SCHEDULING STATUS

S4

GONAPEPTYL DAILY 100 microgram/1 ml Triptorelin acetate

Solution for subcutaneous injection

Sugar free.

Read all of this leaflet carefully before you start taking GONAPEPTYL DAILY

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- GONAPEPTYL DAILY has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What GONAPEPTYL DAILY is and what it is used for
2. What you need to know before you use GONAPEPTYL DAILY
3. How to use GONAPEPTYL DAILY
4. Possible side effects
5. How to store GONAPEPTYL DAILY
6. Contents of the pack and other information

1. What GONAPEPTYL DAILY is and what it is used for

GONAPEPTYL DAILY reduces the levels of LH and FSH (so-called downregulation) important for ovulation. This results in preventing premature ovulation (release of egg cells).

GONAPEPTYL DAILY is provided as an injection fluid in a disposable syringe for single use. It is given as an injection under the skin of the lower abdomen.

GONAPEPTYL DAILY is used to treat women in assisted reproduction techniques (ART). In ART occasionally ovulation may occur too early, causing a significant reduction in the chance of getting pregnant. GONAPEPTYL DAILY is used to prevent the early release of egg cells.

2. What you need to know before you use GONAPEPTYL DAILY

Do not use GONAPEPTYL DAILY:

- if you are hypersensitive (allergic) to triptorelin or any of the other ingredients of GONAPEPTYL DAILY
- if you are allergic (hypersensitive) to gonadotrophin releasing hormone (GnRH) or any other GnRH analogue (medicines similar to GONAPEPTYL DAILY)
- if you are pregnant or breastfeeding your baby

Women of childbearing potential should be examined carefully and have a pregnancy test before treatment with GONAPEPTYL DAILY to exclude pregnancy.

Warnings and precautions

Take special care with GONAPEPTYL DAILY

The use of GONAPEPTYL DAILY may increase the risk of ovarian hyperstimulation syndrome (OHSS) and ovarian cysts. OHSS is a syndrome that can manifest itself with increasing degrees of severity. If you notice the following symptoms, immediately inform your doctor: abdominal pain, abdominal distension, weight gain, difficult or laboured breathing, the production of abnormally small amounts of urine, and gastrointestinal symptoms including nausea, vomiting and diarrhoea.

Inform your doctor if you suffer from

- Polycystic Ovarian Syndrome (condition where a women's sex hormones are out of balance)
- osteoporosis (a medical condition in which the bones become brittle and fragile) or a family history thereof.
- depression
- an active allergic condition or if you suffered easily from allergic reactions in the past.

Treatment with GONAPEPTYL DAILY may bring out the presence of a previously unknown/hidden tumour of the pituitary gland (little gland in the brain). If you experience sudden headache, vomiting, decreased ability to see and weakening of eye movements, please inform your doctor urgently.

Children and adolescents

GONAPEPTYL DAILY, a product for assisted reproduction techniques (ART), is not indicated for use in children and adolescents.

Other medicines and GONAPEPTYL DAILY

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

Using GONAPEPTYL DAILY with food and drink

GONAPEPTYL DAILY is a subcutaneous injection and is unaffected by food and drink.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using GONAPEPTYL DAILY.

GONAPEPTYL DAILY is contraindicated for use during pregnancy and breastfeeding.

Driving and using machinery

GONAPEPTYL DAILY is not expected to influence your ability to drive or use machinery.

It is not always possible to predict to what extent GONAPEPTYL DAILY may interfere with your daily activities. You should ensure that you do not engage in driving or using machinery until you are aware of the measure to which GONAPEPTYL DAILY affects you.

GONAPEPTYL DAILY contains sodium

GONAPEPTYL DAILY contains less than 1 mmol of sodium.

3. How to use GONAPEPTYL DAILY

Do not share medicines prescribed for you with any other person.

Always use GONAPEPTYL DAILY exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

If your clinic has asked you to self-administer GONAPEPTYL DAILY, you should follow these step-by-step instructions for subcutaneous injection.

Do not self-inject GONAPEPTYL DAILY until you are sure how to do it.

Your doctor or nurse will demonstrate how you should inject your medicine at home.

The fist dose must occur in your doctor's office and he/she should observe you for at least 30 minutes to make sure you do not have an allergic reaction.

The usual dose of GONAPEPTYL DAILY is one 1 ml subcutaneous injection into the lower abdominal wall, once a day.

Before you start

Your pack contains:

• pre-filled syringes with attached needles

You will need:

• antiseptic swabs

• sharps disposal unit

Have these items ready before you start.

