

DIPHERELINE™

Triptorelin embonate

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you are given Diphereline.

This leaflet answers some common questions about Diphereline. 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. Sometimes new risks are found even when a medicine has been used for many years.

Your doctor has weighed the risks of you being given Diphereline against the benefits they expect 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 Diphereline is used for?

The name of your medicine is Diphereline. It contains the active ingredient triptorelin embonate.

Diphereline is used to treat prostate cancer that has spread into surrounding tissue and/or to other parts of the body. It is not a cure for prostate cancer.

Diphereline belongs to a group of medicines called Gonadotrophin Releasing Hormone analogues (GnRH_a).

Diphereline works by lowering the production of testosterone in men.

Testosterone is the natural male sex hormone.

In some types of prostate cancer, testosterone may help the cancer cells to grow. By lowering testosterone, Diphereline may slow or stop the growth of cancer.

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.

Before you are given Diphereline

When you must not be given it

Diphereline should only be given to men. It must not be given to women or children.

Do not be given Diphereline if you are allergic to:

- triptorelin embonate, the active ingredient in Diphereline
- any of the other ingredients listed at the end of this leaflet, in particular, polysorbate 80
- any other anti-hormone medicine (e.g anti-oestrogen, anti-androgen, GnRH_a).

Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.

Do not be given the medicine if:

- you have had another GnRH_a or anti-androgen medicine that did not work

- you have severe back pain as a result of your prostate cancer spreading and pressing into the nerves of your backbone
- the expiry date printed on the pack has passed
- the packaging is torn or shows signs of tampering.

Before you start to use it

Tell your doctor if:

- you have cancer related pain (metastatic pain)
- you experience difficulty or pain when passing urine
- you have osteoporosis, a family history of osteoporosis or risk factors for developing osteoporosis (such as heavy drinking, smoking, a diet low in calcium, poor mobility, a slight build or treatment with steroid medicines or anticonvulsants)
- you get sudden headaches, and/or have blurred vision
- you are allergic to food, dyes, preservatives or any other medicines
- you have high blood sugar or diabetes
- you have heart or vascular problems or other cardiovascular risk factors
- you have any heart or blood vessel conditions, including heart rhythm problems (arrhythmia), or are being treated with medicines for these conditions. The risk of heart rhythm problems may be increased when using Diphereline
- you are taking medicines to lower your blood pressure.

There have been reports of mood changes and depression in patients taking GnRH analogues, such as Diphereline, which may be severe. If you are taking Diphereline and develop depressed mood, inform your doctor.

Taking other medicines

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

There are some medicines which may interfere with the action of Diphereline. These include:

- medicines used to prevent blood clots (anti-coagulants), including warfarin, as there is a possible risk of haematoma (bruising, bleeding) formation at the site of intramuscular injection
- medicines that increase levels of another hormone, prolactin
- medicines affecting secretion of gonadotrophins.

Diphereline might interfere with some medicines used to treat heart rhythm problems (e.g. quinidine, disopyramide, amiodarone, and sotalol) or might increase the risk of heart rhythm problems when used with some other drugs (e.g. methadone (used for pain relief and part of drug addiction detoxification), moxifloxacin (an antibiotic), antipsychotics used for serious mental illnesses).

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

How is Diphereline given?

How it is given

Diphereline is given as an injection into your muscle (intramuscular) by your doctor or nurse.

How much and how often is it given

Diphereline is available in 3 dose formulations:

- a 3.75mg injection given once a month
- a 11.25mg injection given once every 3 months (4 times a year)
- a 22.5mg injection given every 6 months (2 times a year).

Your doctor will prescribe which dose formulation is most suitable for you.

If you forget to have it

Make sure you keep a diary of when your doses are due.

You will have made a doctor's appointment for your next date so you will not forget it.

If you are given too much (overdose)

As Diphereline is given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

However, if you feel you have been given too much, contact the Poisons Information Centre on 131126 for advice.

While you are using Diphereline

Things you must do

At the start of treatment you will have an increased amount of testosterone in your body which may cause the symptoms of your cancer to get worse.

If you experience any of the following symptoms within the first few weeks of treatment, tell your doctor:

- pain in the bones or backbone
- difficulty passing urine
- weakness, tingling or numbness in your arms and legs.

These symptoms usually only happen with the first treatment with Diphereline. You should not experience them with further treatments. Your doctor may give you additional medicines with your first dose to treat these symptoms.

If you continue to experience them, tell your doctor immediately as it may mean that the cancer is growing.

Keep follow-up appointments with your doctor.

It is important to have your follow-up doses at the appropriate times to get the best effects from your treatments.

