Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is to be supplied by doctor's prescription only

Firmagon 80 mg
Firmagon 120 mg
Powder and solvent for preparing a solution for subcutaneous injection

Composition:
Firmagon 80 mg contains: degarelix (as acetate) 80 mg
Firmagon 120 mg contains: degarelix (as acetate) 120 mg

Inactive ingredients – see section 6 "Additional information".

Read the entire leaflet carefully in its entirety before you start using this medicine.
This leaflet contains concise information about the medicine. If you have any further questions, refer to the doctor or the pharmacist.
This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar.

This medicine is intended for adult men only.
This medicine is not intended for women.

1. What is this medicine intended for?

For treatment of advanced prostate cancer in adult men.

Therapeutic group: GnRH antagonist.

2. Before using this medicine

Do not use this medicine if:
You are sensitive (allergic) to the active ingredient or to any of the other ingredients that this medicine contains.

Special warnings regarding the use of this medicine:
Before the treatment with Firmagon, tell your doctor if:
- You have diabetes; your existing diabetes may get worse. If you did not have diabetes previously it may occur now. If you have diabetes you must measure glucose levels in your blood more often.
- You have problems with your heart, blood vessels, or heart-rate (heart rhythm disorders-arrhythmia), or if you have been given medication to treat this problem. Heart rhythm disorders may get worse while using Firmagon.
- You have or have had in the past impaired function of the liver. Liver function must be monitored.
- You have kidney disease. Treatment with Firmagon has not been tested in patients with severe kidney disease.
- You have osteoporosis or any other condition which may affect bone strength. Decrease in testosterone concentration may cause a decrease in calcium in the bones (osteoporosis).
- You have severe hypersensitivity reactions; this medicine has not been tested in patients with severe hypersensitivity reactions.

Children and adolescents

This medicine is not intended for children and adolescents.

If you are taking or have recently taken other medicines, including nonprescription medications and nutritional supplements, inform your doctor or pharmacist. In particular inform the doctor or the pharmacist if you are taking:
Medicines for treating heart rhythm disorders (such as quinidine, procainamide, amiodarone, and sotalol) or medicines that may affect heart rhythm such as methadone (a pain-relief medicine and part of drug addiction treatment), moxifloxacin (antibiotic), and anti-psychotic medicines.

Pregnancy and breastfeeding: This medicine is not intended for use in women.

Driving and using machines:
Tiredness and dizziness are common side effects which can impair your ability to drive or operate dangerous machinery. These effects may be linked to the medicine or to the disease itself.

3. How should you use the medicine?

Always use according to the doctor's instructions.
You should check with the doctor or the pharmacist if you are unsure.
This medicine is usually injected by a doctor or nurse.
The dosage and treatment will be determined only by the doctor. The recommended dose is usually:
Starting dose of 240 mg, given in two consecutive injections of 120 mg.
Maintenance treatment of 80 mg, given one month after the starting dose, once in a month.
Do not exceed the recommended dose.
The injected liquid forms a gel from which degarelix is released over a period of one month.

Firmagon must be injected **subcutaneously only** (under the skin).
Do not inject Firmagon into a blood vessel (intravenously).
Apply precautionary measures to prevent accidental intravenous injection. The injection site, in the stomach area, should be changed periodically.

Firmagon is intended for long-term treatment. The doctor will determine treatment duration.

If you accidentally took an overdose or if a child has accidentally swallowed the medicine, go immediately to a doctor or a hospital emergency room and bring the medicine package with you.
If you forget to take the medicine at the scheduled time, consult your doctor.
Persist with the treatment as recommended by the doctor.
Even if there is an improvement in your health, do not stop treatment with this medicine without consulting the doctor or the pharmacist.

Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.
If you have any further questions regarding the use of this medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, Firmagon may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

Severe allergic reactions to this preparation are rare. Seek immediate medical attention in case of severe rash, itch, shortness of breath or difficulty breathing, which may be symptoms of a severe allergic reaction.

Very common side effects (affect more than one user out of ten):
Hot flushes, pain and redness at the injection site. Side effects at the injection site are most common when receiving the starting dose and less common when receiving the maintenance dose.

Common side effects (affect 1-10 users out of 100):
- swelling, bumps, and hardness at the injection site
- chills, fever or feeling flu-like symptoms after injection
- insomnia, fatigue, dizziness, headache
- weight gain, nausea, diarrhoea, increase in liver enzymes
- excessive sweating (including night sweats), rash
- anaemia
- bone and muscle pain and discomfort
- reduced size of the testicles, breast swelling, impotence

Uncommon side effects (affect 1-10 users out of 1000):
- loss of libido, testicular pain, pelvic pain, ejaculation problems, genital irritation, breast pain
- mental impairment, depression
- skin redness, hair loss, skin nodule, numbness
- allergic reaction, hives, itching
- decreased appetite, constipation, vomiting, dry mouth, abdominal pain and discomfort, increase in the blood sugar levels, increase in cholesterol, changes in the blood calcium levels, weight loss
- high blood pressure, changes in heart rhythm, changes in ECG (prolongation of the QT interval), sensation of irregular heart rate, breathing difficulties, peripheral oedema
- muscle weakness, muscle spasms, joint swelling and stiffness, osteoporosis/ osteopaenia, joint pain
- urgent and frequent urination, difficult or painful urination, nocturnal urination, renal function problems, leaking of urine
- blurred vision
- discomfort upon injection, including decrease in blood pressure and decrease in heart rhythm
- weakness

Rare side effects (affect 1-10 users out of 10000):
- Neutropenic fever (decline in number of white blood cells associated with fever), heart attack, heart failure
- Unexplained muscle pain or cramps, muscle tenderness or weakness. A problem in your muscles could be serious, including muscle breakdown which causes kidney damage.

Very rare side effects (affect 1-10 users out of 100000):
Infection at the injection site, abscess, necrosis

If a side effect occurs, if any side effect gets worse, or if you suffer from a side effect not mentioned in the leaflet, you should consult the doctor.

Side effects can be reported to the Ministry of Health (MoH) by clicking on the "Report on side effects due to medication therapy" link on the MoH home page (www.health.gov.il) which refers to the online form for side effects reporting, or by entering the link: https://sideeffects.health.gov.il

5. How to store the medicine?

Avoid poisoning! This medicine and all other medicine should be kept in a close place out of the reach of children and/or infants in order to avoid poisoning.

Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
Do not store above 25°C.
Use immediately after reconstitution.

6. Additional information

In addition to the active ingredients the medicine also contains:
Powder - Mannitol.
Solvent - Water for injection.

What does the medicine look like and what are the contents of the package:
This preparation is a powder and a solvent for preparing an injection solution; the powder is creamy-white and the solvent is a colorless, clear solution.
Firmagon 80 mg is distributed in a package containing a vial of powder, a prefilled syringe containing 4.2 ml of solvent, a plunger rod, an adapter for the vial, and a needle for injection. After reconstitution, 1 ml of solution contains 20 mg degarelix.
Firmagon 120 mg is distributed in a package containing two vials of powder, two prefilled syringes containing 3 ml of solvent, two plunger rods, two adapters for the vials, and two needles for injection. After reconstitution, 1 ml of solution contains 40 mg of degarelix.

Registration holder name and address: Ferring Pharmaceuticals Ltd., 8 Hashita St., Industrial Park, Caesarea, 3088900.
Manufacturer name and address: Ferring, Germany.

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Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Firmagon 80 mg: 145 05 32954
Firmagon 120 mg: 145 04 32955