a larger volume of drug is administered per dose. Also, because of the viscosity of the Nutropin Depot resuspension, a larger-gauge needle (21-gauge) is required to administer a dose. The length of the needle ($\frac{1}{2}$ "") is similar to that used for daily injections.

Q: What are the best sites for injection of Nutropin Depot?

A: The recommended injection sites for subcutaneous administration of Nutropin Depot are the abdomen (which is the preferred site), thighs, buttocks, and upper arms. Note: The upper arm is not recommended for repeated or multiple injections in smaller children.

Please see accompanying full prescribing information for Nutropin Depot.

Q: Will patients still need to rotate injection sites?

A: Just as for other growth hormone formulations, a different injection site should be selected each time Nutropin Depot™ [somatropin (rDNA origin) for injectable suspension] is administered. Genentech will provide calendar stickers that you can give to patients and caregivers to remind them when to take injections and to encourage injection-site rotation.

Reconstitution and Storage

Q: Does Nutropin Depot require reconstitution?

A: Nutropin Depot is supplied as a dry, white powder. Unlike lyophilized growth hormone, which dissolves into a solution when reconstituted, Nutropin Depot microspheres are resuspended in solution by mixing with Diluent for Nutropin Depot (which is provided in each Nutropin Depot carton). **Remember: Only Diluent for Nutropin Depot should be used to resuspend Nutropin Depot.**

Q: How will the reconstituted suspension look?

A: The resuspended medication should appear thick and milky, with a viscosity similar to that of testosterone or penicillin.

Q: How much Diluent for Nutropin Depot is added to each vial?

A: The amount of diluent needed will vary according to the size of the vial of Nutropin Depot. The 13.5 mg vial of Nutropin Depot requires 0.8 mL of diluent, the 18 mg vial requires 1.0 mL of diluent, and the 22.5 mg vial requires 1.2 mL of diluent. Using these diluent volumes results in a final concentration of 19 mg/mL of somatropin per vial for all three vial sizes. Healthcare professionals will be provided with a dosage guide to help calculate the weight-based dose of Nutropin Depot.

Q: How are Nutropin Depot and Diluent for Nutropin Depot stored?

A: The Nutropin Depot carton must be refrigerated at 2–8°C/36–46°F. The Nutropin Depot vial, and the vial of diluent, must not be frozen. To aid the injection process, remove the Nutropin Depot carton from the refrigerator and allow the vials to come to room temperature prior to mixing. Do not expose Nutropin Depot vials to temperatures above 25°C/77°F.

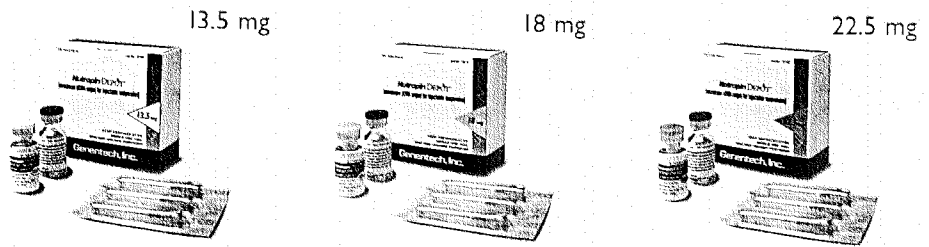
Q: How long can the vial of resuspended Nutropin Depot sit before administration?

A: Because Nutropin Depot contains no preservatives, the injection must be given immediately after mixing. Resuspended vials of Nutropin Depot cannot be stored for later use, nor can medication remaining in the vial after injection be used for a future injection. Discard unused portions. Vials of Nutropin Depot and Diluent for Nutropin Depot are intended for single use only.

Q: How long can the syringe containing the resuspended medication be allowed to sit before administration?

A: To prevent settling, the injection should be given as soon as the medication is prepared.

How Supplied



Q: How is Nutropin Depot™ [somatropin (rDNA origin) for injectable suspension] supplied?

A: Nutropin Depot is supplied in single-use vials containing 13.5 mg (white cap), 18 mg (yellow cap), or 22.5 mg (orange cap) of preservative-free somatropin microspheres for injectable suspension. A combination of different vial sizes may be needed for each dose, based on the patient's weight.

