Welcome to the LUPRON DEPOT-PED[®] Support PLUS Program

Designed for your child-and you

We are committed to helping you and your child understand LUPRON DEPOT-PED treatment, answering your questions, and supporting you throughout your child's prescribed treatment.

Starting a new medication can raise a lot of questions. That's why we are here to help you along the way.

With LUPRON Support PLUS you can expect:



Help with navigating your insurance coverage



Assistance with identifying possible ways to save on your child's medicine



Live nurse support*



Answers to your questions about LUPRON DEPOT-PED



Scan the QR Code to download the Getting Started Brochure

Contact **Support PLUS**, toll-free, at **1-855-LUPRON-P (1-855-587-7667)**, Monday through Friday, 7 AM-7 PM CT.

*Certified nurses are provided by AbbVie and do not work under the direction of your healthcare professional (HCP) or give medical advice. They are trained to direct patients to their HCP for treatment-related advice, including further referrals.

For more information about AbbVie's privacy practices and your privacy choices, visit https://abbvie/corpprivacy

Please see Use and Important Safety Information on page 2.

Please click here for <u>Consumer Brief Summary</u> or visit <u>https://www.rxabbvie.com/pdf/lupronpediatric.pdf</u> for full Prescribing Information.



USE AND IMPORTANT SAFETY INFORMATION

Use for LUPRON DEPOT-PED® (leuprolide acetate for depot suspension)

LUPRON DEPOT-PED 7.5 mg, 11.25 mg, and 15 mg for 1-month, 11.25 mg and 30 mg for 3-month, and 45 mg for 6-month administration are prescribed for the treatment of children with central precocious puberty (CPP).

It is not known if LUPRON DEPOT-PED is safe and effective in children less than 1 year old.

Important Safety Information for LUPRON DEPOT-PED

What is the most important information I should know about LUPRON DEPOT-PED?

- During the first 2 to 4 weeks of treatment, LUPRON DEPOT-PED can cause an increase in some hormones. During this time, you may notice more signs of puberty in your child, including vaginal bleeding. Call your child's doctor if these signs continue after the second month of treatment with LUPRON DEPOT-PED.
- Some people taking gonadotropin-releasing hormone (GnRH) agonists like LUPRON DEPOT-PED have had new or worsened mental (psychiatric) problems. Mental (psychiatric) problems may include emotional symptoms such as:
- Crying Anger
- Irritability Acting aggressive
- Restlessness (impatience)

Call your child's doctor right away if your child has any new or worsening mental symptoms or problems while taking LUPRON DEPOT-PED.

- Some people taking GnRH agonists like LUPRON DEPOT-PED 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 LUPRON DEPOT-PED.

- Increased pressure in the fluid around the brain can happen in children taking gonadotropin-releasing hormone (GnRH) agonist medicines, including LUPRON DEPOT-PED. Call your child's doctor right away if your child has any of the following symptoms during treatment with LUPRON DEPOT-PED:
 - Headache
 - Eye problems including blurred vision, double vision, and decreased eyesight
 - Eye pain
 - Ringing in the ears
 - Dizziness
 - Nausea

LUPRON DEPOT-PED should not be taken if your child is:

- Allergic to GnRH, GnRH agonist medicines, or any ingredients in LUPRON DEPOT-PED. See the end of the Medication Guide for a complete list of ingredients in LUPRON DEPOT-PED.
- Pregnant or becomes pregnant. LUPRON DEPOT-PED can cause birth defects or loss of the baby. If your child becomes pregnant, call your child's doctor.

Before your child receives LUPRON DEPOT-PED, tell their doctor about all of your child's medical conditions, including if they:

- Have a history of mental (psychiatric) problems
- Have a history of seizures

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Please click here for <u>Consumer Brief Summary</u> or visit <u>https://www.rxabbvie.com/pdf/lupronpediatric.pdf</u> for full Prescribing Information.

- 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)
- Are breastfeeding or plan to breastfeed. It is not known if LUPRON DEPOT-PED passes into the breast milk

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

How will your child receive LUPRON DEPOT-PED?

- Your child's doctor should do tests to make sure your child has CPP before treating them with LUPRON DEPOT-PED.
- LUPRON DEPOT-PED is given as a single-dose injection into your child's muscle each month, every 3 months, or every 6 months by a doctor or trained nurse. Your child's doctor will decide how often your child will receive the injection.
- Keep all scheduled visits to the doctor. If a scheduled dose is missed, your child
 may start having signs of puberty again. The doctor will do regular exams and
 blood tests to check for signs of puberty.

