

SCHEDULING STATUS

GONAPEPTYL® Depot Powder for injection

S4

GONAPEPTYL® Depot Injection vehicle

S4

GONAPEPTYL® Depot Powder for injection, 3,75 mg, Powder for injection, Triptorelin acetate equivalent to

triptorelin

Sugar free.

GONAPEPTYL® Depot Injection vehicle, 104,0 mg, Injection vehicle

1 ml contains 104,0 mg dextran and water for injection to 1 ml

Sugar free.

Read all of this leaflet carefully before you start treatment with GONAPEPTYL® Depot

- 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® Depot 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® Depot is and what it is used for
2. What you need to know before you are given GONAPEPTYL® Depot
3. How to be given GONAPEPTYL® Depot
4. Possible side effects

5. How to store GONAPEPTYL® Depot
6. Contents of the pack and other information

1. What GONAPEPTYL® Depot Powder for injection is and what it is used for

GONAPEPTYL® Depot Powder for injection contains triptorelin (as triptorelin acetate).

Triptorelin belongs to a group of medicines called GnRH analogues. One of its actions is to decrease the production of sex hormones in the body.

It is used:

In men:

- For the treatment of hormone dependent locally advanced or metastatic prostate cancer.

In women:

To suppress the levels of ovarian hormones in order to

- Reduce the size of uterine myomas (commonly known as fibroids), which are non-cancerous tumours arising from the myometrium (smooth muscle layer) of the uterus.
- Treat endometriosis (the formation of uterine tissue outside the uterus).

In children:

- For the treatment of central precocious puberty (CPP) (puberty that occurs prematurely but with the physical and hormonal changes of normal puberty).

2. What you need to know before you use GONAPEPTYL® Depot

Do not use GONAPEPTYL® Depot:

- if you are hypersensitive (allergic) to triptorelin or any of the other ingredients of GONAPEPTYL® Depot.
- if you suffer from a condition that puts pressure on your spinal cord.
- if you have been previously treated with hormonal therapy that has failed.

In men:

- if you have hormone independent prostate cancer.

- after surgical removal of one or both testicles (in case of surgical castration triptorelin does not cause further decrease of serum testosterone).

In women:

- if you are pregnant or breastfeeding your baby.
- if you suffer from physical results of osteoporosis (thinning of the bones).

In children:

- if you suffer from progressive brain tumours.

Warnings and precautions

Take special care with GONAPEPTYL® Depot

In men:

- if you have pains in your bones, or difficulty passing urine.

During treatment:

During the beginning of therapy with GONAPEPTYL® Depot you may experience a worsening in your disease symptoms. Contact your doctor if any of your symptoms of the disease get worse.

In women:

Tell your doctor

- if you are experiencing bleeding mid-cycle during treatment (except for the first month).

During treatment:

You should use non-hormonal methods of contraception, such as a condom or a diaphragm during therapy with GONAPEPTYL® Depot and it should be continued until the return of your periods (menstruation).

Your periods will stop during treatment. Once treatment has finished, your periods (menstruation) will resume 7 – 12 weeks after the final injection.

Your treatment should not exceed a duration of 6 months due to a decrease in bone density that can be caused by GONAPEPTYL® Depot. After withdrawal of treatment, the bone loss is generally reversible within 6 – 9 months.

In children:

- The age at the beginning of therapy with GONAPEPTYL® Depot should be under 8 years in girls.

Other medicines and GONAPEPTYL® Depot

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

(This includes complementary or traditional medicines.)

Medicine containing oestrogen (hormone treatment) should not be used during treatment with GONAPEPTYL® Depot.

Using GONAPEPTYL® Depot with food and drink

GONAPEPTYL® Depot 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 given GONAPEPTYL® Depot.

GONAPEPTYL® Depot must not be used during pregnancy and breastfeeding (see also the section ‘You must not be given GONAPEPTYL® Depot’).

If you are possibly pregnant, pregnancy should be ruled out by your doctor before you are given GONAPEPTYL® Depot. Women of childbearing potential should use effective non-hormonal contraception, such as a condom or a diaphragm, during treatment with GONAPEPTYL® Depot until your periods (menstruation) resumes.

Driving and using machinery

There are no known effects on the ability to drive and use machinery.

However, it cannot be ruled out that the ability to drive or use machinery can be affected during treatment due to some of the side effects (dizziness, sleep disturbances and disturbed eye vision). Take extra caution if you experience these side effects.

GONAPEPTYL® Depot contains sodium

GONAPEPTYL® Depot contains less than 1 mmol of sodium (3,69 mg/ml or 0,160 mmol/ml) per dose, i.e. it is essentially 'sodium free'.

3. How you will be given GONAPEPTYL® Depot

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

You will not be expected to give yourself GONAPEPTYL® Depot. The powder and solvent for injection are normally mixed and injected by a healthcare professional.

