

Medication Guide
SIGNIFOR® [sig-na-for]
(pasireotide)
Injection

Read this Medication Guide before you start using SIGNIFOR and each time you get a refill. There may be new information. This information does not take the place of talking to your doctor about your medical condition or your treatment.

What is the most important information I should know about SIGNIFOR?

SIGNIFOR can cause serious side effects, including:

- **Low cortisol levels in your blood (hypocortisolism).** Tell your doctor right away if you have any signs and symptoms of hypocortisolism. Signs and symptoms of hypocortisolism may include:
 - weakness
 - fatigue
 - loss of appetite
 - nausea
 - vomiting
 - low blood pressure
 - low level of sodium in your blood
 - low blood sugar

If you get hypocortisolism while taking SIGNIFOR, your doctor may change your dose or ask you to stop taking it.

- **High blood sugar (hyperglycemia).** Your doctor should check your blood sugar level before you start taking SIGNIFOR and while you take it. Signs and symptoms of hyperglycemia may include:
 - excessive thirst
 - high urine output
 - increased appetite with weight loss
 - tiredness

If you get hyperglycemia while taking SIGNIFOR, your doctor may give you another medicine to take to lower your blood sugar. Your doctor may also change your dose of SIGNIFOR or ask you to stop taking it.

What is SIGNIFOR?

SIGNIFOR is a prescription medicine used to treat Cushing's disease in adults who cannot have surgery or have failed surgery.

It is not known if SIGNIFOR is safe and effective in children.

What should I tell my doctor before using SIGNIFOR?

Before you take SIGNIFOR, tell your doctor if you:

- have or have had high blood sugar (hyperglycemia)
- have diabetes
- have or have had heart problems
- have a history of low levels of potassium or magnesium in your blood
- have or have had liver problems
- have or have had gallstones
- have any other medical conditions
- are pregnant or plan to become pregnant. SIGNIFOR may harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if SIGNIFOR passes into your breast milk. You and your doctor should decide if you will take SIGNIFOR or breastfeed. You should not do both.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Taking SIGNIFOR with certain other medicines can affect each other and cause side effects. Especially tell your doctor if you take:

- medicines to control your heart beat (anti-arrhythmics)
- medicines that can affect the electrical system of your heart (QT prolongation)
- medicines to control your blood pressure (such as beta-blockers or calcium channel blockers)
- medicines to control the electrolyte (such as potassium or magnesium) levels in your blood
- cyclosporine (Gengraf[®], Neoral[®], Restasis[®], Sandimmune[®])
- bromocriptine (Cycloset[®], Parlodel[®])

Ask your doctor for a list of these medicines, if you are not sure.

Know the medicines you take. Keep a list of them to show to your doctor and pharmacist when you get a new medicine.

How should I use SIGNIFOR?

- Read the **“Instructions for Use”** at the end of this Medication Guide for information about the right way to use SIGNIFOR.
- Use SIGNIFOR exactly as your doctor tells you to.
- Your doctor may change your dose if needed.
- Before you use SIGNIFOR for the first time, your doctor should do a blood test to check your blood sugar levels and your liver tests.
- Before you use SIGNIFOR for the first time, your doctor should do a test to check your heart (electrocardiogram) and your gallbladder (ultrasound).
- SIGNIFOR should be clear and colorless. Before you inject your dose, check to make sure that SIGNIFOR is clear and colorless, and does not have any clumps or particles in it.
- SIGNIFOR is given as an injection into the fat just under your skin (subcutaneous injection).
- **Do not** inject SIGNIFOR into skin that is red or irritated.
- The recommended injection sites for SIGNIFOR are the top of your thigh or stomach area (abdomen).
- Change (rotate) your injection site with each dose. **Do not** inject SIGNIFOR into the exact same spot for each injection.
- Your doctor should show you how to prepare and give your dose of SIGNIFOR before you use it for the first time.
- You should not inject SIGNIFOR until your doctor has shown you how to use it the right way.

If you take too much SIGNIFOR, tell your doctor right away.

What are the possible side effects of SIGNIFOR?