Q: What will the patient receive?

A: Each vial of Nutropin Depot is supplied to the patient in a convenient carton containing one single-use vial of Nutropin Depot powder (13.5 mg, 18 mg, or 22.5 mg); one 1.5 mL, single-use vial of Diluent for Nutropin Depot; and three 21-gauge, 1/2 inch needles (one for resuspension, one for injection, and one extra). Other required supplies include 3 mL Luer-Lok® syringes for resuspension and injection, alcohol swabs, gauze pads, and a sharps disposal container.

Q: How will Nutropin Depot be shipped?

A: Nutropin Depot will be packed, along with a combination of refrigerated and frozen gel bags, in an insulated shipping container. It will be sent overnight. The medication should be refrigerated as soon as it arrives.

Q: What diluent is used to mix the Nutropin Depot powder?

A: Each carton of Nutropin Depot contains a vial of Diluent for Nutropin Depot. The diluent is a sterile, aqueous solution containing carboxymethylcellulose. This diluent is specially formulated to resuspend the Nutropin Depot microspheres, and is not interchangeable with diluents used to reconstitute lyophilized growth hormone products. Only Diluent for Nutropin Depot should be used to prepare Nutropin Depot for injection.

Support Materials

Q: What materials will Genentech provide to educate and assist healthcare professionals, parents, and patients in the proper use of Nutropin Depot?

A: Genentech will provide a variety of clinical and educational materials to serve healthcare providers, patients, and parents. These include a caregiver instructional booklet and video, dosing guidelines, product information, injection instruction and reminder aids, and full prescribing information.

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visit growthhormone.gene.com

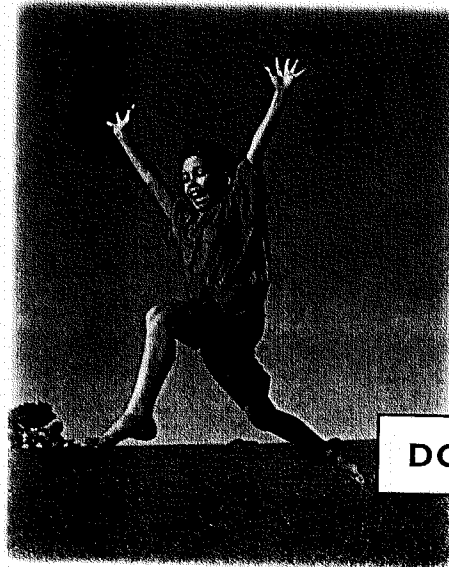
Please see accompanying full prescribing information for
Nutropin Depot™ [somatropin (rDNA origin) for injectable suspension].

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Nutropin DEPOT™

[somatropin (rDNA origin) for injectable suspension]
for subcutaneous administration

Please see accompanying full prescribing information.



DOSAGE GUIDE

Nutropin DEPOT™

[somatropin (rDNA origin) for injectable suspension]
for subcutaneous administration

40 kg-70 kg
(88 lb-154 lb)

DOSAGE GUIDE

For patients 40 kg to 70 kg (88 lb to 154 lb)
See inside for patients 5 kg to 40 kg (11 lb to 88 lb)

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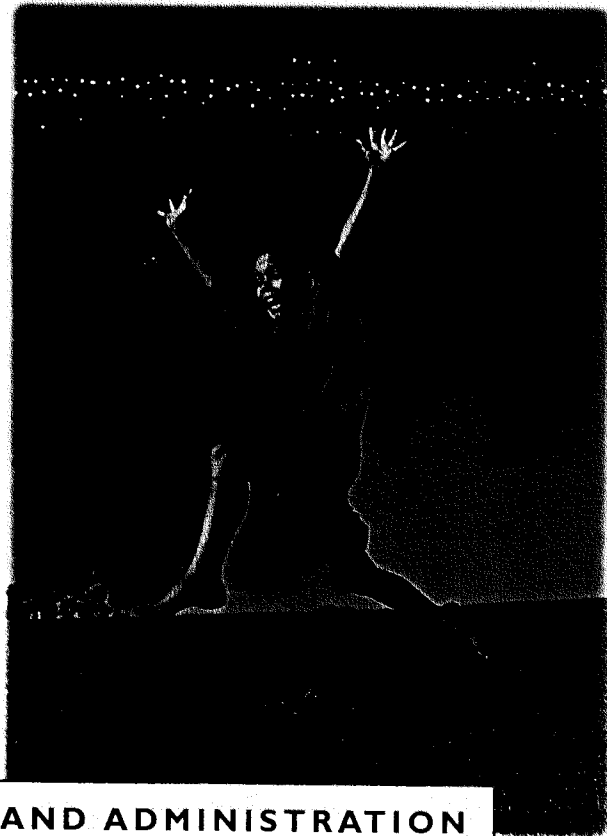
Please see accompanying full
prescribing information.