What are the possible side effects of LUPRON DEPOT-PED?

LUPRON DEPOT-PED may cause serious side effects. See "What is the most important information I should know about LUPRON DEPOT-PED?"

- The most common side effects of LUPRON DEPOT-PED received 1 time each month include:
- Injection site reactions such as pain, swelling, and abscess
- Weight gain
 - Pain throughout body
 - Headache
 - Acne or red, itchy rash and white scales (seborrhea)
 - Serious skin rash (erythema multiforme)
 - Mood changes
 - Swelling of vagina (vaginitis), vaginal bleeding, and vaginal discharge
 - The most common side effects of LUPRON DEPOT-PED received every 3 months include:
 - Injection site reactions such as pain and swelling
 - Weight gain Headache Mood changes
 - The most common side effects of LUPRON DEPOT-PED received every 6 months include:
 - Injection site reactions such as pain, swelling, and abscess
 - Headache
 Fever
 Weight gain

 Mood changes
 Itching
 Fracture

 Upper stomach pain
 Pain in extremities
 Breast tenderness
 - Diarrhea
 Rash
 Difficulty sleeping

 Bleeding
 Back pain
 Chest pain
 - Ligament sprain Excessive sweating

These are not all the possible side effects of LUPRON DEPOT-PED. Call your child's doctor for medical advice about side effects.

This is the most important information to know about LUPRON DEPOT-PED. For more information, talk to your child's doctor or healthcare provider.

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

If you are having difficulty paying for your medicine, AbbVie may be able to help. Visit <u>AbbVie.com/myAbbVieAssist</u> to learn more.



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Nausea and vomiting

1. Please fax the completed form to Support PLUS at 1-866-866-0325. 2. Give patient's parent/legal guardian the attached Support PLUS Welcome sheet.

PATIENT INFORMATION* To be completed by the parent or legal guardian. Please print clearly. All fields marked with an asterisk (*) are required.				
*First name:	*Last name:		*Date of birth:	/ / month/date/year
Gender: 🗆 M 🛛 🛛 F	Check here if an interpreter is needed	Preferred language:		
Name of patient's parent or legal	guardian:	Relationship to	patient:	
*Preferred phone number:	Email address:			
*Address:	*City:	*State:	*ZIF)

For information on how we collect and process your personal data, including the categories we collect, purposes for their collection, and disclosures to third parties, visit <u>https://abbv.ie/PrivacyPatient</u>.

Through my submission of the LUPRON DEPOT-PED Support PLUS Enrollment Form, I consent to the collection, use, and disclosure of my personal health data, as described in the Privacy Notice above and in AbbVie's Privacy Notice in the "<u>How We May Disclose Personal</u> <u>Data</u>" section. My consent is required to process sensitive personal data under certain privacy laws, and I have the right to withdraw my consent by visiting "<u>Your Privacy Choices</u>" on AbbVie's website.

2 INSURANCE INFORMATION*				
Primary Insurance:		Secondary Insurance:		
Policyholder Name:	DOB:	Policyholder Name:	DOB:	
Prescription Insurance:		Prescription Insurance:		
Rx Group #:	Rx ID #:	Rx Group #:	Rx ID #:	
Rx BIN:	Rx PCN:	Rx BIN:	Rx PCN:	
Phone:		Phone:		

▼ TO BE COMPLETED BY A HEALTHCARE PROFESSIONAL ONLY ▼

3 PRESCRIBER INFORMATION* To be completed by the prescriber.		
*Prescriber Name:	_*NPI:	*Office Contact Name:
Address:	_ City:	State: ZIP:
*Phone:	Extension:	_*Fax:

Important Information

By submitting this form, you are referring the above patient to AbbVie's patient support program to determine eligibility and receive support related to an AbbVie product. Please share this information with your patient.

For information on how we collect and process your personal data, including the categories we collect, purposes for their collection, and disclosures to third parties visit <u>https://abbv.ie/PrivacyHCP</u>.

Please see Indication and Important Safety Information on page 4. Please click here for full Prescribing Information.