If you feel that your medicine is not helping your condition, talk to your doctor.

Tell any other doctors, dentists, and pharmacists who are treating you that you are being treated with Diphereline.

Things you must not do

Do not stop your treatment with Diphereline unless you have discussed it with your doctor first.

Things to be careful of

Be careful driving or operating machinery until you know how Diphereline affects you.

Make sure you know how you react to it before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed, sleepy or have blurred vision or seizures, which are possible side effects of treatment or due to the underlying disease. If this occurs do not drive. If you drink alcohol, dizziness or light-headedness may be worse.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are receiving Diphereline.

Diphereline helps most people with prostate cancer, but it may have unwanted side effects in a few people.

It can be hard to work out whether side effects are caused by Diphereline or prostate cancer.

Like all medicines, Diphereline can have side effects. Generally these are mild but you may need medical attention if you get some of the side effects.

If you get any side effects, do not cancel your follow-up dose of Diphereline without first talking to your doctor.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

You may need urgent medical attention. (These side effects are rare.)

- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing
- chest pain
- sharp, stabbing pain or swelling in your lower leg
- swelling and redness along a vein which is extremely tender when touched
- seizures or convulsions.

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

These side effects may be serious. You may need medical attention.

- sudden headaches
- severe back pain
- difficulty breathing
- temporary worsening of symptoms of your cancer (tumour flare)
- high blood pressure

- gout (disease with painful swollen joints, particularly in the big toe)
- inability to pass urine.

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

Very common side effects affecting more than 1 in 10 patients:

- hot flushes
- weakness
- back pain
- pins and needles sensation in the legs
- excess sweating
- reduced libido
- impotence

Common side effects affecting more than 1 in 100 patients:

- nausea
- dry mouth
- mood changes, depression
- pain, bruising, redness and swelling at injection site
- oedema (build up of fluid in the body tissues)
- muscle and bone pain, pain in the arms and legs, lower abdominal pain
- dizziness, headache
- allergic reactions
- loss of libido
- hypersensitivity
- high blood pressure
- increase in weight

The following side effects have also been reported since Diphereline was approved for use: general discomfort, anxiety, urinary incontinence, rapid formation of wheals due to swelling of the skin or mucous membranes, anaphylactic shock and changes in ECG (QT prolongation).

If you have an enlargement (benign tumour) of the pituitary gland that you were unaware of, this may be discovered during treatment with Diphereline. Symptoms include sudden headache, vomiting,

problems with eye sight and paralysis of the eyes.

An increase in white blood cell count may be found, as with other GnRH analogues, in patients being treated with Diphereline.

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

Your doctor will monitor you during treatment to check that you do not develop high blood sugar or diabetes. You will also be monitored for any symptoms or signs of cardiovascular disease.

Some side effects (for example, high blood pressure or changes in liver function) can only be found when your doctor does tests to check on your progress.

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

How to store Diphereline?

Storage

Diphereline is usually stored in the doctor's surgery or clinic, or at the pharmacy. However, if you need to store it at home:

- **Keep it in a cool, dry place where the temperature stays below 25°C**
 - **Keep your medicine where children cannot reach it.**
- A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines
- **Keep it in the original container until it is time for it to be given.**

If you take your medicine out of the original container, it will not keep well.

Any Diphereline which is not used will be disposed in a safe manner by your doctor.

If you are storing the product at home and your doctor tells you to

stop treatment or it has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

109854 (Diphereline 3.75mg 1 month formulation)

109856 (Diphereline 11.25mg 3 month formulation)

159173 (Diphereline 22.5mg 6 month formulation)

Product description

What it looks like

Diphereline 3.75mg

1 month formulation

Diphereline 11.25mg

3 month formulation

Diphereline 22.5mg

6 month formulation

Each pack contains 1 vial of Diphereline (3.75, 11.25 or 22.5 mg triptorelin), 1 ampoule, and 1 blister pack containing 1 empty polypropylene syringe and 2 needles.

The vial contains a small pellet of white to slightly yellow powder which must be mixed with the contents of the ampoule (solvent) before injection.

Ingredients

Active ingredients:

- triptorelin embonate

Other ingredients:

- polyglactin
- mannitol
- carmellose sodium
- polysorbate 80
- The solvent is composed of water for injections

Manufacturer/ Supplier

Diphereline is manufactured in France and distributed in Australia by:

Ipsen Pty Ltd

Level 2, Building 4

Brandon Office Park

540 Springvale Road

Glen Waverley, Victoria 3150

AUST R No:

Date of preparation of this leaflet.

March 2015