Injecting your medicine

1. Remove the protective foil and take the syringe out of the blister packaging.

2. Keep the syringe upright with the grey protective cap facing up.



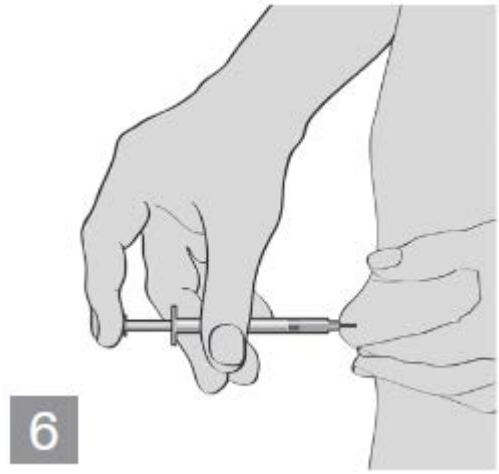
3. Remove the grey protective cap.



4. Gently push the plunger until the first drops of liquid appear at the needle tip.



5. 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.
6. Lift up a fold of skin between 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.



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

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 signs/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.

Disposing your medicine

- If you are self-injecting, you should discard the used needles and syringes into a sharps disposal unit.
- If you have any GONAPEPTYL DAILY that has expired or is left over from your treatment refer this to your clinic.

Your doctor will tell you how long your treatment with GONAPEPTYL DAILY will last. Do not stop treatment unless your doctor advises you to.

If you have the impression that the effect of GONAPEPTYL DAILY is too strong or too weak, tell your doctor or pharmacist.

If you use more GONAPEPTYL DAILY than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison control centre.

If possible, show them the GONAPEPTYL DAILY pack.

If you forget to use a dose of GONAPEPTYL DAILY

If you miss a dose, do not double dose, and contact your doctor or nurse.

If you stop taking GONAPEPTYL DAILY

Use GONAPEPTYL DAILY for as long as your doctor recommends. Don’t stop unless your doctor advises you to.

4. Possible side effects

GONAPEPTYL DAILY can have side effects.

Not all side effects reported for GONAPEPTYL DAILY are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking GONAPEPTYL DAILY, please consult your healthcare provider for advice.

If any of the following happens, stop taking GONAPEPTYL DAILY and tell your doctor immediately or go to the casualty department of your nearest hospital:

- skin rash or itching
- swelling, sometimes of the face or mouth (angioedema), causing difficulty in breathing

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to GONAPEPTYL DAILY. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects

- Termination of pregnancy
- Ovarian hyperstimulation syndrome – characterised by swollen and painful ovaries. Severe cases can cause rapid weight gain, abdominal pain, vomiting and shortness of breath.
- Painful menstruation
- Injection site inflammation

Less frequent side effects:

- Upper respiratory tract infection, sore throat
- Dizziness
- Hot flushes
- Abdominal pain and swelling, nausea and vomiting, diarrhoea
- Back pain
- Pelvic pain, ovarian cyst
- Injection site pain, injection site reaction, fatigue

- Headache
- Vaginal bleeding
- Difficult or laboured breathing
- General feeling of discomfort, illness
- Post procedural and post-operative pain

Frequency unknown:

- ectopic pregnancy (fertilised egg attaches somewhere outside the uterus)
- Paraesthesia (an abnormal sensation, typically tingling or pricking (‘pins and needles’)
- pulmonary oedema (excessive fluid in the lungs)
- genital pain
- Pregnancy complication characterised by severe nausea, vomiting, weight loss, and possibly dehydration
- Inflammation of the cerebellum (part of the brain), low blood platelet count, and blood pressure increased

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of GONAPEPTYL DAILY.

5. How to store GONAPEPTYL DAILY

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

Store in the original package, to protect from light.

Store all medicines out of reach of children.

Do not use after the expiry date stated on the label and carton

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What GONAPEPTYL DAILY contains

The active substance is triptoreline acetate. Each syringe with 1 ml solution contains 100 µg triptorelin acetate equivalent to 95,6 micrograms triptorelin free base.

The other ingredients are sodium chloride, glacial acetic acid and Water for injections.

GONAPEPTYL DAILY contains less than 1 mmol sodium per dosage unit.

What GONAPEPTYL DAILY looks like and contents of the pack

Clear colourless solution.

1 ml solution in a pre-filled syringe (glass) with plunger stopper (chlorobutyl rubber), plunger rod (polystyrene), integrated needle and rigid needle shield.

Pack sizes of 7.

Holder of Certificate of Registration

Ferring (Pty) Ltd.

6 Regency Drive, Route 21 Corporate Park

Nellmapius Drive, Irene, Pretoria

Tel no. (012) 345 6358

This leaflet was last revised in

31 August 2023

Registration number

46/21.10/0169