SIGNIFOR may cause serious side effects, including:

- **See “What is the most important information I should know about SIGNIFOR?”**
- **slow heart rate (bradycardia).** SIGNIFOR can cause your heart to beat slower, which may cause you to feel weak, dizzy or even faint. People who have, or have had, heart problems are at higher risk for bradycardia.
- **problems with the electrical system of your heart (QT interval prolongation) which can put you at risk for abnormal heart beats, dizziness and fainting spells that can be very serious. Call your doctor right away if you experience such spells.**
- **elevation of your liver tests.** Your doctor should do blood tests to monitor your liver tests while you use SIGNIFOR.
- **gallstones (cholelithiasis).** Your doctor should do an ultrasound to check for gallstones before you start using SIGNIFOR and while you use it.

The most common side effects of SIGNIFOR include:

- diarrhea
- nausea
- high blood sugar
- headache
- abdominal pain

- fatigue
- diabetes mellitus
- injection site reactions
- common cold
- hair loss
- weakness
- fluid retention
- Abnormal blood test result for glycosylated hemoglobin (the level of glycosylated hemoglobin indicates the average blood sugar level over the previous months)

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of SIGNIFOR. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store SIGNIFOR?

- Store SIGNIFOR at 68°F to 77°F (20°C to 25°C).
- Keep SIGNIFOR out of the light.

Keep SIGNIFOR and all medicines out of the reach of children.

General information about the safe and effective use of SIGNIFOR.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use SIGNIFOR for a condition for which it was not prescribed. Do not give SIGNIFOR to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about SIGNIFOR. If you would like more information, talk to your doctor. You can ask your pharmacist or doctor for information about SIGNIFOR that is written for health professionals.

For more information go to www.SIGNIFOR.com or call 1-877-503-3377.

What are the ingredients in SIGNIFOR?

Active ingredient: Pasireotide

Inactive ingredients: Mannitol, tartaric acid, sodium hydroxide and water for injection.

Instructions for Use
SIGNIFOR® [sig-na-for]
(pasireotide)
Injection

Supplies you will need to give your SIGNIFOR injection:

- 1 SIGNIFOR ampule (See Figure A)
- 1 sterile syringe (See Figure B)
- 1 long sterile needle (See Figure B)
 - This needle is used to draw up your SIGNIFOR from the ampule. You should only use this needle if your doctor or nurse tells you to.
- 1 short sterile needle (See Figure B)
- Alcohol wipes
- 1 cotton ball or gauze
- A sharps disposal container or other closeable, puncture resistant disposal container

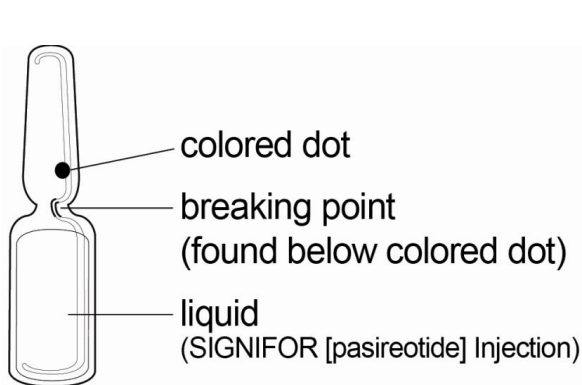


Figure A

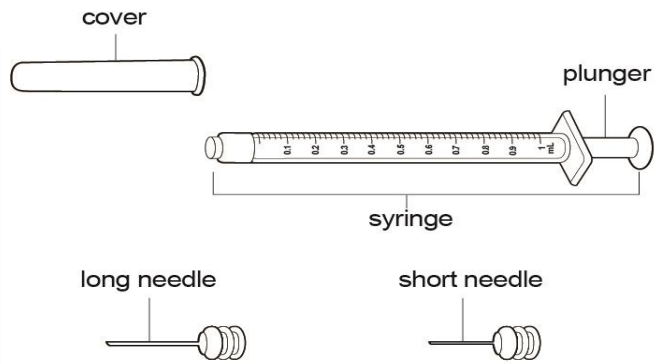


Figure B

Getting started:

Step 1: Wash your hands well with soap and water and dry them.

Step 2: Take 1 SIGNIFOR ampule out of the box.

Step 3: Look at the SIGNIFOR ampule. Check that the ampule is not cracked or broken and that the liquid medicine in the ampule is clear and colorless.

Do not use SIGNIFOR if the ampule is cracked or broken or if the liquid looks cloudy or contains particles. Take the whole box back to the pharmacy and get a new one.

Ampules should be opened just prior to administration and any unused portion discarded.

Step 4: Check the dose and expiration date printed on the ampule (See Figure C).