Depending on the condition you are being treated for, the appropriate dose will be administered by intramuscular injection (into a muscle) or subcutaneous injection (just under the skin).

In men:

One injection of GONAPEPTYL® Depot (3,75 mg triptorelin) is normally given every four weeks (28 days).

In women:

One injection of GONAPEPTYL® Depot (3,75 mg triptorelin) is normally given every four weeks (28 days) for up to six months.

Treatment must be started during the first 5 days of the menstrual cycle.

In children:

At the beginning of treatment one injection should be injected on day 0, 14 and 28.

The dose is adjusted according to body weight. Children weighing less than 20 kg are given 1,875 mg (½ dose); children weighing 20 – 30 kg are given 2,5 mg (2/3 dose); children weighing more than 30 kg are given 3,75 mg.

Thereafter, injections are given every three to four weeks, according to effect.

The treatment duration is monitored by your doctor.

If you are given more GONAPEPTYL® Depot than you should

Since a healthcare provider will administer GONAPEPTYL® Depot, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to receive a dose of GONAPEPTYL® Depot

Since a healthcare provider will administer GONAPEPTYL® Depot, it is unlikely that the dose will be missed.

If you stop receiving GONAPEPTYL® Depot

You should receive GONAPEPTYL® Depot for as long as your doctor recommends. Don't stop unless your doctor advises you to.

4. Possible side effects

GONAPEPTYL® Depot can have side effects.

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

If any of the following happens, stop receiving GONAPEPTYL® Depot 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® Depot. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Men and women:

Frequent side effects

- temporary pain at the injection site
- depressed mood; irritability; fatigue; sleep disturbances; hot flushes
- nausea
- muscle aches and pains; joint stiffness

Less frequent side effects

- injection site reaction
- elevated values of some liver enzymes

Men:

Frequent side effects

- breast enlargement in males; loss of libido; impotence
- excessive sweating; sensation of tingling, pricking or numbness; physical weakness or lack of energy; compression of the spinal cord

Less frequent side effects

- blood clots
- testicular wasting
- high blood pressure; swelling of the legs
- loss of appetite; weight changes
- hair loss and reduced hair growth
- difficulty and pain in passing urine
- bone pain and muscle tiredness

Women:

Less frequent side effects

- decrease in blood oestrogen levels, increased blood cholesterol
- vaginal dryness; painful sexual intercourse; vaginal bleeding/spotting; loss of libido
- nervousness; mood swings; sensation of tingling, pricking or numbness
- back pain; loss of bone mineral leading to increased bone weakness
- eye disturbances

Children:

Less frequent side effects

- vaginal bleeding or discharge may occur
- nausea; vomiting
- headache

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® Depot.

5. How to store GONAPEPTYL® Depot

Store all medicines out of reach of children.

Store in a refrigerator at or between 2 °C – 8 °C.

After reconstitution of the suspension, the injection should be administered **immediately**.

Any unused portion must be discarded.

Keep the container in the outer carton, to protect from light.

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® Depot contains

The powder for injection:

- The powder in each pre-filled syringe contains triptorelin acetate equivalent to 3,75 mg of the active substance, triptorelin.

- The other ingredients are Poly-(glycolic acid, lactic acid), propylene glycol dicaprylocaprat.

The solvent for injection:

- The solvent contains Dextran 70, polysorbate 80, sodium chloride, sodium dihydrogen phosphate dehydrate, sodium hydroxide, water for injection

GONAPEPTYL® Depot contains less than 1 mmol sodium per dosage unit, i.e it is essentially 'sodium free'.

The powder and solvent for injection are normally mixed and injected by a healthcare professional (see section 3).

What GONAPEPTYL® Depot looks like and contents of the pack

The powder for injection:

White or faintly yellow microcapsules in 2,25 ml pre-filled glass syringe.

The solvent for injection:

Clear colourless to slightly yellow aqueous liquid in 2,25 ml pre-filled glass syringe.

After reconstitution:

Homogenous milky white to faintly yellow suspension.

It is presented in packs of 1 set of the following: 1 or 3 pairs of pre-filled syringes (powder and solvent).

Ferring (Pty) Ltd

GONAPEPTYL® Depot Powder for injection

GONAPEPTYL® Depot Injection Vehicle

Each powder for injection vial contains triptorelin acetate equivalent to triptorelin 3,75 mg.

Each injection vehicle 1 ml suspension contains dextran 104,0 mg and water for injection to 1 ml.

Proposed Clean Patient Information Leaflet

PI update: C.I.0.1 Type IA_{IN} Format Update

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Not all pack sizes may be marketed.

Holder of Certificate of Registration

Ferring (Pty) Ltd.

6 Regency Drive, Route 21 Corporate Park

Nellmapius Drive, Irene, Pretoria

Tel no. (012) 345 6358

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