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58 kg Patient Weight
127.9 lb

Once-a-Month Dosing	87.00	Total 28-Day Dose in mg (1.5 mg/kg per dose) up to 60 kg
Number of 13.5 mg vials (0.8 mL) required	4	Minimum Number of Injections Required to Deliver Dose
Number of 18 mg vials (1.0 mL) required	0	1st] Volume of Nutropin Depot needed per injection (mL)
Number of 22.5 mg vials (1.2 mL) required	0	2nd]
	0	1st] Volume of Nutropin Depot needed per injection (mL)
	0	2nd]
	0	3rd]
	0	4th]
	4	Volume of Nutropin Depot needed per injection (mL)
	1.18	1st]
	1.18	2nd]
	1.18	3rd]
	1.05	4th]
	43.50	Total 14-Day Dose in mg (0.75 mg/kg per dose)
	2	Minimum Number of Injections Required to Deliver Dose
	0	1st] Volume of Nutropin Depot needed per injection (mL)
	0	1st]
	0	2nd] Volume of Nutropin Depot needed per injection (mL)
	0	3rd]
	2	Volume of Nutropin Depot needed per injection (mL)
	1.15	1st]
	1.15	2nd]

40 kg-70 kg
(88 lb-154 lb)



PREPARATION AND ADMINISTRATION

Quick Reference

***Nutropin* DEPOT™**

[somatotropin (rDNA origin) for injectable suspension]
for subcutaneous administration

ESCAPE FROM THE EVERYDAY

INJECTION TIPS FOR CAREGIVERS

Be Positive About Your Child's Growth Hormone Therapy

- Keep an upbeat attitude—emphasize how the treatment can help your child.
- Establish a date for injections (once or twice a month), and let your child mark the date(s) on the calendar with a sticker or drawing.
- Involve older children in the process by asking them to gather supplies, choose the injection site, and cleanse the area.
- As a reward, give your child a small treat or plan a fun activity to take place immediately after the injection.

Tips to Make Injections More Comfortable

- To reduce injection-related pain, your doctor may prescribe a numbing medication, which can be applied to the injection site before giving the injection; or you can apply ice to the site a few minutes before the injection.
- To reduce stinging, be sure that the alcohol has dried from the skin before giving the injection.
- Distract your child during the injection with a favorite video or with music.
- Give your child something to hold or squeeze during the injection, such as a stuffed animal or a ball.

Injection Tips

- Give the injection as soon as the medication is prepared.
- If the needle clogs, replace it with the extra needle provided in the medication carton. Test the new needle by pushing in the plunger just enough to get a drop of medication.

- Gently squeeze the skin between your thumb and index finger before the injection. Release the skin once the needle is inserted.
- To help prevent the development of a nodule, or lump, at the injection site, gently massage the injection site after the injection. (If a nodule does form, don't be alarmed. It is the area containing the medication, and will shrink over the next couple of weeks as the medication is absorbed.)

After the Injection

- Comfort your child after the injection with hugs or other forms of affection.
- It may help to gently massage the site or to apply ice after an injection.
- If your child complains of discomfort after the injection, a mild, over-the-counter pain reliever may ease this. You may also soak the area in a warm bath or apply a warm, moist compress. If the discomfort becomes severe or lasts more than a few days, call your child's doctor.
- Keep an eye out for severe reactions. To familiarize yourself with the severe reactions that may occur in rare cases, carefully review the information on page 19 of your booklet titled *Your Family's Guide to Preparing and Administering Nutropin Depot™* [somatropin (rDNA origin) for injectable suspension].

