

GETTING STARTED WITH SUPPRELIN[®] LA



SUPPRELIN[®] LA
(histrelin acetate) subcutaneous implant

Please see Important Safety Information on pages 14-15 and full Prescribing Information for SUPPRELIN[®] LA at www.supprelinla.com.



ONCE-YEARLY

SUPPRELIN[®]LA

(histrelin acetate) subcutaneous implant



YOU'VE CHOSEN SUPPRELIN® LA, THE ONCE-YEARLY OPTION FOR TREATMENT OF CHILDREN WITH CENTRAL PRECOCIOUS PUBERTY (CPP)

Now that you and your child's doctor have determined that SUPPRELIN® LA (histrelin acetate) subcutaneous implant is right for your child, you may have some questions about how to get started and what you may expect from your child's treatment.

THIS BOOKLET PROVIDES HELPFUL INFORMATION ON:

- Treatment of CPP with SUPPRELIN LA—how it all works
- The SUPPRELIN LA Support Center—assistance with the treatment process
- Getting your child started on treatment—a time frame and checklist



INDICATION

- SUPPRELIN® LA (histrelin acetate) subcutaneous implant, is an under-the-skin (subcutaneous) implant that contains the medicine histrelin, a gonadotropin releasing hormone (GnRH). SUPPRELIN LA is used for treatment of children with central precocious puberty (CPP).

IMPORTANT SAFETY INFORMATION

- 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 the genital area in boys and girls. SUPPRELIN LA works by reducing the amount of sex hormones in the blood to delay early puberty.
- SUPPRELIN LA should not be used in children under 2 years of age or in women who are or may become pregnant. SUPPRELIN LA can cause birth defects or loss of the baby.
- Your child's doctor should do tests to make sure your child has CPP before treating your child with SUPPRELIN LA.





THE SUPPRELIN® LA IMPLANT

WHAT IS THE SUPPRELIN® LA IMPLANT?

The SUPPRELIN® LA (histrelin acetate) subcutaneous implant is a small, flexible tube that is made out of material similar to a soft contact lens. It is placed just under the skin of your child's inner upper arm. The implant is designed to deliver a continuous, steady flow of GnRH-agonist medicine called histrelin for 12 full months. Histrelin is known to lower sex hormone levels, which are elevated in children with CPP.

PUTTING IN THE SUPPRELIN® LA IMPLANT

The SUPPRELIN LA implant is usually inserted by a pediatric surgeon or a pediatric endocrinologist in a minor surgical procedure. The doctor will numb the area, make a small incision, and then place SUPPRELIN LA under the skin. After the implant is in place, the small incision may be closed with stitches or surgical strips and then covered with a bandage. Usually it is recommended that your child avoid heavy play and vigorous sports for one week following insertion of the SUPPRELIN LA implant.



SIDE EFFECTS WITH SUPPRELIN® LA

SUPPRELIN LA, like other GnRH agonists, may cause a temporary increase in sex hormones, which may cause more signs of puberty in your child during the first few weeks of treatment. Within 4 weeks of treatment, however, you should see signs that your child's puberty is stopping.

With SUPPRELIN LA, the most common side effects are skin reactions where the implant has been inserted. These could include bruising, soreness, tingling, itching, and swelling. They usually go away within 2 weeks. There could also be other side effects. Please see Important Safety Information on this page and pages 14-15. This information is not intended to replace the doctor's counseling.

IMPORTANT SAFETY INFORMATION

- 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 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.



TREATMENT WITH SUPPRELIN® LA

MONITORING YOUR CHILD'S PROGRESS

Your child may be asked to have blood tests a month after the SUPPRELIN® LA (histrelin acetate) subcutaneous implant has been inserted. After that, his or her progress will typically be checked every 6 months.

AFTER A YEAR

After a year, the implant needs to be removed. If you and the doctor decide to continue your child's treatment with SUPPRELIN LA, a new implant can be inserted—often in the same place.

THE LENGTH OF TREATMENT

Your child's doctor will recommend when it is the right time to end treatment so that your child's puberty can restart. It is usually about 11 years of age in girls and 12 years of age in boys.



