

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. It is not known if SIGNIFOR will 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

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.

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