

Diphereline®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

- ▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I being given Diphereline?

Diphereline contains the active ingredient triptorelin. In adult men, Diphereline is used to treat prostate cancer that has spread into surrounding tissue and/or to other parts of the body. In children, Diphereline 22.5 mg is used to treat puberty that occurs at a very young age (Central Precocious Puberty).

For more information, see Section [1. Why am I being given Diphereline?](#) in the full CMI.

2. What should I know before I am given Diphereline?

Do not use if you have ever had an allergic reaction to triptorelin or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other**

medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section [2. What should I know before I am given Diphereline?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Diphereline and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How am I given Diphereline?

Your doctor or nurse will give you an injection of Diphereline into your muscle (intramuscular). More instructions can be found in Section [4. How am I given Diphereline?](#) in the full CMI.

5. What should I know while being given Diphereline?

Things you should do	
	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Diphereline.• Keep your follow-up appointments with your doctor.

	<ul style="list-style-type: none"> ● Call your doctor straight away if you: <ul style="list-style-type: none"> - (in children) develop a persistent headache with one or more other symptoms such as vision/eye disturbances, severe headaches, ringing in the ears, dizziness, nausea. These could be signs of increased pressure around the brain. - if you notice a rash, blistering or peeling of the skin, sores in the mouth, throat, nose or eyes, fever or flu-like symptoms - (in men) experience any of these symptoms a few weeks after receiving your injection: pain in the bones or backbone, difficulty passing urine, weakness, tingling or numbness in your arms and legs.
<p>Things you should not do</p>	<ul style="list-style-type: none"> ● Do not stop using this medicine suddenly.

<p>Driving or using machines</p>	<ul style="list-style-type: none"> ● Be careful driving or operating machinery until you know how Diphereline affects you. ● If your child is begin given Diphereline, be careful of riding bicycles or climbing until you know how the medicine affects them.
<p>Drinking alcohol</p>	<ul style="list-style-type: none"> ● Tell your doctor if you drink alcohol.
<p>Looking after your medicine</p>	<ul style="list-style-type: none"> ● Keep your medicine in a cool, dry place where the temperature stays below 25°C.

For more information, see Section [5. What should I know while being given Diphereline?](#) in the full CMI.

6. Are there any side effects?

Like all medicines, Diphereline can cause side effects, although not everybody gets them. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI. Some side effects may need immediate medical attention. Tell your doctor straight away if you notice any of the serious side effects listed in Section [5. What should I know while being given Diphereline?](#) or Section [6. Are there any side effects?](#)

- ▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

Diphereline®

Active ingredient(s): *triptorelin*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Diphereline. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about being given Diphereline.**

Where to find information in this leaflet:

- [1. Why am I being given Diphereline?](#)
- [2. What should I know before I am given Diphereline?](#)
- [3. What if I am taking other medicines?](#)
- [4. How am I given Diphereline?](#)
- [5. What should I know while being given Diphereline?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being given Diphereline?

Diphereline contains the active ingredient triptorelin. Diphereline belongs to a group of medicines called Gonadotrophin Releasing Hormone agonists (GnRHa).

In males, Diphereline works by lowering the production of testosterone. Testosterone is a 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.

In females, Diphereline lowers the levels of the hormone oestrogen. Oestrogen is a natural female sex hormone.

In adult men, 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.

In children, Diphereline 22.5 mg is used to treat puberty that occurs at a very young age (Central Precocious Puberty).

2. What should I know before I am given Diphereline?

Warnings

You should not be given Diphereline if:

- there are signs that the tumour doesn't rely on hormones to grow (check with your doctor).
- you have had surgical removal of your testes.
- you have severe back pain as a result of your prostate cancer spreading and pressing into the nerves of your backbone.
- you are allergic to triptorelin, polysorbate 80, Gonadotropin Releasing Hormone (GnRH) or any other Gonadotrophin Releasing Hormone agonists (GnRHa), or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Some of the symptoms of an allergic reaction may include:

- 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

Check with your doctor if you:

- take any medicines for any other condition.
- have an enlargement (benign tumour) of your pituitary gland. If you are unaware of any enlargement, it may be discovered during treatment with Diphereline.
- are allergic to food, dyes, preservatives or any other medicines.

In men:

- have cancer related pain (metastatic pain).
- experience difficulty or pain when passing urine.
- 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).
- get sudden headaches, and/or have blurred vision.
- have high blood sugar or diabetes.
- have heart or vascular problems or other cardiovascular risk factors.
- 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.
- are taking medicines to lower your blood pressure.

In children:

- If your child has progressive brain tumour, tell their doctor. This may affect the way your doctor decides to treat your child.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

You should not be given Diphereline if you are pregnant or breastfeeding.

