

▼ This medicine is subject to additional monitoring in Australia due to approval of an extension of indications. 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®

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.

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 (Precocious Puberty). This is called “early puberty” in the rest of this leaflet.

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 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.

In females, DIPHERELINE lowers the levels of the hormone oestrogen.

Ask your doctor if you have any questions about why this medicine 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 not be given to pregnant or lactating women.

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
- Gonadotropin Releasing Hormone (GnRH) or any other Gonadotrophin Releasing Hormone agonists (GnRHa)

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:

- the expiry date printed on the pack has passed
- the packaging is torn or shows signs of tampering.

In men:

- you have severe back pain as a result of your prostate cancer spreading and pressing into the nerves of your backbone

Before you are given it

Tell your doctor if:

In men:

- 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.

In children:

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

Taking other medicines

Tell your doctor or pharmacist 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 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 it is given

DIPHERELINE is available in 3 dose formulations:

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

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

In children:

Only the 22.5 mg injection is used to treat early puberty in children with one injection every 6 months. Your child's doctor will decide when treatment should be stopped (normally when your child is about

12-13 if they are a girl and about 13-14 if they are a boy).

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 or your child will receive too much.

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

WHILE YOU ARE BEING GIVEN DIPHERELINE

Things you must do

In men:

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.

In children:

Girls who have early puberty may have some vaginal bleeding in the first month of treatment.

All patients:

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 (or your child's condition), talk to your doctor.

Tell any other doctors, dentists, and pharmacists who are treating you that you (or your child) 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.

Children should be careful when riding bicycles or climbing trees until you know how DIPHERELINE affects them.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you or your

child do not feel well while you are receiving DIPHERELINE

DIPHERELINE helps most men with prostate cancer and most children with early puberty, but it may have unwanted side effects in a few people.

In men, 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 or your child 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.

In men:

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.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

In children:

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

Your child 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
 - changes to vision
 - increased pressure in the head or brain
- Monitor/watch your child for signs and symptoms of increased

pressure in the head or brain including: headache, blurred vision, double vision, loss of vision, pain behind the eye or pain with eye movement, ringing in the ears, dizziness, nausea.

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

Very common side effects which may affect more than 1 in 10 patients:

- vaginal bleeding which may occur in girls in the first month of treatment.

Common side effects which may affect up to 1 in 10 patients:

- pain in abdomen
- pain, redness and swelling at injection site
- headache
- hot flushes
- weight gain
- acne
- hypersensitivity reactions.

Uncommon side effects which may affect up to 1 in 100 patients:

- blurred vision
- vomiting, constipation, nausea
- general discomfort
- overweight,
- neck pain
- changes in mood
- pain in breast
- nosebleeds
- itching, rash or hives in the skin.

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

AFTER BEING GIVEN 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.

Disposal

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

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

SPONSOR

Ipsen Pty Ltd

Level 5

627 Chapel Street

South Yarra, Victoria 3141

Australian Registration Numbers:

AUST R 109854 (DIPHERELINE
3.75mg 1 month formulation)

AUST R 109856 (DIPHERELINE
11.25mg 3 month formulation)

AUST R 159173 (DIPHERELINE
22.5mg 6 month formulation)

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