

**PATIENT PACKAGE INSERT IN ACCORDANCE
WITH THE PHARMACISTS REGULATIONS
(PREPARATIONS) – 1986**

The dispensing of this medicine requires
a doctor's prescription.

**Read this package insert carefully
in its entirety before using this medicine.**

**DECAPEPTYL® CR
3.75 mg**

Injection

**For subcutaneous or intramuscular
use after full dilution.**

Composition:

Each injection contains:
Triptorelin acetate 4.12 mg equivalent to 3.75 mg
Triptorelin.

Inactive ingredients:

Microcapsules: poly (glycolic acid, lactic acid) 1:1,
propylene glycoloctanoat decanoat.
Suspension: polysorbate 80, dextran 70, sodium
chloride solution, sodium dihydrogen phosphate-
dihydrate, sodium hydroxide, water for injection.

Therapeutic activity:

Decapeptyl CR lowers sexual hormones and is
indicated in prostate cancer, endometriosis, uterus
myomatosis, fertility treatment IVF.
Decapeptyl CR is intended for precocious puberty.

When should the preparation not be used?

Do not use this medicine if you are pregnant or
breastfeeding.
Do not use following surgical removal of the
testicles.
Do not use when maintenance of sex hormone
activity is essential.
Do not use in children suffering from progressive
brain tumor.
Do not use this medicine if you suffer from
hypersensitivity to the preparation or to one of its
ingredients.

**Do not take this medicine without consulting a
doctor before starting treatment:**

If you are suffering or have suffered in the past
from:
Depression – you must be checked regularly by
your doctor.
Hypertension – you must be checked regularly by
your doctor.

Diabetes – you must check your blood sugar level
regularly.

How will this medicine affect your daily life?

Use of this medicine may impair alertness and
therefore caution should be exercised when
engaging in activities such as driving a car, operating
dangerous machinery and in any other activity which
requires alertness.

Drug interactions:

If you are taking another drug concomitantly or if you
have just finished treatment with another medicine,
inform the attending doctor, in order to prevent
hazards or lack of effectiveness arising from drug
interactions.

Side effects:

In addition to the desired effect of the medicine,
adverse reactions may occur, for example: bone pains
in the legs and joint pain (for patients suffering from
bone metastases), muscular weakness in the legs,
increased urination, blood clots. Most of these effects
can be avoided by simultaneously administering anti-
androgen treatment at the beginning of treatment.
Additional side effects: hot flushes, loss of sexual libido,
rise in blood pressure (especially in patients suffering
from hypertension), redness on the skin surface,
burning, decrease in blood sugar levels (especially
in diabetes), change in serum lipid levels, increase
in liver enzymes, changes in bilirubin, changes in
blood profile, tremors, headaches, nervousness,
sleep disturbances, fatigue, dizziness, disturbances
in memory or concentration, emotional instability,
and in rare cases depression, especially in patients
who have tendency towards depression, nausea,
vomiting, feeling of thirst, diarrhea, constipation,
changes in appetite, changes in weight.

Side effects that require special attention:

In rare cases, temporary pain at the injection site was
reported: continue treatment and consult a doctor.
Hypersensitivity reactions at the injection site or all
over the body (rash) or being expressed as shortness
of breath, sudden decrease of blood pressure and
facial swelling: consult the doctor immediately!
In the event that you experience side effects not
mentioned in this leaflet, or if there is a change in your
general health, consult your doctor immediately.

**Adverse reactions and drug interactions in
children:**

In addition to the desired effect of the medicine,
adverse reactions may occur, for example: vaginal
bleeding, nausea, vomiting, hypersensitivity reactions
(see above).
Parents must inform the attending doctor about any
side effects, as well as any additional medicine being
taken by the child!

Dosage:

The doctor or nurse will inject the entire amount of
medicine subcutaneously or intramuscularly every
month. You can shorten/extend the time period by
a few days.

The dosage is according to doctor's instructions
only.

Precocious puberty – dosage is according to doctor's
instructions only.

This medicine is to be taken at specific time intervals
as determined by the attending doctor.

Directions for use:

Decapeptyl CR is intended for prolonged treatment.
The duration of treatment will be determined by the
doctor.

Avoid poisoning!

This medicine, and all other medicines, must be
stored in a safe place out of the reach of children
and/or infants, to avoid poisoning.

If you have taken an overdose, or if a child has
accidentally swallowed this medicine, proceed
immediately to a hospital emergency room and bring
the package of the medicine with you.

Do not induce vomiting unless explicitly instructed
to do so by a doctor.

This medicine has been prescribed for the treatment
of your ailment; in another patient it may cause
harm.

**Do not give this medicine to your relatives,
neighbours or acquaintances.**

Do not take medicines in the dark! Check the label
and the dose each time you take your medicine.
Wear eye glasses if you need them.

Storage:

Store in a cool place between (+2)^o - (+8)^o
Celsius.

Even if kept in their original container and stored
as recommended, medicines may be kept for a
limited period only. Please note the expiry date of
the medicine! In case of doubt, consult the pharmacist
who dispensed the medicine to you.

Do not store different medications in the same
package.

License Number: 105 92 28885 00

Manufacturer: Ferring GmbH, Germany.

Manufacturer's agent:

A. Lapidot Pharmaceuticals Ltd.,
8 Hashita Street, Industrial Park, Caesarea 38900.

The format of this leaflet was determined by the
Ministry of Health and its content was checked and
approved in March 2006.