IMPORTANT SAFETY INFORMATION

- 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.
- Serious and life-threatening allergic reactions have happened with GnRH medicines (the type of medicine in 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.

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

THE SUPPRELIN® LA SUPPORT CENTER

Completing all of the steps to start treatment with SUPPRELIN® LA (histrelin acetate) subcutaneous implant may be difficult without guidance. Further, some families may feel stress and strain due to out-of-pocket treatment costs.

Endo Pharmaceuticals, the maker of SUPPRELIN LA, has established the SUPPRELIN LA Support Center to provide assistance to help get treatment started.

THE SUPPRELIN® LA SUPPORT CENTER SERVICES INCLUDE:

- Assistance with verification of insurance coverage
- Clarifying deductibles and co-pay for treatment and procedures
- Information to eligible families on the SUPPRELIN LA SHARES Program, a financial support program
- Assistance with general reimbursement questions
- Coordination of the SUPPRELIN LA shipment directly to the procedure center identified by your doctor



8 CONTACT THE SUPPRELIN® LA SUPPORT CENTER WITH ANY QUESTIONS DURING ANY PART OF THIS PROCESS AT (1-855-270-0123)

THE SUPPRELIN® LA GUIDE TO GETTING STARTED

The following is an estimated timeline* and checklist to guide you through the steps you'll need to take to arrange for the SUPPRELIN® LA implant insertion procedure, followed by what to do after the procedure. You can use this guide to keep track of where you are in the process and what you will need to do next. In addition, this guide is a good place to record appointments and other important dates and milestones along the way.

FOLLOWING TODAY'S APPOINTMENT:

The SUPPRELIN LA Support Center will need to receive a signed Service Request Enrollment (SRE) form from your child's doctor. This form serves as a "letter of medical necessity," which verifies that your child is eligible to receive SUPPRELIN LA.

- I have confirmed with the doctor's office that they have submitted the SRE form to the Support Center.

The SUPPRELIN LA Support Center may require a signed Patient Authorization Form (PAF) in order to begin the process. Please call the Support Center ([1-855-270-0123](tel:1-855-270-0123)) to determine if this applies to you.

*The time frames mentioned may vary.

Please see Important Safety Information on pages 14-15 and full Prescribing Information for SUPPRELIN® LA at www.supprelinla.com.



WITHIN 1 TO 2 BUSINESS DAYS OF RECEIPT OF SRE FORM AND PAF:

Once the SUPPRELIN® LA Support Center receives the SRE form and the PAF, your child's case will be assigned to a representative who will contact you to review steps, process, and timeline.

- The SUPPRELIN LA Support Center has contacted me to review steps, process, and timeline.

WITHIN 2 TO 5 BUSINESS DAYS:

The SUPPRELIN LA Support Center will verify your child's benefits and coverage details with your insurance company, including any necessary prior authorizations, and then contact you to provide an update.

- The Support Center has contacted me to explain my child's benefits to me.

The Support Center will determine whether SUPPRELIN® LA (histrelin acetate) subcutaneous implant will be shipped directly to the doctor or obtained through a specialty pharmacy.

A specialty pharmacy handles special types of medications such as SUPPRELIN LA. If a specialty pharmacy is involved, the Support Center will forward them the SRE form. It is very important that you return all phone calls from a specialty pharmacy.

- I have confirmed with the Support Center how SUPPRELIN LA will be shipped.

WITHIN 7 TO 10 BUSINESS DAYS:

If the hospital/medical center will acquire the product directly, SUPPRELIN® LA will be delivered directly to the hospital/medical center.

If a specialty pharmacy is involved, they will coordinate shipment of SUPPRELIN LA to the hospital/medical center. Before shipping, the specialty pharmacy will contact you to review your financial responsibilities, discuss co-pay options, and receive your approval to ship SUPPRELIN LA.

If applicable, the specialty pharmacy has contacted me to discuss financial issues and receive shipping approval.

The SUPPRELIN LA Support Center may contact you regarding the SUPPRELIN LA SHARES program, a financial support program available for eligible patients who need assistance paying for SUPPRELIN LA.