For more helpful tips on making injection time easier for your child, refer to *Your Family's Guide to Preparing and Administering Nutropin Depot* and watch the accompanying video. Also, be sure to discuss the potential risks and benefits of growth hormone treatment with your child's doctor so you are familiar with any possible side effects. As always, call your doctor or nurse if you have any questions or concerns.

For more information, visit our Web site at growthhormone.gene.com

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Please see accompanying full prescribing information for Nutropin Depot.



Firmly attach the needle by twisting it onto the syringe. Pull the plastic needle guard straight off and set it aside for later use.

PREPARING AND MEASURING THE DOSE



Draw air into the syringe by pulling on the plunger until the end of the stopper indicates an amount of air equal to the amount of diluent you will need. Then inject the air into the vial of Diluent for Nutropin Depot™ [somatropin (rDNA origin) for injectable suspension]. Next, draw the correct amount of diluent into the syringe.



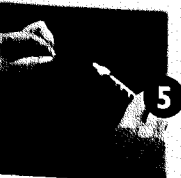
Inject the diluent into the vial of Nutropin Depot. Withdraw the needle and carefully replace the needle guard, using the "scoop" technique. Set the needle guard on a table. Without touching or holding the guard, slide the needle into it and "scoop" it up. Then use your free hand to click the guard onto the syringe. Vigorously swirl the vial until the powder is **completely mixed**.



To measure the dose, slowly insert the needle straight through the center of the rubber stopper; turn the vial upside down with the syringe still in it, and slowly pull back on the plunger in a continuous motion until the correct amount of Nutropin Depot is in the syringe.



Tap the syringe to dislodge any large air bubbles, and check to be sure you have the correct amount of Nutropin Depot in the syringe. Carefully recap the needle, using the "scoop" technique.

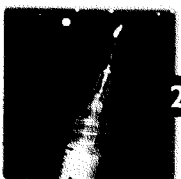


Replace the needle with a new needle, which will be used to give the injection.

GIVING THE INJECTION



Cleanse the injection site with an alcohol swab, starting from the center and working outward. Let the alcohol dry from the skin before giving the injection, to help reduce stinging.



Remove the needle guard by pulling it straight off and away from the syringe. Gently push the plunger until a drop of medication appears.

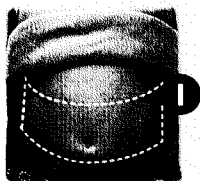


Hold the syringe the way you would hold a pencil, and keep the slanted portion of the needle tip facing down. Gently lift and hold the skin between your fingers and thumb. Insert the needle directly into the skin at the angle you were taught, with a quick, firm motion; release the skin; then smoothly and slowly (but not for more than 5 seconds) push the plunger in.



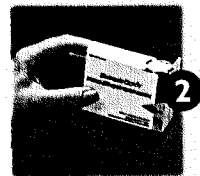
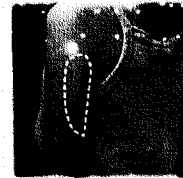
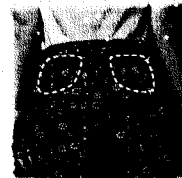
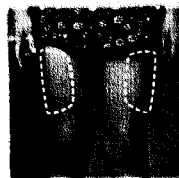
Wait a few seconds before withdrawing the needle. This helps prevent the medication from leaking from the injection site. Withdraw the needle quickly by pulling it straight out. Apply gentle pressure to the injection site with a dry gauze pad or cotton ball. Immediately put the syringe and needle into the disposal unit. Also, discard all used vials, even if they contain unused portions of medication or diluent. Vials containing Nutropin Depot and Diluent for Nutropin Depot are intended for single use only.

GETTING STARTED



Select the injection site, choosing a different site each time you give the medication.

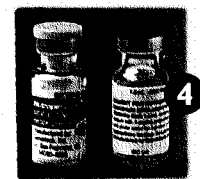
Expose the injection site completely. Never give an injection through clothing.



Always check the expiration date on the Nutropin Depot™ [somatropin (rDNA origin) for injectable suspension] carton.



Wash your hands thoroughly before preparing the medication.



After removing the Nutropin Depot carton from the refrigerator, let the vials warm to room temperature before mixing.



Before adding the diluent, **tap** the Nutropin Depot vial to help loosen the powder.



