

Patient Information
Plenaxis™
(plen·AK·sis)
(abarelix for injectable suspension)

Read the Patient Information that comes with Plenaxis™ before you start getting injections. Sign the last page if you agree with treatment with Plenaxis™. (Your signature will be required to start treatment.)

What is the most important information I should know about Plenaxis™?

- **Plenaxis™ can cause serious or life threatening allergic reactions that may need emergency medical treatment right away.** These serious reactions may include:
 - low blood pressure and fainting (shock)
 - swelling of your face, eyelids, tongue, or throat
 - asthma, wheezing, or other breathing problems such as chest tightness or shortness of breath

Your chances of getting a serious or life threatening allergic reaction may increase with each Plenaxis™ injection that you get.

If a serious or life threatening allergic reaction happens, it is usually soon after getting a Plenaxis™ injection. **Therefore, you must wait in your doctor's office or health care facility for 30 minutes after each Plenaxis™ injection.** Tell your doctor right away if you feel any warmth, redness, light-headedness, swelling or thickness in your throat. This could mean you are having a serious allergic reaction.

- **Only doctors signed up with PRAECIS PHARMACEUTICALS INCORPORATED can prescribe Plenaxis™ because they know about treating prostate cancer and allergic reactions from Plenaxis™.**
- **Plenaxis™ is only for treating advanced prostate cancer when a patient cannot have or refuses other treatments for prostate cancer, such as other hormone treatments or surgery to remove the testicles, and there are serious symptoms from the prostate cancer such as the cancer is near or pressing on the spinal cord, causing problems urinating or blockage of urine from the kidneys or bladder, or there is very bad bone pain even when taking narcotic pain medicines.**
- **Plenaxis™ may not keep working for everyone over time, so doctors should do blood tests about every 8 weeks to make sure Plenaxis™ is working by keeping your testosterone hormone level low.**

What is Plenaxis™?

Plenaxis™ is a type of medicine called a gonadotropin-releasing hormone (GnRH) antagonist that lowers the male hormone testosterone in your blood. Testosterone makes most prostate cancers grow. Other ways to treat your prostate cancer are taking other hormone medicines to lower testosterone or surgery to remove your testicles. Plenaxis™ is used when these other ways to treat prostate cancer cannot be used or are refused.

Who should not take Plenaxis™?

Do not take Plenaxis™ if you are:

- **a woman.** There is no approved use of Plenaxis™ in women. Plenaxis™ can cause serious allergic reactions. Plenaxis™ can cause the death of an unborn child in a pregnant woman. Plenaxis™ may also pass into breast milk.
- **a child under the age of 18 years.** There are no studies that show that Plenaxis™ is safe or effective for use in children for any condition.
- **allergic to any of the ingredients in Plenaxis™.** The ingredients include abarelix and carboxymethylcellulose. The mixing solution contains sodium chloride.

Tell your doctor before taking a Plenaxis™ injection:

- if you or any family members have a rare heart condition known as prolongation of the QTc interval
- about all the medicines you take including prescription and nonprescription medicines, vitamins and herbal supplements. Plenaxis™ has not been studied with other medicines. Plenaxis™ and some of your other medicines may affect each other and could cause side effects.

How do I take Plenaxis™?

Plenaxis™ is only prescribed by doctors who are part of the Plenaxis™ **PLUS** Program (Plenaxis™ User Safety Program) run by PRAECIS PHARMACEUTICALS INCORPORATED.

- Plenaxis™ is given as an injection in your buttocks. Your doctor or nurse gives a Plenaxis™ injection every two weeks for the first month, and then every four weeks (every 28 days). It is important that you keep your appointment with your doctor's office for the times when your injection is due.

Always wait in your doctor's office for **30 minutes** after getting each Plenaxis™ injection. (See "What is the most important information I should know about Plenaxis™?")

Your doctor should do regular blood tests about every 8 weeks to check your testosterone level to see if Plenaxis™ is working for you. If you weigh more than 225 pounds, there

may be a greater chance that Plenaxis™ may stop working. Your doctor should also do blood tests to check on your liver because Plenaxis™ may cause changes in your liver tests.

What are the possible side effects of Plenaxis™?

Plenaxis™ can cause:

- **serious allergic or life threatening reactions.** (See "What is the most important information I should know about Plenaxis™?")
- **allergic skin reactions** such as a rash, hives, itching, tingling, and redness (flushing). A skin reaction may happen right away after injection with Plenaxis™ or several days later. Tell your doctor right away if you get an allergic skin reaction or rash after a Plenaxis™ injection.
- **a change in heart rhythm called prolongation of the QTc interval.** This condition may change the way your heart beats, cause fainting and even death in some patients.
- **changes in liver function, which usually go away after you stop taking Plenaxis™.** Your doctor should do blood tests to check your liver function before you start getting Plenaxis™ and during your treatment with it.
- **loss in bone mineral density with extended treatment.** Low bone mineral density can lead to thinning of the bones (osteoporosis).

The most common side effects of Plenaxis™ are:

- hot flashes
- problems sleeping
- pain, including back pain
- breast enlargement or breast pain
- constipation

Talk to your doctor if you get a side effect that bothers you.

These are not all the possible side effects of Plenaxis™. For more information ask your doctor.

General Information about Plenaxis™

This leaflet summarizes the most important information about Plenaxis™. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider for information about Plenaxis™ that is written for health professionals.

Patient Signature for Treatment with Plenaxis™

- I have read and understood the Patient Information leaflet. My doctor has answered my questions about treatment with Plenaxis™ for treating advanced prostate cancer.
- I cannot have or refuse treatments for my prostate cancer, such as other hormone treatments or surgery to remove my testicles, and my doctor has told me I have serious signs and/or symptoms from my prostate cancer such as the cancer is near or pressing on the spinal cord, or it is causing problems urinating or blockage of urine from the kidneys or bladder, or I have very bad bone pain even when taking narcotic pain medicines.
- Plenaxis™ can cause serious allergic reactions right after an injection. Therefore, after each injection I will wait in my doctor's office or health care facility for 30 minutes so if I have a serious allergic reaction, I can be treated.
- I know that my doctor should be getting blood tests to check my testosterone level about every 8 weeks to check if Plenaxis™ is working for me.
- I understand that I can only get Plenaxis™ from doctors who have signed up with the company that makes Plenaxis™.

My signature shows that I have read, understood and agree with **all** the statements above. I allow my doctor to begin treatment with Plenaxis™. I only need to sign this page one time to start my treatment.

Name of Patient (Print): _____

Signature of Patient: _____ Date: _____

Name of Physician (Print): _____

Signature of Physician _____ Date: _____

Instructions to Physician:

As part of beginning Plenaxis™ treatment, give the patient a copy of the entire leaflet with the signed page, and put the original patient signature page in the patient's medical chart.

This information leaflet has been approved by the U.S. Food and Drug Administration.

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