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Mood changes and depression

There have been reports of mood changes and depression in patients taking GnRH analogues, such as Diphereline, which may be severe. In very rare cases, severe depression can lead to suicidal thoughts or attempts. If you are being given Diphereline and develop depressed mood or have any thoughts of self-harm, inform your doctor or nurse straight away.

3. What if I am taking other medicines?

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

Some medicines may interfere with Diphereline and affect how it works.

- medicines used to prevent blood clots (anti-coagulants), including warfarin. There is a possible risk of haematoma formation (bruising, bleeding) at the site of the 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, such as:

- quinidine
- disopyramide
- amiodarone
- sotalol

Diphereline might increase the risk of heart rhythm problems when used with some other drugs, such as:

- methadone (used for pain relief and part of drug addiction detoxification)
- moxifloxacin (an antibiotic)
- antipsychotics (used for serious mental illnesses)

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Diphereline.

4. How am I given Diphereline?

How much is given

Your doctor will decide how much to give depending on the condition being treated:

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

Only the 22.5 mg injection is used to treat Central Precocious puberty in children.

When am I given Diphereline

- Your doctor will decide how frequently and for how long you will be given the injection.
- Your child's doctor will decide when treatment should be stopped. Normally this will happen when your child is about 12-13 years old if they are a girl, and about 13-14 years old if they are a boy.

How am I given Diphereline

Your doctor or nurse will inject Diphereline into a muscle, usually your bottom.

If you forget to get your Diphereline injection

Tell your doctor as soon as you realise that you have missed an injection. You will then be given your next injection.

Make a doctor's appointment for your next injection date. Keep a diary of when your next dose is due.

If you are given too much Diphereline

Diphereline is given to you by a doctor or nurse, so it is unlikely that you or your child will be given too much. However, if you think that you or your child have been given too much Diphereline, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre **(by calling 13 11 26)**, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while being given Diphereline?

Things you should do

In men:

Call your doctor straight away if you:

experience any of the following symptoms within the first few weeks of treatment:

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

At the start of treatment with medicines like Diphereline (GnRHa medicines), you will have an increased amount of testosterone in your body which may cause the symptoms of your cancer to get worse.

Tell your doctor immediately if you continue to experience these symptoms. It may be a sign that the cancer is growing. Your doctor may give you other medicines to manage these symptoms.

In children:

Call your doctor straight away if you/your child:

develop a persistent headache with one or more other symptoms. Diphereline is rarely associated with a serious condition called pseudotumour cerebri (PTC) or idiopathic intracranial hypertension (IIH) which can cause blurred vision, double vision, loss of vision, pain behind the eye or pain with eye movement ringing in the ears, dizziness or nausea.

Call your doctor/your child's doctor immediately if you experience these symptoms or go straight to the Emergency Department at your nearest hospital.

Loss of vision may be irreversible in very rare cases if PTC/IIH is not promptly treated.

In men or children:

Call your doctor/your child's doctor straight away if you:

notice any of the following:

- Rash, blistering or peeling of the skin
- Sores in the mouth, throat, nose or eyes
- Fever or flu-like symptoms with a rash

Serious skin reactions have been reported with Diphereline. These may include a rare condition called Stevens-Johnson syndrome.

Contact your doctor/your child's doctor immediately or go to the nearest hospital emergency department if you experience these symptoms. In children, the rash can be mistaken for an infection, so it is important your doctor/your child's doctor considers the possibility of a serious allergic skin reaction.

Talk to your doctor or pharmacist if:

- your female child experiences some vaginal bleeding in the first month of treatment.
- you feel that your medicine is not helping your condition (or your child's condition).

Remind any doctor, dentist or pharmacist you visit that you (or your child) are using Diphereline.

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.

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.

Things you should not do

- Do not stop using this medicine suddenly.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Diphereline affects you.

Diphereline may cause dizziness, blurred vision, or seizures in some people.

Be careful of your child riding bicycles or climbing (such as trees or playground equipment) until you know how Diphereline affects them.

Drinking alcohol

Tell your doctor if you drink alcohol.

Drinking alcohol may make dizziness or light-headedness worse when you are taking Diphereline.

Looking after your medicine

Your doctor will keep the medicine at the doctor's clinic or surgery, or at the pharmacy.

