

## **PHYSICIAN ATTESTATION of QUALIFICATIONS and ACCEPTANCE of PRESCRIBING RESPONSIBILITIES**

### **Plenaxis™ PLUS Program**

I wish to participate in the Plenaxis™ PLUS Program (Plenaxis™ User Safety Program) and by my signature below, attest that I have the qualifications and accept the responsibilities described below.

#### ***RISKS AND BENEFITS OF Plenaxis™ AND APPROPRIATE USE***

- I understand that for safety reasons Plenaxis™ (abarelix) is approved with marketing restrictions of which the PLUS Program for Plenaxis™ is a required element. I will not distribute Plenaxis™ to other physicians or facilities. By my signature below, I attest that I have the qualifications and accept the prescribing responsibilities described in this document.
- I understand that because of the risk of immediate-onset systemic allergic reaction, including hypotension and/or syncope, and because of the risk of loss of effectiveness over time, Plenaxis™ is only indicated for the palliative treatment of men with advanced symptomatic prostate cancer, in whom LHRH agonist therapy is not appropriate and who refuse surgical castration, and have one or more of the following: (1) risk of neurological compromise due to metastases, (2) ureteral or bladder outlet obstruction due to local encroachment or metastatic disease, or (3) severe bone pain from skeletal metastases persisting on narcotic analgesia.
- I understand that the effectiveness of Plenaxis™ in suppressing serum testosterone to castrate levels decreases with continued dosing in some patients, and effectiveness beyond 12 months has not been established. Treatment failure can be detected by measuring serum testosterone concentrations just prior to administration on Day 29 and every 8 weeks thereafter.
- I understand that Plenaxis™ is not indicated in women or children.

#### ***QUALIFICATION OF PRESCRIBING PHYSICIANS***

- I can diagnose and manage advanced symptomatic prostate cancer.
- I can diagnose and treat allergic reactions, including anaphylaxis.
- I have access to medication and equipment necessary to treat these reactions, including anaphylaxis.
- I have reviewed the complete Package Insert for Plenaxis™ and I am thoroughly familiar with the important information in the Boxed Warning, Indication and Usage, Contraindications, Warnings, Precautions, Adverse Reactions, Dosage and Administration, and Patient Information sections.

#### ***RESPONSIBILITIES OF PRESCRIBING PHYSICIANS***

- I will have patients observed for development of allergic reactions for 30 minutes following each administration of Plenaxis™.
- I understand the risks and benefits of palliative treatment with Plenaxis™, including information from the Package Insert, Patient Information, and this Attestation.
- I will educate the patients I am considering for treatment with Plenaxis™ on the risks and benefits of treatment with Plenaxis™, obtain the patient's signature on the Patient Information leaflet's signature page, sign the form myself, place the original signed form in the patient's medical record, and give a copy of the Patient Information leaflet with the signed page to the patient.

- I will give any patient who is considering treatment with Plenaxis™ a copy of the Patient Information leaflet, and instruct the patient to read it and to ask any questions the patient may have, as a preliminary step to signing the Patient Information leaflet's signature page.
- I will report serious adverse events, such as any immediate-onset systemic allergic event (anaphylaxis, hypotension and syncope) to PRAECIS PHARMACEUTICALS INCORPORATED at 1-866 PLENAXIS (1-866-753-6294) or the Food and Drug Administration's MEDWATCH Program at 1-800-FDA-1088.
- I understand that I may withdraw as a prescriber of Plenaxis™ by a written statement submitted to PRAECIS PHARMACEUTICALS INCORPORATED (contact information below), or that PRAECIS PHARMACEUTICALS INCORPORATED may withdraw me from the Plenaxis™ **PLUS** Program if I do not meet the agreed upon responsibilities.

By signing, I acknowledge receipt of the Plenaxis™ full prescribing information, agree that I meet the qualifications and will follow the listed conditions for use described above.

\_\_\_\_\_  
Name (typed or printed) \_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Title

UPIN/Medicare# \_\_\_\_\_

Specialty (circle one)    Urologist    Oncologist    Internist    Other \_\_\_\_\_  
(Specify specialty)

**Office Name** \_\_\_\_\_  
Address \_\_\_\_\_ E-mail \_\_\_\_\_  
City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_  
Phone Number \_\_\_\_\_ Fax Number \_\_\_\_\_  
State License Number \_\_\_\_\_

**Second Office or Hospital Name** \_\_\_\_\_  
Address \_\_\_\_\_ E-mail \_\_\_\_\_  
City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_  
Phone Number \_\_\_\_\_ Fax Number \_\_\_\_\_

Fax completed and signed PHYSICIAN'S ATTESTATION to:

PRAECIS PHARMACEUTICALS INCORPORATED

Attention: Plenaxis™ **PLUS** Program  
c/o SENTRX  
Overlook at Great Notch  
150 Clove Road  
Little Falls, New Jersey 07424  
Fax: 1-800-648-8180

You may also complete this form online by visting [www.plenaxisplus.com](http://www.plenaxisplus.com). Then print, sign and fax the Attestation to PRAECIS.

**Request Additional Materials:**

Package Inserts    Patient Information forms    Physician Attestations    Hospital Pharmacy Agreements