

Lucrin[®] Depot Paediatric 30 mg Injection

Leuprorelin acetate

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about Lucrin Depot Paediatric 30 mg Injection.

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. Your child's doctor has weighed the risks of your child being given this medicine against the benefits he/she expects it will have for him/her.

If you have any concerns about your child being given this medicine, ask your child's doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What Lucrin is used for

Lucrin Depot Paediatric 30 mg is used to treat central precocious puberty, or CPP, a condition causing children to

enter puberty too soon. This results in faster than normal bone growth and development of sexual characteristics in girls usually younger than 8 years of age and in boys usually younger than 9 years of age.

It belongs to a group of medicines called gonadotropin releasing hormone agonists.

It works by decreasing the amount of certain hormones in the body.

Ask your child's doctor or pharmacist if you have any questions about why it has been prescribed for your child.

Lucrin is available only with a doctor's prescription.

Before your child is given Lucrin

When your child must not be given it

Your child must not receive Lucrin if he/she has an allergy to:

- **any medicine similar to Lucrin**
- **any of the ingredients listed at the end of this leaflet**

Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

Although it is very unlikely that your child will be pregnant or breastfeeding, Lucrin Depot Paediatric 30 mg

should not be given if they are. If you have concerns or suspect that your child might be pregnant before or during the course of treatment, it is important to discuss this with your doctor.

Do not use after the expiry date printed on the pack or if the packaging is damaged or shows signs of tampering.

If it has expired or is damaged return it to your pharmacist for disposal.

Before your child is given Lucrin

Tell your child's doctor if your child has any allergies to any other medicines, foods, preservatives or dyes.

Tell your child's doctor if your child has or has had any of the following medical conditions:

- history of convulsions, fits or seizures

Young Children

The safety of Lucrin in children under the age of 2 years has not been established. Therefore, the use of Lucrin Depot Paediatric 30 mg Injection in children under the age of 2 years is not recommended.

If you have not told your child's doctor about any of the above, tell him/her before your child is given Lucrin.

Taking other medicines

Tell your child's doctor if your child is taking any other medicines, including any that you buy without a

prescription from your pharmacy, supermarket or health food store.

Lucrin would not be expected to interact with other commonly used medicines. If you have any questions or concerns, discuss them with your child's doctor or pharmacist.

How Lucrin is given

How often Lucrin is given

Lucrin Depot Paediatric 30 mg Injection is given once every three months as a single injection into the muscle.

The site of injection should be varied from time to time.

How to take it

This medicine is given as an injection into the muscle by a doctor or trained nurse.

How long to take it

Your child should continue to receive the medicine for as long as his/her doctor tells him/her to.

When used in children with CPP, Lucrin Depot Paediatric 30 mg injection will likely be stopped by your child's doctor around 11 years of age in girls and 12 years of age in boys.

Continuous therapy is important and adherence to administration every three months is essential for successful

treatment. If this dosing schedule is not followed, pubertal development may begin again.

If you forget to have your injection

If your child has missed his/her injection or you are not sure what to do, check with your child's doctor or pharmacist.

Overdose

As Lucrin Depot Paediatric 30 mg is given to your child under the supervision of a doctor, it is very unlikely that he/she will receive too much. However, if your child experiences any side effects after being given this medicine, telephone your child's doctor, or the National Poisons Information Centre (telephone Australia 13 11 26), or go to Accident and Emergency at your nearest hospital.

There have not been any unexpected side effects seen with the high doses of Lucrin in adults.

While your child is being given Lucrin

Things you must do

When Lucrin Depot Paediatric 30 mg is first started, there may be a temporary increase in some hormones in the first few weeks after the injection. Your child's doctor will monitor your child carefully for any new or worsening symptoms during this time.

This increase in symptoms usually only happen with the first treatment with this medicine; your child should not experience them with future treatments.

If your child is about to be started on any new medicine, remind your child's doctor and pharmacist that he/she is receiving Lucrin Depot Paediatric 30 mg.

Tell any other doctors, dentists and pharmacists who treat your child that he/she is receiving Lucrin Depot Paediatric 30 mg.

If your child is going to have surgery, tell the surgeon that he/she is receiving Lucrin Depot Paediatric 30 mg.

If your child is about to have any blood tests, tell your child's doctor that he/she is receiving Lucrin Depot Paediatric 30 mg.

Lucrin Depot Paediatric 30 mg may interfere with the results of some tests.