Remove the plastic caps from the vials. Try not to touch the tops of the vials. If you do, use an alcohol swab to clean the top of any vial you touched.

SYRINGE AND INJECTION GUIDE

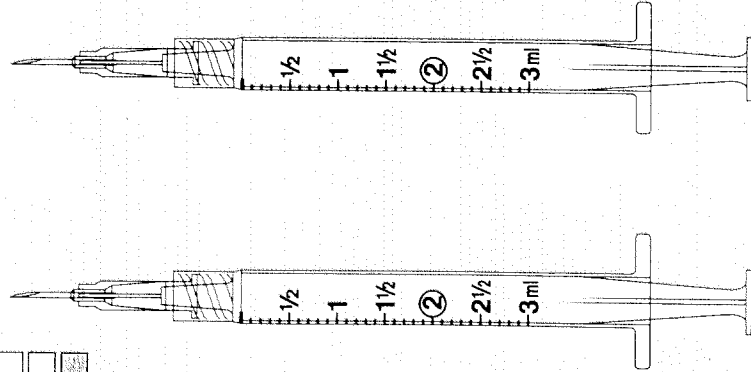
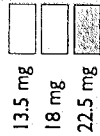
Today's date: _____ Patient's name: _____ Height: _____ Weight: _____

Doctor's/Nurse's name: _____ Office phone: _____

Date/time of next visit: _____ Questions for next visit: _____

FIRST INJECTION

Note: For each injection, you will use the same syringe to mix the medication with diluent and to administer the injection. After you prepare the medication, you will need to replace the diluent needle with a new needle for the injection. The needles are provided in your Nutropin Depot carton.



DILUENT AMOUNT:

Add _____ mL* of diluent to your vial of growth hormone

INJECTION AMOUNT:

Inject _____ mL* of mixed growth hormone

FOR EACH NUTROPIN DEPOT DOSE, YOU WILL NEED:

13.5 mg carton

Number of 13.5 mg Nutropin Depot vials needed _____
 Mix 0.8 mL of diluent in each 13.5 mg vial(s)

FIRST INJECTION: Give _____ mL
SECOND INJECTION (if needed): Give _____ mL
 _____ Once a month _____ Twice a month

18 mg carton

Number of 18 mg Nutropin Depot vials needed _____
 Mix 1.0 mL of diluent in each 18 mg vial(s)

FIRST INJECTION: Give _____ mL
SECOND INJECTION (if needed): Give _____ mL
 _____ Once a month _____ Twice a month

22.5 mg carton

Number of 22.5 mg Nutropin Depot vials needed _____
 Mix 1.2 mL of diluent in each 22.5 mg vial(s)

FIRST INJECTION: Give _____ mL
SECOND INJECTION (if needed): Give _____ mL
 _____ Once a month _____ Twice a month

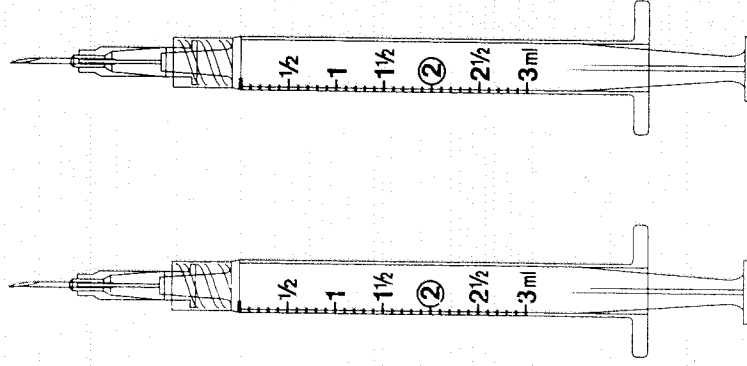
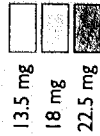
Standard concentration is 19 mg per mL

Date(s) of next injection(s): _____

*One milliliter (mL) represents the same amount as one cubic centimeter (cc).

SECOND INJECTION (if needed)

Note: For each injection, you will use the same syringe to mix the medication with diluent and to administer the injection. After you prepare the medication, you will need to replace the diluent needle with a new needle for the injection. The needles are provided in your Nutropin Depot carton.



