

DECAPEPTYL®

Solution for injection

Triptorelin acetate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Decapeptyl.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given Decapeptyl against the benefits she/he expects it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Decapeptyl is used for

Decapeptyl contains triptorelin, which is a synthetic version of the natural gonadotropin releasing hormone (GnRH). GnRH regulates the release of two gonadotropins that are involved in the development of follicles and release of eggs from the ovaries: follicle-stimulating hormone (FSH) and luteinising hormone (LH).

Assisted Reproductive Technology (ART) include gonadotropins that replace the activities of naturally produced FSH and LH.

Occasionally, in response to ART treatment, the release of eggs may occur too early due to an early surge in LH levels and this may lead to that ART cycle being cancelled,

without retrieval of any eggs.

Decapeptyl blocks the action of GnRH and is therefore intended to prevent an LH surge, thereby lessening the chances of premature ovulation and a cancelled ART cycle.

Ask your doctor if you have any questions about why it has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

This medicine is not expected to affect your ability to drive a car or operate machinery.

Before you use Decapeptyl

When you must not use it

Do not use Decapeptyl if you are allergic to:

- triptorelin acetate, the active ingredient in Decapeptyl
- any of the other ingredients listed at the end of this leaflet
- GnRH or synthetic versions of GnRH (medicines similar to Decapeptyl).

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not use Decapeptyl if:

- you are pregnant
- you are breast feeding
- you are prone to allergies.

Do not use Decapeptyl after the expiry date printed on the pack.

Do not use Decapeptyl if the packaging is torn or shows signs of tampering.

If you are not sure whether you should have this medicine, talk to your doctor.

Before you use it

Tell your doctor if you have allergies to:

- any other medicines
- any other substances such as foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially the following:

- if you are possibly pregnant
- if you have a mild to severe liver disease
- if you have an active allergic condition or if you are prone to allergic reactions
- if you administer Decapeptyl yourself. You should be aware of possible allergic reactions (e.g. itching, skin rash, fever).

If you have not told your doctor about any of the above, tell him/her before you are given Decapeptyl.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

There are some medicines which may interfere with the action of Decapeptyl. These include medicines affecting secretion of gonadotropins.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while you are receiving this medicine.

How to use Decapeptyl

This medicine contains a solution of triptorelin provided in a pre-filled disposable syringe for single use. It is given as an injection under the skin (subcutaneous) of the lower abdomen.

If your doctor or nurse decides you can give the injections to yourself, they will train you appropriately on the injection technique.

Do not self-inject Decapeptyl until you are sure of how to do it.

The first injection of Decapeptyl should be under medical supervision.

Follow all instructions given to you by your doctor carefully.

An instruction leaflet is supplied with your medicine and the following information is included:

Injecting your medicine

- Remove the protective foil and take the syringe out of the blister packaging.
- Keep the syringe upright with the grey protective cap facing up.
- Remove the grey protective cap.
- Gently push the plunger until the first drops of liquid appear at the needle tip.
- The medicine is to be injected under the skin of the lower abdomen. Clean the injection site with an antiseptic swab immediately prior to injection.
- Lift up a fold of skin between the thumb and forefinger. With your free hand hold the syringe

at a right angle to the skin like a dart and quickly insert the needle all the way into the skin fold. Press down slowly on the plunger to inject the contents of the syringe.

- Remove the syringe and needle from the skin and discard this immediately into a sharps disposal unit.
- For each dose, choose a different injection site along the lower abdomen.

Other important information

- Each pre-filled syringe is for single use only.
- Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you experience sign/symptoms of an allergic reaction (e.g. difficulty in breathing or swelling of the lips).
- The first injection of this medicine should be supervised by your doctor or nurse.
- The syringe should be disposed into a sharps disposal unit.

How much to use

Always use this medicine exactly as your doctor has told you. You should check with your doctor if you are not sure.

The usual dosage of Decapeptyl is one injection under the skin of your lower abdomen once-daily.

Treatment can be started on day 2 or 3, or on day 21 to 23, of the menstrual cycle.

After 2 to 4 weeks of Decapeptyl treatment, other hormones (gonadotropins) will be given in order to stimulate follicle growth.

In general, Decapeptyl treatment will continue until follicles have reached a suitable size, usually 4 to 7 weeks.

If enough follicles are present, Decapeptyl treatment will be stopped and you will be given a medicine to induce ovulation.

Your doctor will closely monitor your progress for at least another 2 weeks.

How long to use it

Usually one dose of Decapeptyl is used each day. The length of Decapeptyl treatment is usually from 4-7 weeks. However, your doctor will be able to answer this question more precisely.

If you forget to use it

It is important that you do not miss a dose of Decapeptyl.

If you do miss a dose, contact your doctor or nurse. Do not take a double dose to make up for the dose that you missed.