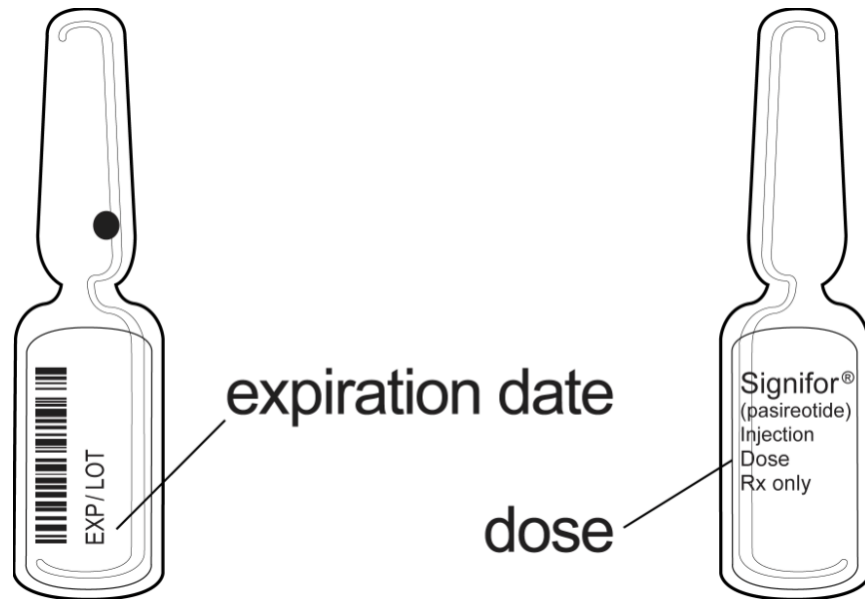


Figure C

Preparing your SIGNIFOR dose:

Step 5: Hold the SIGNIFOR ampule at the bottom with 1 hand. With your other hand, tap the top of the SIGNIFOR ampule with your finger to make sure there is no liquid in the top of the ampule when you open it (See Figure D).



Figure D

Step 6: Hold the ampule with 1 hand. With your other hand, hold the top of the ampule and pull it sideways until the top snaps off at the line marked on the ampule neck (See Figure E).

- Put the ampule upright on a clean and flat surface.



Figure E

Step 7: Open the sterile needle package. Place the needle on the top of the syringe. Push down on the needle and twist it clockwise until it is tight (See Figure F).

- If you have been told to use 1 long and 1 short needle, you should use the long needle for this step.

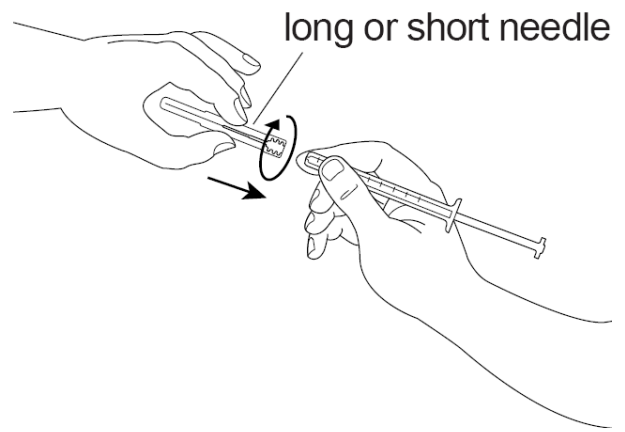


Figure F

Step 8: Pull the needle cover straight off the sterile needle (See Figure G).

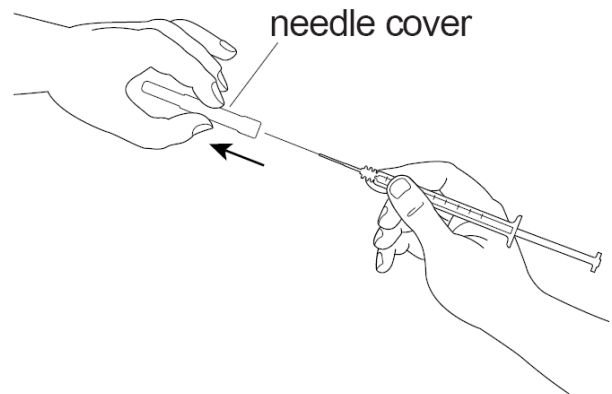


Figure G

Step 9: Put the needle into the ampule making sure you do not touch the outside of the ampule and pull up on the plunger to draw up all of the SIGNIFOR liquid into the syringe (See Figure H).

