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Degarelix for Injection (Firmagon)

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Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

A total of 1325 patients with prostate cancer received FIRMAGON either as a monthly treatment (60-160 mg) or as a single dose (up to 320 mg). A total of 1032 patients (78%) were treated for at least 6 months and 853 patients (64%) were treated for one year or more. The most commonly observed adverse reactions during FIRMAGON therapy included injection site reactions (e.g., pain, erythema, swelling or induration), hot flashes, increased weight, fatigue, and increases in serum levels of transaminases and gamma-glutamyltransferase (GGT). The majority of the adverse reactions were Grade 1 or 2, with Grade 3/4 adverse reaction incidences of 1% or less.

FIRMAGON was studied in an active-controlled trial (N = 610) in which patients with prostate cancer were randomized to receive FIRMAGON (subcutaneous) or leuprolide (intramuscular) monthly for 12 months. Adverse reactions reported in 5% of patients or more are shown in Table 1.

Table 1: Adverse Reactions Reported in ? 5% of Patients in an Active Controlled Study

Leuprolide 7.5 mg (intramuscular) N = 201	FIRMAGON 240/80 mg (subcutaneous) N = 207	FIRMAGON 240/160 mg (subcutaneous) N = 202	
78%	79%	83%	Percentage of subjects with adverse events
			Body as a whole
< 1%	35%	44%	Injection site adverse events
12%	9%	11%	Weight increase
6%	3%	6%	Fatigue
0%	5%	4%	Chills
			Cardiovascular system
21%	26%	26%	Hot flash
4%	6%	7%	Hypertension
			Musculoskeletal system
8%	6%	6%	Back pain
9%	5%	4%	Arthralgia
			Urogenital system
9%	5%	2%	Urinary tract infection
			Digestive system
5%	10%	10%	Increases in Transaminases and GGT
5%	5%	3%	Constipation

The most frequently reported adverse reactions at the injection sites were pain (28%), erythema (17%), swelling (6%), induration (4%) and nodule (3%). These adverse reactions were mostly transient, of mild to moderate intensity, occurred primarily with the starting dose and led to few discontinuations (< 1%). Grade 3 injection site reactions occurred in 2% or less of patients receiving degarelix.

Hepatic laboratory abnormalities were primarily Grade 1 or 2 and were generally reversible. Grade 3 hepatic laboratory abnormalities occurred in less than 1% of patients.

In 1-5% of patients the following adverse reactions, not already listed, were considered related to FIRMAGON by the investigator:

Asthenia, fever, night sweats; Digestive system: Nausea; Nervous system: Dizziness, headache, insomnia. **Body as a whole:**

The following adverse reactions, not already listed, were reported to be drug-related by the investigator in ? 1% of patients: erectile dysfunction, gynecomastia, hyperhidrosis, testicular atrophy, and diarrhea.

The safety of FIRMAGON administered monthly was evaluated further in an extension study in 385 patients who completed the above active-controlled trial. Of the 385 patients, 251 patients continued treatment with FIRMAGON and 135 patients crossed over treatment from leuprolide to FIRMAGON. The median treatment duration on the extension study was approximately 43 months (range 1 to 58 months). The most common adverse reactions reported in > 10% of the patients were injection site reactions (e.g., pain, erythema, swelling, induration or inflammation), pyrexia, hot flush, weight loss or gain, fatigue, increases in serum levels of hepatic transaminases and GGT. One percent of patients had injection site infections including abscess. Hepatic laboratory abnormalities in the extension study included the following: Grade ½ elevations in hepatic transaminases occurred in 47% of patients and Grade 3 elevations occurred in 1% of patients.

Decreased bone density has been reported in the medical literature in men who have had orchiectomy or who have been treated with a **Changes in bone density:** GnRH agonist. It can be anticipated that long periods of medical castration in men will result in decreased bone density.

Anti-degarelix antibody development has been observed in 10% of patients after treatment with FIRMAGON for 1 year. There is no indication that the efficacy or safety of FIRMAGON treatment is affected by antibody formation.