FIRMAGON® (degarelix for injection)

**INDICATIONS AND USAGE**

FIRMAGON® is a completely different agent indicated for treatment of patients with advanced prostate cancer (1).

**CONTRAINDICATIONS**

FIRMAGON® is contraindicated in patients who have previously experienced an anaphylactic reaction to FIRMAGON® or any of its components.

**WARNINGS AND PRECAUTIONS**

- **Monitoring of Laboratory Tests**: Results of diagnostic tests of the pituitary gonadotropic and gonadal functions conducted during and after FIRMAGON® may be misleading. You should not do both without talking with your healthcare provider. Your healthcare provider should decide if you will take FIRMAGON® or breast-feed.

**ADVERSE REACTIONS**

- **Hepatic Impairment**: CYP450 pharmacokinetic drug-drug interactions may be exacerbated by mild or moderate liver or kidney function impairment.

**DRUG INTERACTIONS**

FIRMAGON® is a CYP3A4 inhibitor. Avoid concomitant use of FIRMAGON® with strong CYP3A4 inhibitors, weak CYP3A4 inducers, and CYP3A4 metabolized drugs.

**DOSE AND ADMINISTRATION**

- **Maintenance dose**
  - For patients with hepatic or renal impairment: FIRMAGON® should be administered at the standard dose of 80 mg to the hepatic or renal impaired patients.

**HOW SHOULD I RECEIVE FIRMAGON?**

- **Subcutaneous Administration**
  - The injection site will always be in the abdominal area but will change from time to time.

**ADVERSE REACTIONS**

- **SUSPECTED ADVERSE REACTIONS**
  - Report SUSPECTED ADVERSE REACTIONS, contact your healthcare provider, or call 1-800-332-1122 (for patients in the United States).
  - The injection site should be allowed to dry after the injection before a new injection is given.

**FULL PRESCRIBING INFORMATION**

**UNPACKING INSTRUCTIONS**

- **Storage**
  - Store at 2°C to 8°C (36°F to 46°F) protected from light.

**What is FIRMAGON®?**

FIRMAGON® is a synthetic gonadotropin-releasing hormone (GnRH) analog.

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DEGARELIX (FIRMAGON) 
INTRA-ARTERIAL INFUSION

1. INDICATIONS

FIRMAGON is a GnRH antagonist indicated for use in men who are at risk of or have local or metastatic prostate cancer, with or without bone metastases, who have previously received primary androgen deprivation treatment, such as surgery or radiation, and who are not candidates for or have progressed during therapy with a LHRH agonist.

2. DESCRIPTION

FIRMAGON is a single-use, sterile, lyophilized powder intended for subcutaneous or intravenous injection. It contains the active ingredient degarelix, a GnRH antagonist. The inactive ingredients are mannitol, sodium hydroxide, and hydrolyzed bovine serum albumin.

3. CONTRAINDICATIONS

Do not use FIRMAGON in patients with a history of allergy to the active or inactive ingredients of FIRMAGON.

4. WARNINGS

Hyponatremia associated with the use of FIRMAGON has been reported. Hyponatremia should be monitored during FIRMAGON therapy, and appropriate interventions should be taken if it occurs.

5. PRECAUTIONS

Patients should be instructed to read the Patient Labeling carefully.

6. ADVERSE REACTIONS

Common adverse reactions include injection-site pain, edema, and myalgia.

7. DRUG INTERACTIONS

No significant drug-drug interactions are anticipated. FIRMAGON is not expected to affect the concentration or pharmacokinetics of testosterone.

8. USE IN SPECIFIC POPULATIONS

Age: There is no evidence to suggest that the use of FIRMAGON is contraindicated in older patients.

9. PREGNANCY

FIRMAGON is a pregnancy Category X drug. There is no evidence of embryotoxicity or teratogenicity in humans. It is recommended that women of childbearing potential use reliable contraception during FIRMAGON therapy.

10. USE IN WOMEN

FIRMAGON is not approved for use in women. However, data from a randomized clinical trial in men suggest that FIRMAGON may be effective in the treatment of nonmalignant conditions such as prostate hyperplasia.

11. DESCRIPTION

FIRMAGON is a GnRH antagonist indicated for use in men who are at risk of or have local or metastatic prostate cancer, with or without bone metastases, who have previously received primary androgen deprivation treatment, such as surgery or radiation, and who are not candidates for or have progressed during therapy with a LHRH agonist.

12. CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Degarelix is a GnRH antagonist that binds reversibly to the GnRH receptor at the cell membrane.

12.2 Pharmacokinetics

A single dose of degarelix administered as an intravenous infusion resulted in a Cmax of 164 ng/mL and a Tmax of 10 hours. The mean terminal half-life was approximately 5.4 days.

13. PHARMACOLOGY

FIRMAGON demonstrates a high degree of bioavailability with a Cmax of 164 ng/mL and a Tmax of 10 hours. The mean terminal half-life was approximately 5.4 days.

14. CLINICAL STUDIES

The safety and efficacy of FIRMAGON were evaluated in a 24-week, randomized, controlled trial comparing placebo, 1 mg, 3 mg, and 6 mg of degarelix administered every 2 weeks. The primary endpoint was the proportion of patients who achieved testosterone suppression below 50 ng/dL.

Table 1: Medical Castration Rates (Testosterone ≤ 50 ng/dL) from Baseline

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