- If you have been told to use 1 long and 1 short needle, you should now take the long needle off of the syringe and put on the short one.

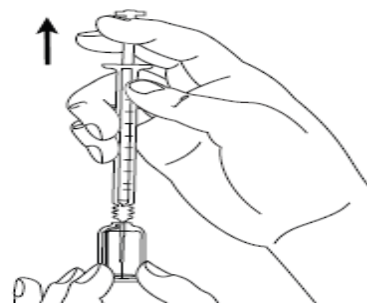


Figure H

Step 10: Hold the syringe upright in 1 hand between 2 fingers with your thumb at the bottom of the plunger. With your other hand, tap the syringe with your finger to get rid of air bubbles (See Figure I).

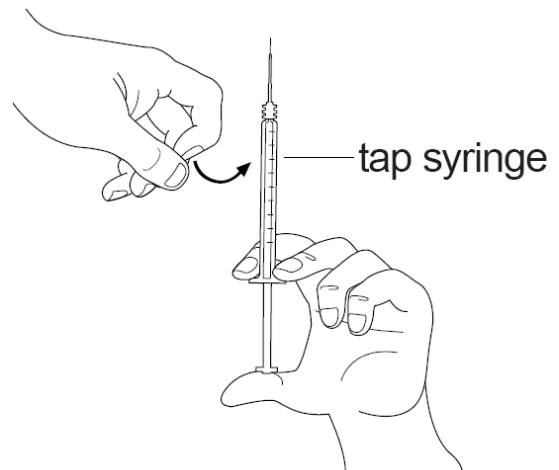


Figure I

Step 11: Push up on the plunger until you see a drop of liquid on the tip of the needle (See Figure J).

- Do not let the needle touch anything. You are now ready to inject your dose of SIGNIFOR.

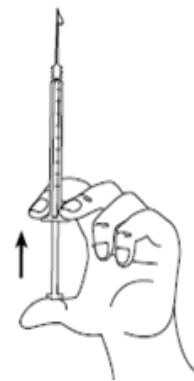


Figure J

Injecting your SIGNIFOR dose:

Step 12: Choose your injection site and wipe the site with an alcohol wipe (See Figure K). Let the site dry.



Figure K

Step 13: With 1 hand, gently pinch the skin at the injection site you have chosen and wiped with an alcohol wipe. With your other hand, pick up the syringe and hold it like a pencil. Insert the needle into the pinched skin at a 45 degree angle using a quick dart like motion (See Figure L).

- **Do not** let go of the skin.

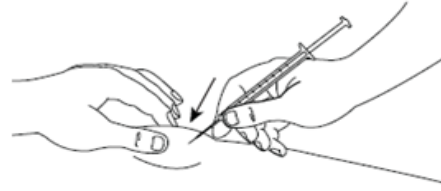


Figure L

Step 14: Gently press the plunger all the way down, until the syringe is empty (See Figure M).

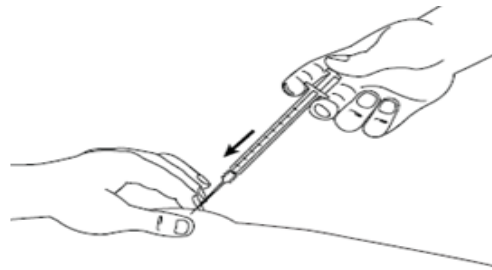


Figure M

Step 15: When the syringe is empty, slowly let go of the skin and gently pull the needle out of the skin (See Figure N).

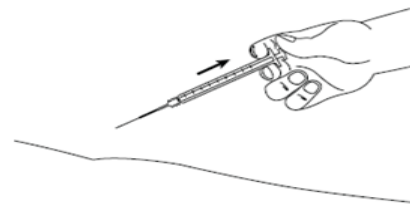


Figure N

Step 16: Place a cotton ball or gauze over the injection site and press for about 5 seconds. **Do not** massage the injection site.

- If there is bleeding, cover it with a bandage.

After injecting your SIGNIFOR dose:

- Put your used needles and syringes in a FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) loose needles and syringes in your household trash.
 - If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:

- made of a heavy-duty plastic,
 - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
 - upright and stable during use,
 - leak-resistant, and
 - properly labeled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>
 - Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.

This Medication Guide and Instructions for Use has been approved by the U.S. Food and Drug Administration.

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