

Patient Labeling for Supprelin® LA [Suh-Preh-Lin El-Ay] (histrelin acetate) subcutaneous implant

Read the Patient Information that comes with Supprelin LA before your child begins treatment. This information does not take the place of talking with your child's doctor about their medical condition or treatment.

What is Supprelin LA?

Supprelin LA is an under-the-skin (subcutaneous) implant that contains the medicine histrelin, which blocks the action of the gonadotropin releasing hormone (GnRH). Supprelin LA is used for treatment of children with central precocious puberty (CPP).

CPP makes puberty come early in girls (before 8 years of age) and in boys (before 9 years of age). Signs of early puberty include breast enlargement in girls and the appearance of hair in genital area in boys and girls. Supprelin LA works by reducing the amount of sex hormones in the blood to delay early puberty.

Who should not use Supprelin LA?

Your child should not use Supprelin LA if he/she is allergic to gonadotropin releasing hormone (GnRH), GnRH agonist medicines, or anything in the Supprelin LA implant.

Supprelin LA should not be used in:

- children under 2 years of age
- women who are or may become pregnant (Supprelin LA can cause birth defects or loss of the baby).

How is Supprelin LA used?

- Your child's doctor should do tests to make sure your child has CPP before treating your child with Supprelin LA.
- Supprelin LA lasts for 12 months. One implant provides the medicine for 12 months. After 12 months, Supprelin LA must be removed. The doctor may insert a new Supprelin LA at this time to continue treatment.
- Supprelin LA is placed under the skin of the inside of the upper arm. The doctor will temporarily numb the arm of your child, make a small cut, and then place Supprelin LA under the skin. The cut may be closed with stitches or surgical strips and covered with a pressure bandage.
- Your child should keep the arm clean and dry and should not swim or bathe for 24 hours. The bandage can be removed after 24 hours. Do not remove any surgical strips. They will fall off on their own in several days.
- Your child should avoid heavy play or exercise that uses the implanted arm for 7 days. After the cut has healed, your child can go back to his or her normal activities. The doctor will give you complete instructions.
- Keep all scheduled visits to the doctor. Your child's doctor will do regular exams and blood tests to check for signs of puberty. Sometimes the doctor will have to do special examinations, such as ultrasound or MRI, if the Supprelin LA implant is difficult to find under your child's skin.

What are the possible side effects of Supprelin LA?

In the first few weeks of treatment, Supprelin LA can cause a brief increase in some hormones, and during this time you may notice more signs of puberty in your child, including light vaginal bleeding and breast enlargement in girls. Within 4 weeks of treatment, you should see signs in your child that puberty is stopping.

- The most common side effects of Supprelin LA are skin reactions at the place where the implant is inserted. Such reactions may include bruising, soreness, pain, tingling, itching, and swelling. They usually go away without treatment within 2 weeks. Call your child's doctor if your child has bleeding, redness or pain at the insertion site.
- Serious and life-threatening allergic reactions have happened with GnRH medicines (the type of medicine in Supprelin LA).

These may not be all the side effects of Supprelin LA. Ask your child's doctor for more information.

General information about Supprelin LA

This patient labeling summarizes the most important information about Supprelin LA. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Supprelin LA that is written for health professionals. You can also visit www.supprelinla.com on the internet.

Rx Only

Manufactured by:

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