Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

DECAPEPTYL 0.1
solution for subcutaneous injection

Composition:
Each syringe of Decapeptyl 0.1 contains 0.1 mg of triptorelin (as acetate).

Inactive ingredients and allergens: see section 2 'Important information about some of this medicine's ingredients' and section 6 'Additional information'.

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

1. What is this medicine intended for?

This medicine is intended for infertility treatments.

Therapeutic group: synthetic analogue of the gonadotropin-releasing hormone (GnRH).

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to triptorelin acetate or to any of the other ingredients in this medicine (see section 6).
- You are sensitive (allergic) to the gonadotropin-releasing hormone (GnRH) or its analogues.
- You are pregnant or breastfeeding (see section 'Pregnancy and breastfeeding').

Special warnings about using this medicine

Before using this medicine, tell your doctor if:

- There have been reports on depression that may be severe among patients taking Decapeptyl. If you are taking this medicine and develop a depressed mood, tell your doctor.
- There have been reports on mood changes during the course of treatment with this medicine. Your doctor will monitor your condition if you have depression.
- In rare cases, treatment with this medicine can cause brain hemorrhage (pituitary apoplexia). If you experience a sudden headache, vomiting or vision disturbances – contact your doctor immediately.
- Treatment with this medicine may lead to thinning of bones and an increase in the risk of bone injury. Tell your doctor if you have additional risk factors for thinning of bones (osteoporosis). Risk factors include:
  - family members with thinning of bones
  - consumption of high quantities of alcohol, poor nutrition, heavy smoking
  - treatment with additional medicines that may weaken bones
- you have or previously had moderate to severe liver disease.
- you have or previously had allergic reactions (itching, skin rash, fever) (see section 4 'Side effects').
- If you inject this medicine yourself, you need to be aware of possible allergic reactions (itching, skin rash, fever) (see section 4 'Side effects').

- If, after injecting the medicine, the following symptoms develop, **inform your doctor immediately:**
  - pain in the abdominal area
  - abdominal bloating
  - nausea
  - vomiting
  - diarrhoea
  - weight gain
  - difficulties breathing
  - decreased urination.

Inform your doctor immediately, even if the symptoms develop a few days after the last injection. These may be symptoms of ovarian hyperstimulation, which may worsen (see section 4 'Side effects'). If the symptoms become worse, the infertility treatments should be stopped and you should receive treatment in the hospital.

Treatments for infertility using hormones like this medicine may increase the risk of:
- Ectopic pregnancy (pregnancy outside of the womb), if you have a history of fallopian tube disease
- Miscarriage
- Multiple pregnancy (twins, triplets, etc.)
- Congenital malformations (defects in the newborn's body).

Tests and follow-up
During the course of treatment with this medicine, your doctor will usually send you for ultrasound scans, and sometimes for blood tests in order to monitor the effect of the medicine.

Drug interactions
If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.

Pregnancy and breastfeeding
Do not use this medicine if you are pregnant, think that you may be pregnant or are breastfeeding. The doctor must rule out pregnancy before starting treatment with this medicine.
If you discover that you are pregnant during the course of treatment with Decapeptyl, do not continue the treatment.
Use non-hormonal contraceptives (such as a condom or a diaphragm) during the treatment with Decapeptyl.

Driving and using machines
Decapeptyl does not affect, or negligibly affects, the ability to drive or use tools and operate devices.

Important information about some of this medicine's ingredients
Decapeptyl contains less than 23 mg of sodium per dose; therefore, it is considered to be "sodium-free".

3. How to use this medicine?

Always use the medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.
Treatment can be started with one subcutaneous injection in the lower abdominal area, once a day. Treatment can be started on day 2 or 3 or day 21 to 23 of the menstrual cycle (or 5-7 days before the expected start of menstruation). After 2 to 4 weeks, other hormones will be given in order to stimulate follicle growth (egg sac growth). In general, Decapeptyl 0.1 treatment will continue until the follicles reach the suitable size. This usually lasts 4 to 7 weeks.
If enough follicles are present, you will be given a single injection of a medicine containing hCG to induce ovulation (release of eggs).
Your doctor will monitor the treatment progress for at least 2 weeks after administration of the hCG injection.
Only your doctor will determine your dose and how you should take this medicine.

Do not exceed the recommended dose.
Instructions for injection
If your doctor has told you to inject this medicine yourself, you should follow the instructions he provided to you. The first injection will be always given under a doctor's supervision.

- Remove the protective foil and take the syringe out of the blister packaging. Hold the syringe straight, with the grey protective cap upwards. Remove the grey protective cap. Gently push the plunger until the first drop appears at the needle tip.
- Lift up a skin fold in the abdominal area and hold it between the thumb and forefinger. Insert the needle with a quick movement at an angle of 90 degrees into the skin fold. Press down on the plunger and slowly inject the contents of the syringe.

If you have accidentally injected an overdose or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.
If you forget to receive an injection at the scheduled time, consult the treating physician.
Adhere to the treatment as recommended by your doctor.
Even if your health improves, do not stop the treatment with this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and dose <u>every time</u> you take a medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. <u>Side effects</u>

Like with all medicines, using Decapeptyl may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

- <u>Very common side effects (affect more than 1 in 10 users):</u>
  Headache, vaginal bleeding/spotting, inflammation at the injection site, abdominal pain, nausea

- <u>Common side effects (affect 1-10 in 100 users):</u>
  Infections in the upper respiratory tract, laryngitis, hot flushes, abdominal bloating, miscarriages, ovarian hyperstimulation (see section 2 'Before using this medicine'), menstrual pain, tiredness, flu-like symptoms, dizziness, vomiting, back pain, pelvic pain, ovarian cysts (at the beginning of the treatment), pain or reaction at the injection site

- <u>Uncommon side effects (affect 1-10 in 1,000 users):</u>
  Mood changes, depression

- <u>Side effects of unknown frequency (the frequency of these effects has not yet been established):</u>
  Abdominal discomfort, excessive sweating, allergic reactions (see section 2 'Before using this medicine'), sleep disorders, blurred vision, itching, rash, angioedema (swelling below the skin), weakness, muscle cramps, joint pain, diminished libido, shortness of breath, vision disturbances, heavy, prolonged and/or irregular menstrual bleeding, vaginal dryness, pain during sexual intercourse, breast pain, redness at the injection site, weight gain

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects
You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il), which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
Store in a refrigerator at 2°C-8°C.

6. Additional information

In addition to the active ingredient, this medicine also contains:
Sodium chloride, acetic acid (glacial) and water for injection.

What the medicine looks like and contents of the pack:
This medicine is a clear, colourless liquid. The medicine is packed in prefilled syringes with a needle attached. The syringe and needle are closed with a protective rubber cap.
The pack of this medicinal product contains 7 syringes with solution for injection.

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

Manufacturer's name and address: FERRING GmbH, Germany

This leaflet was revised in July 2022 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
023 76 24855