If you use too much (overdose)

As your treatment will be closely monitored it is unlikely you will be prescribed too large a dose of Decapeptyl. However, Decapeptyl can be associated with some symptoms (see Side effects). If you use more than the prescribed dose contact a doctor immediately.

While you are using Decapeptyl

In case you suffer from a reaction after injecting Decapeptyl you should contact your doctor immediately. Symptoms of a reaction can include:

- pain in the abdomen
- swelling in the abdomen
- nausea
- vomiting
- diarrhoea
- weight gain
- difficulty breathing
- decreased urination.

Tell your doctor straight away, even if the symptoms develop some days after the last injection has been given. These can be signs of high

levels of activity in the ovaries which might become severe (see also section Side effects).

If these symptoms become severe, the infertility treatment should be stopped and you should receive treatment in hospital.

Undergoing infertility treatment with hormones, like this medicine, has been associated with increased 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 (physical defects present in baby at birth).

Things you must do

Tell your doctor immediately if you become pregnant while using Decapeptyl.

Tell your doctor if you have abnormal vaginal bleeding while using Decapeptyl.

Be sure to keep all your doctor's appointments so your progress can be checked.

Your doctor will normally arrange for you to have ultrasound scans and sometimes blood tests to monitor your response to treatment.

Tell any other doctors, dentists, and pharmacists who are treating you that you are using Decapeptyl.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are using Decapeptyl.

If you are going to have surgery, tell the surgeon or anaesthetist that you are using Decapeptyl.

Things to be careful of

Decapeptyl should not normally interfere with your ability to drive or operate machinery.

Take special care with Decapeptyl

Decapeptyl can lead to mood changes (including depression).

Long-term use (over many months or years) of Decapeptyl for other conditions can lead to thinning of bones, which may increase risk of bone fracture.

If you are at additional risk of thinning of the bones (osteoporosis) you should tell your doctor before taking Decapeptyl.

Side effects

Tell your doctor or nurse or pharmacist as soon as possible if you do not feel well after you use Decapeptyl.

This medicine may have unwanted side effects in some people. All medicines can have side effects. Sometimes they are serious. Most of the time they are not. You may need medical attention if you experience side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your doctor or nurse or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- headache
- abdominal pain
- vaginal bleeding/spotting
- nausea
- inflammation at the injection site.

These are mild side effects and are usually short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- cold
- sore throat
- flu-like symptoms
- pharyngitis

- mood alterations
- dizziness
- hot flushes
- vomiting
- abdominal bloating
- back pain
- abortion
- pelvic pain
- overstimulation of the ovaries
- ovarian-cysts (at the beginning of the Decapeptyl treatment)
- pain during menstruation
- heavy, prolonged and/or irregular periods
- vulvovaginal dryness
- painful sexual intercourse
- decreased libido
- breast pain
- joint pain
- pain or other reactions at the injection site
- tiredness.

The above list includes serious side effects which may require medical attention.

Contact your doctor immediately if you experience sudden headache, vomiting or visual disturbances while using Decapeptyl.

Medicines like Decapeptyl can uncover a rare pituitary condition that a person may not be aware of and use of the medicine in this case may lead to these symptoms.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if any of the following happen.

- allergic reactions
- angioedema (swelling of the face, lips, mouth, tongue or throat, which may cause difficulty in swallowing or breathing)
- abdominal discomfort
- swelling in the abdomen
- blurred eye vision
- visual impairment
- diarrhoea
- excessive sweating

- weight gain
- difficulty breathing, shortness of breath
- decreased urination.

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using Decapeptyl

Storage

Keep Decapeptyl where children cannot reach it.

Keep Decapeptyl in the original pack until it is time for it to be used.

Store Decapeptyl in a refrigerator (2°C to 8°C). Do not freeze.

Disposal

If you are self-injecting, you should discard all sharps into a disposal unit.

If you have any Decapeptyl that has expired or is left over from your treatment refer this to your clinic.

Product description

What it looks like

This medicine is supplied as a colourless solution in a glass syringe of 1 mL to which a needle is connected. The syringe and needle are closed with a rubber stopper and a needle shield. This product is supplied as a pack of 7 or 28 pre-filled syringes.

Not all pack sizes may be marketed in Australia.

Ingredients

Each 1 mL pre-filled syringe of Decapeptyl contains, as the active

ingredient, 100 micrograms triptorelin acetate (equivalent to 95.6 micrograms triptorelin).

The other ingredients are:

- sodium chloride
- glacial acetic acid
- water for injections.

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

Decapeptyl is distributed in Australia by:

Ferring Pharmaceuticals Pty Ltd
Suite 2, Level 1, Building 1,
20 Bridge Street, Pymble NSW
2073

This leaflet was prepared in August 2015.

#36096-v2A

Australian Register Number:
AUST R 219857

Decapeptyl 100 micrograms/1 mL
solution for injection