If applicable, the Support Center has contacted me to discuss the SUPPRELIN LA SHARES program.

Once financial and shipping matters are addressed, contact the doctor's office or hospital/medical center to schedule the SUPPRELIN LA implant insertion procedure.

I have scheduled the implant insertion procedure.

Insertion procedure date and location

Once the procedure date is set, contact the SUPPRELIN LA Support Center to let them know the procedure date.

I have informed the Support Center of the procedure date.

WITHIN 2 TO 10 DAYS PRIOR TO PROCEDURE:

If a specialty pharmacy is involved, SUPPRELIN® LA will be delivered to the hospital/medical center where the implant will be inserted.

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AFTER THE IMPLANT INSERTION PROCEDURE

Following the SUPPRELIN® LA (histrelin acetate) subcutaneous implant insertion procedure, the doctor may want to schedule a follow-up appointment to assess your child's condition.

I have scheduled a follow-up appointment with the doctor.

Follow-up appointment date and location

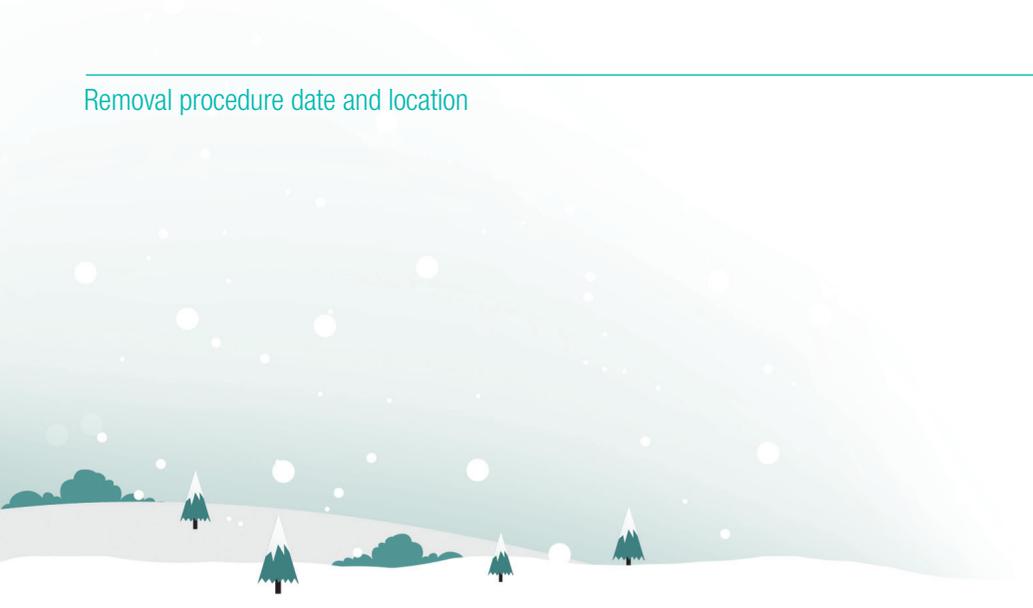
WITHIN 12 MONTHS OF THE IMPLANT INSERTION PROCEDURE

After 12 months, SUPPRELIN® LA must be removed.

Prior to 12 months, contact the doctor's office to schedule an appointment to have the SUPPRELIN LA implant removed. Depending on what you and the doctor decide, he or she may insert a new SUPPRELIN LA implant at this time to continue treatment.

I have contacted the doctor's office to schedule the implant removal procedure.

Removal procedure date and location



IMPORTANT INFORMATION

FILL IN RELEVANT INFORMATION AND KEEP THIS GUIDE WITH YOU.

Doctor

Phone number

Address/Location

Specialty Pharmacy Contact

Phone number

Address/Location

**PATIENT AUTHORIZATION FORM (PAF) AND FULL PRESCRIBING
INFORMATION ARE LOCATED AT WWW.SUPPRELINLA.COM**

Insertion procedure date and location

Follow-up appointment date and location

Removal procedure date and location

Comments

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**You are encouraged to report negative side effects of prescription drugs to the FDA.
Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.**



Rx Only

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