Medication Guide
SUPPRELIN® LA [Suh-Preh-Lin El-Ay]
(histrelin acetate) subcutaneous implant

What is the most important information I should know about SUPPRELIN LA?

- In the first week of treatment, SUPPRELIN LA can cause an increase in some hormones. 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.
- Some people who had SUPPRELIN LA placed in their arm have had the implant come through the skin (extrusion).
  Call your child's doctor right away if the SUPPRELIN LA implant comes through the skin.
- Some people taking GnRH agonists like SUPPRELIN LA have had new or worsening mental (psychiatric) problems. Mental (psychiatric) problems may include emotional symptoms such as:
  - crying
  - irritability
  - restlessness (impatience)
  - anger
  - acting aggressive

  Call your child's doctor right away if your child has any new or worsening mental symptoms or problems while taking SUPPRELIN LA.
- Some people taking GnRH agonists like SUPPRELIN LA have had seizures. The risk of seizures may be higher in people who:
  - have a history of seizures
  - have a history of epilepsy
  - have a history of brain or brain vessel (cerebrovascular) problems or tumors
  - are taking a medicine that has been connected to seizures such as bupropion or selective serotonin reuptake inhibitors (SSRIs)

  Seizures have also happened in people who have not had any of these problems.
  Call your child's doctor right away if your child has a seizure while taking SUPPRELIN LA.
- Severe cutaneous (skin) adverse reactions can happen during treatment with GnRH agonists like SUPPRELIN LA.
  Stop SUPPRELIN LA and call your child's doctor right away if your child has any of the following signs or symptoms during treatment with SUPPRELIN LA:
  - skin rash or acne
  - dry skin
  - itching
  - blisters on your skin
  - redness or swelling of your face, hands, or soles of your feet
  - blisters or sores in your mouth
  - peeling of your skin
  - fever
  - muscle or joint aches
  - swollen glands
- Increased pressure in the fluid around the brain can happen in children taking GnRH agonist medicines including SUPPRELIN LA.
  Call your child's doctor right away if your child has any of the following symptoms during treatment with SUPPRELIN LA:
  - headache
  - eye problems, including blurred vision, double vision, and decreased eyesight
  - eye pain
  - ringing in the ears
  - dizziness
  - nausea

What is SUPPRELIN LA?

- SUPPRELIN LA is an implanted gonadotropin releasing hormone (GnRH) medicine used for the treatment of children with central precocious puberty (CPP).
- It is not known if SUPPRELIN LA is safe and effective in children under 2 years of age.

SUPPRELIN LA should not be taken if your child is:

- allergic to gonadotropin releasing hormone (GnRH), GnRH agonist medicines, or any ingredients in the SUPPRELIN LA implant. See the end of this Medication Guide for a complete list of ingredients in SUPPRELIN LA.
- pregnant or becomes pregnant. SUPPRELIN LA can cause birth defects or loss of the baby. If your child becomes pregnant call your doctor.

Before your child receives SUPPRELIN LA, tell the doctor about all of your child's medical conditions, including if they:

- have a history of mental (psychiatric) problems.
- have a history of seizures.
- have a history of epilepsy.
- have a history of brain or brain vessel (cerebrovascular) problems or tumors.
- are taking a medicine that has been connected to seizures such as bupropion or selective serotonin reuptake inhibitors (SSRIs).

Tell your doctor about all the medicines your child takes, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will your child receive SUPPRELIN LA?

- Your child's doctor should do tests to make sure your child has CPP before treating with SUPPRELIN LA.
- SUPPRELIN LA lasts for 12 months. One implant will give the medicine for 12 months. After 12 months, the SUPPRELIN LA implant must be removed. The doctor may place a new SUPPRELIN LA implant at this time to continue treatment.
- SUPPRELIN LA is placed under the skin of the inside of the upper arm. The doctor will numb the arm of your child, make a small cut, and then place the SUPPRELIN LA implant 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 after receiving the SUPPRELIN LA implant. The bandage can be removed after 24 hours. **Do not** remove any surgical strips. Surgical strips will fall off on their own in a few days.
- Your child should avoid heavy play or exercise that uses the arm where the implant was placed 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. The doctor will do regular exams and blood tests to check for signs of puberty.
- Sometimes the doctor will have to do special tests, such as an ultrasound, computed tomography (CT) scan, or magnetic resonance imaging (MRI) if the SUPPRELIN LA implant is hard to find under your child's skin.

What are the possible side effects of SUPPRELIN LA?
SUPPRELIN LA may cause serious side effects. See **"What is the most important information I should know about SUPPRELIN LA?"**

The most common side effect of SUPPRELIN LA includes skin reactions at the place where the implant is inserted. These reactions may include pain, redness, bruising, soreness, and swelling in and around the implant site. Call your child's doctor if your child has bleeding, redness, or severe pain where the implant was inserted.

These are not all the possible side effects of SUPPRELIN LA. **Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.**

What are the ingredients in SUPPRELIN LA?
Active ingredient: histrelin acetate

Inactive ingredients: stearic acid NF, hydrogel polymer reservoir composed of 2-hydroxyethyl methacrylate, 2-hydroxypropyl methacrylate, trimethylolpropane trimethacrylate, benzoin methyl ether, Perkadox-16, and Triton X-100

Manufactured for: Endo USA, Malvern, PA 19355, **www.endo.com or call 1-800-462-3636.**

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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