DILUENT AMOUNT:

Add _____ mL* of diluent to your vial of growth hormone

INJECTION AMOUNT:

Inject _____ mL* of mixed growth hormone

Nutropin DEPOT

(somatropin (rDNA origin) for injectable suspension)

Started _____

1x _____ 2x _____ per month

Vial(s) Prescribed _____ **13.5mg**_____ **18mg**_____ **22.5mg**

Current Dose _____ Date _____

Distributor Information _____

Insurance Information _____

Nutropin DEPOT

(somatropin (rDNA origin) for injectable suspension)

Started _____

1x _____ 2x _____ per month

Vial(s) Prescribed _____ **13.5mg**_____ **18mg**_____ **22.5mg**

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(somatropin (rDNA origin) for injectable suspension)

Started _____

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Current Dose _____ Date _____

Distributor Information _____

Insurance Information _____

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(somatropin (rDNA origin) for injectable suspension)

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1x _____ 2x _____ per month

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Current Dose _____ Date _____

Distributor Information _____

Insurance Information _____

Peel and place on patients' files.

Nutropin DEPOT™
[somatropin (rDNA origin) for injectable suspension]

NAME _____ DATE _____

DISPENSE: Nutropin Depot

Sig: Give Nutropin Depot _____ subcutaneously
Total mg/dose

Dosing regimens:
____ Once monthly (1.5 mg/kg/monthly) ____ Twice monthly (0.75 mg/kg/twice monthly)

Vial Size & Dilution	13.5 mg/0.8 mL	18.0 mg/1.0 mL	22.5 mg/1.2 mL
Fill in injection number (1-4 by vial size)			
Injection Number			
Injection Volume			
Total injections (vials) per dose:			
Number of vials prescribed per month:			
Number of 3 mL Luer-Lok® syringes per month: (One syringe per injection taken)			
Other medications:			

REFILLS (Months) 1 2 3 DO NOT SUBSTITUTE

Nutropin DEPOT™
[somatropin (rDNA origin) for injectable suspension]

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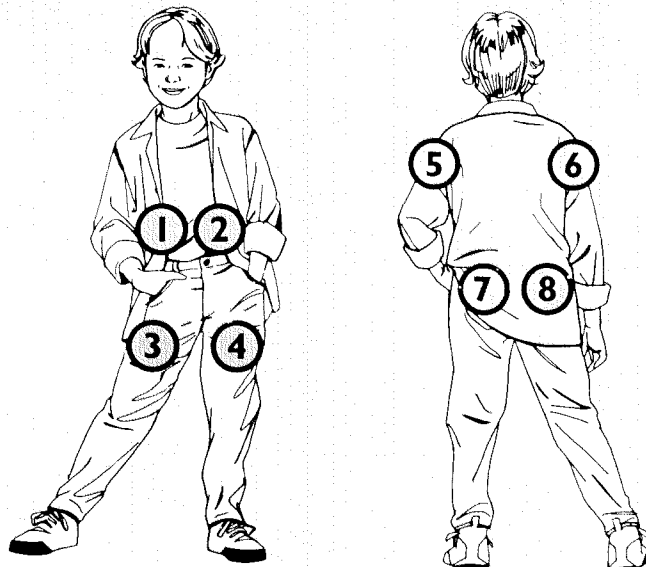


Growth Hormone Encouragement Stickers

These stickers are intended to help you support and encourage your child in taking his or her growth hormone therapy. Be sure to say the sticker message out loud ("You did it!", "Give yourself a hand!"). This way, your child will see—and hear—your valued words of encouragement.



Your Injection-Site Stickers



- 1 = right abdomen
- 2 = left abdomen
- 3 = right thigh
- 4 = left thigh
- 5 = left arm
- 6 = right arm
- 7 = left buttock
- 8 = right buttock

To help you remember your Nutropin Depot days . . .

Place these stickers on your calendar on the days your doctor has prescribed Nutropin Depot injections. Then write a number on the sticker to indicate which injection site you plan to use that day. The picture above shows the different injection sites by number.

If you have any questions, call your doctor or nurse at: _____

Injection Dates: _____

Nutropin DEPOT™
[somatropin (rDNA origin) for injectable suspension]

ESCAPE FROM THE EVERYDAY

Please see accompanying full prescribing information.

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