If you need to store Diphereline at home:

- Keep it in a cool, dry place, where the temperature stays below 25°C.
- Keep it in the original container.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Serious side effects

Serious side effects	What to do
<p>Symptoms of an allergic reaction (including serious allergic skin reactions):</p> <ul style="list-style-type: none">• Fever, tiredness, feeling unwell, sore throat, cough• Red, burning, sore or sticky eyes• Rash (which may be red or purplish), itching or hives on the skin• painful skin or skin that feels burned, blisters on the skin, skin that peels or comes away easily• painful sores or ulcers in the mouth, throat, nose or genitals (that	<p>Call your doctor or your child's doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<p>may make it painful to urinate)</p> <ul style="list-style-type: none"> ● swelling of the face, lips, tongue or other parts of the body ● shortness of breath, wheezing or trouble breathing <p>Prostate cancer:</p> <ul style="list-style-type: none"> ● seizures or convulsions ● difficulty breathing ● high blood pressure <p>Signs of tumour flare:</p> <ul style="list-style-type: none"> ● temporary worsening of symptoms of your cancer ● severe back pain <p>Signs of thrombocytosis:</p> <ul style="list-style-type: none"> ● sharp, stabbing pain or swelling in your lower leg ● swelling and redness along a vein which is extremely tender when touched ● increase in white blood cells 	

Serious side effects	What to do
<ul style="list-style-type: none"> ● chest pain ● sudden headaches <p>Signs of gout:</p> <ul style="list-style-type: none"> ● painful, swollen joints (particularly in the big toe) <p>Signs of enlargement of pituitary gland (benign tumour):</p> <ul style="list-style-type: none"> ● sudden headache ● vomiting ● problems with eyesight ● paralysis of the eyes <p>Signs of changes in ECG (record of the electrical activity of the heart) (QT prolongation):</p> <ul style="list-style-type: none"> ● fast or irregular heartbeats, also called palpitation ● fainting, loss of consciousness ● seizure <p>Central Precocious puberty:</p> <ul style="list-style-type: none"> ● changes to vision ● seizures or convulsions 	

Serious side effects	What to do
<p>Signs of high blood pressure in the brain:</p> <ul style="list-style-type: none"> ● headache ● blurred vision, double vision ● loss of vision ● pain behind the eye or pain with eye movement ● ringing in the ears ● dizziness ● nausea 	

Less serious side effects

Less serious side effects	What to do
<p>Prostate cancer:</p> <p>Gastrointestinal related:</p> <ul style="list-style-type: none"> ● feeling sick (nausea) ● dry mouth <p>Nervous system related:</p> <ul style="list-style-type: none"> ● pins and needles sensation in the legs ● dizziness ● headache 	<p>Speak to your doctor or your child's doctor if you or your child has any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<p>Heart or circulatory system related:</p> <ul style="list-style-type: none"> • hot flushes <p>Mental health related:</p> <ul style="list-style-type: none"> • reduced or no libido • mood changes, depression • anxiety <p>Reproductive system and breast related:</p> <ul style="list-style-type: none"> • impotence (difficulty to get or maintain an erection) <p>Skin related:</p> <ul style="list-style-type: none"> • excess sweating • raised itchy bumps, swollen patches of skin, welts which appear suddenly <p>Muscle or bone related:</p> <ul style="list-style-type: none"> • back pain • muscle and bone pain • pain in the arms and legs • lower abdominal pain <p>Kidney or bladder related:</p>	

Less serious side effects	What to do
<ul style="list-style-type: none"> ● problems passing urine (difficulty or uncontrollable and involuntary) <p>General:</p> <ul style="list-style-type: none"> ● weakness ● pain, bruising, redness and swelling at the injection site ● build-up of fluid in the body tissues (oedema) ● weight gain ● general discomfort <p>Central Precocious puberty:</p> <p>Heart or circulatory system related:</p> <ul style="list-style-type: none"> ● hot flushes <p>Mental health related:</p> <ul style="list-style-type: none"> ● changes in mood <p>Reproductive system and breast related:</p> <ul style="list-style-type: none"> ● vaginal bleeding which may occur in girls in the first month of treatment 	

Less serious side effects	What to do
<ul style="list-style-type: none"> ● pain in breast <p>Gastrointestinal related:</p> <ul style="list-style-type: none"> ● stomach pain or discomfort ● vomiting ● constipation ● nausea <p>Nervous system related:</p> <ul style="list-style-type: none"> ● headache <p>Skin related:</p> <ul style="list-style-type: none"> ● acne <p>General:</p> <ul style="list-style-type: none"> ● pain, redness and swelling at the injection site ● general discomfort <p>Skin related:</p> <ul style="list-style-type: none"> ● overweight <p>Muscle or bone related:</p> <ul style="list-style-type: none"> ● neck pain <p>Respiratory related:</p> <ul style="list-style-type: none"> ● nosebleeds 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Diphereline contains

Active ingredient (main ingredient)	triptorelin embonate
Other ingredients (inactive ingredients)	polyglactin mannitol carmellose sodium polysorbate 80

	sterile water
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Do not take this medicine if you are allergic to any of these ingredients.

What Diphereline looks like

Diphereline is available in 3.75 mg (1 month formulation), 11.25 mg (3 month formulation), and 22.5 mg (6 month formulation) (AUST R 109854, 109856, 159173).

Each pack contains 1 vial of Diphereline, 1 ampoule of solvent, 1 empty polypropylene syringe and 2 needles.

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

Australian Sponsor of Diphereline

Ipsen Pty Ltd
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