Ensure that routine appointments are made with a paediatric endocrinologist to manage their progress, and keep all of your child's doctor's appointments so that your child's progress can be checked and monitored regularly.

Lucrin Depot Paediatric 30 mg would have been prescribed to your child after an initial assessment made by a paediatric endocrinologist. It is important that your child continues to have routine visits to this specialist so that your child's progress can be regularly monitored.

If your child does not feel well or his/her condition worsens, tell your child's doctor immediately.

Things you must not do

Do not give Lucrin Depot Paediatric 30 mg to treat any other medical complaints unless your doctor or pharmacist advises you to.

Do not give Lucrin Depot Paediatric 30 mg to anyone else, even if they have the same condition as your child.

Do not let your child miss a scheduled Lucrin Depot Paediatric 30 mg injection unless your child's doctor or pharmacist advises you to.

Things to be careful of

If your child feels light-headed, dizzy or faint when getting out of bed or standing up, instruct him/her to get up slowly.

Standing up slowly, especially when your child gets up from bed or chairs, will help his/her body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your child's doctor.

Side effects

Tell your child's doctor or pharmacist as soon as possible if your child does not feel well while he/she is taking Lucrin Depot Paediatric 30 mg.

In children receiving Lucrin Depot Paediatric 30 mg for central precocious puberty, new or worsening symptoms of sexual development may occur during the first few weeks of treatment.

In girls receiving Lucrin Depot Paediatric 30 mg injection for central precocious puberty, the onset of menstruation or spotting (light vaginal bleeding) may occur in the first few months of treatment. If bleeding continues, contact your child's doctor.

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your child may need medical attention if he/she gets some of the side-effects.

Do not be alarmed by this list of possible side effects. Your child may not experience any of them.

Ask your child's doctor or pharmacist to answer any questions you may have relating to potential side effects.

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

- pain, swelling, redness, or wound at the injection site
- general pain
- hot flushes
- dizziness or light-headedness

- skin problems such as rash, itching, hives, dry skin or acne
- vaginitis, vaginal bleeding or discharge
- sweating
- headache
- increased weight
- altered or unstable mood
- tearfulness or crying

The above list includes the more common side effects of your child's medicine. They are usually mild and short-lived.

Some people taking Lucrin Depot Paediatric 30mg have had new or worsened mental (psychiatric) problems. Mental (psychiatric) problems may include emotional symptoms such as:

- crying
- irritability
- restlessness (impatience)
- anger
- acting aggressive

Tell your child's doctor as soon as possible if you or your child notice any of the following:

- swelling in limbs
- problems with your eye sight
- difficulty breathing
- numbness or tingling of hands or feet
- blood in the urine
- changes in breast size

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your child's doctor immediately or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, mouth, throat or neck which may cause difficulty in swallowing or breathing or sudden collapse
- unsteadiness when walking

The above list includes very serious side effects. Your child may need urgent medical attention. These side effects are rare.

Tell your child's doctor or pharmacist if you or your child notice anything else that is making your child feel unwell.

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

Storage

Lucrin Depot Paediatric 30 mg Injection should be kept in a cool, dry place where the temperature stays below 25°C, and should be protected from light.

Do not store it or any other medicine in the bathroom, near a sink, or on a windowsill. Do not leave it in the car.

Heat and dampness can destroy some medicines.

Keep it 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.

Disposal

If your doctor advises that your child should stop taking Lucrin Depot Paediatric 30 mg, or the medicine has passed its expiry date, ask your pharmacist what you should do with any medicine that is left over.

Product description

What it looks like

PREFILLED DUAL-CHAMBER SYRINGES

Description:

Lucrin Depot Paediatric 30 mg Injection is a dual-chamber syringe containing active ingredient (white powder) in the

front chamber and diluent (colourless solution) in the rear chamber.

Ingredients

Lucrin Depot Paediatric 30 mg Injection contains 30mg leuprorelin acetate as the active ingredient.

It also contains polylactic acid and mannitol.

The diluent contains carmellose sodium, mannitol, polysorbate 80, water for injections, and glacial acetic acid.

Supplier

Lucrin is supplied in Australia by:

AbbVie Pty Ltd

241 O'Riordan Street

Mascot NSW 2020

1800 043 460

ABN: 48 156 384 262

This leaflet was prepared in

5 April 2018.

Australian Registration Number(s)

Lucrin Depot Paediatric 30 mg 3-Month Injection:

AUST R 218936

Version 3