PRESCRIPTION AND PHARMACY INFORMATION* Required for prescriptions only.						
Patient First Name:	Patient Last Name:	_ Patient Date of Birth:	/ / month/date/year			
LUPRON DEPOT-PED PRESCRIPTION	New Restart Continuing (start date:)					
SHIPPING PREFERENCE Date Needed:	Deliver medication to: 🛛 Prescriber	Deatient				
CENTRAL PRECOCIOUS PUBERTY						
LUPRON DEPOT-PED 7.5 mg (1-month supply)	Sig: Administer IM once a month	#1 kit	Refills:			
LUPRON DEPOT-PED 11.25 mg (1-month supply)	Sig: Administer IM once a month	#1 kit	Refills:			
LUPRON DEPOT-PED 15 mg (1-month supply)	Sig: Administer IM once a month	#1 kit	Refills:			
LUPRON DEPOT-PED 11.25 mg (3-month supply)	Sig: Administer IM once every 3 months	#1 kit	Refills:			
LUPRON DEPOT-PED 30 mg (3-month supply)	Sig: Administer IM once every 3 months	#1 kit	Refills:			
LUPRON DEPOT-PED 45 mg (6-month supply)	Sig: Administer IM once every 6 months	#1 kit	Refills:			
DIAGNOSIS FOR WHICH LUPRON DEPOT-PED IS BEING PRESCRIBED						
Primary Diagnosis: 🛛 ICD-10: <u>E22.8</u> 🔲 ICD-10: <u>E30.1</u> 🔲 ICD-10: <u>E30.9</u> 🗌 Other ICD-10:						
Date of Diagnosis: Date of Onset of Secondary Sexual Characteristics:						
□ I DO <u>NOT</u> WANT LUPRON DEPOT-PED DISPENSED AT T	HIS TIME. PLEASE ONLY VERIFY THE FOLLOWING BE.	NEFITS:				
Patient's coverage through pharmacy/medical benefit Patient's coverage through buy/bill						
Patient Preferred Pharmacy:						

PRESCRIBER SIGNATURE: Prescriber must manually sign (rubber stamps, signature by other office personnel for the prescriber, and computer-generated signatures will not be accepted). I certify that I complied with the Health Insurance Portability and Accountability Act of 1996 and relevant state privacy laws in submitting the patient information described in this Enrollment Form.

Dispense as written/do not substitute.	Date
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I request Health Plans and Pharmacy Benefits Managers (PBMs) provide patient benefit information and the necessary prior authorization forms to RxCrossroads, and authorize plans and PBMs to do so if the plan or PBM requires such authorization. LUPRON DEPOT-PED Support **PLUS** is an AbbVie-sponsored program that provides personalized patient support ("LUPRON DEPOT-PED Support **PLUS**").

INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION¹

Central Precocious Puberty

LUPRON DEPOT-PED[®] (leuprolide acetate for depot suspension) 7.5 mg, 11.25 mg, and 15 mg for 1-month, 11.25 mg and 30 mg for 3-month, and 45 mg for 6-month administration are indicated for the treatment of pediatric patients with central precocious puberty (CPP).

IMPORTANT SAFETY INFORMATION¹

CONTRAINDICATIONS

- Hypersensitivity to gonadotropin-releasing hormone (GnRH), GnRH agonists, or any of the excipients in LUPRON DEPOT-PED. Anaphylactic reactions to synthetic GnRH or GnRH agonists have been reported.
- Pregnancy: LUPRON DEPOT-PED may cause fetal harm.

WARNINGS AND PRECAUTIONS Initial Rise of Gonadotropins and Sex Steroid Levels

 During the early phase of therapy or after subsequent doses, gonadotropins and sex steroids may rise above baseline because of the initial stimulatory effect of the drug. Therefore, an increase in clinical signs and symptoms of puberty, including vaginal bleeding, may be observed during the first weeks of therapy or after subsequent doses.

Psychiatric Events

- Psychiatric events have been reported in patients taking GnRH agonists, including LUPRON DEPOT-PED.
 Postmarketing reports with this class of drugs include symptoms of emotional lability, such as crying, irritability, impatience, anger, and aggression. Monitor for development or worsening of psychiatric symptoms during treatment.
 Convulsions
- Postmarketing reports of convulsions have been observed in patients receiving GnRH agonists, including LUPRON DEPOT-PED. These included patients with a history of seizures, epilepsy, cerebrovascular disorders, central nervous system anomalies or tumors, and patients on concomitant medications that have been associated with convulsions, such as bupropion and SSRIs. Convulsions have also been reported in patients in the absence of any of the conditions mentioned above.

Pseudotumor Cerebri (Idiopathic Intracranial Hypertension)

 Pseudotumor cerebri (idiopathic intracranial hypertension) have been reported in pediatric patients receiving GnRH agonists, including LUPRON DEPOT-PED. Monitor patients for signs and symptoms of pseudotumor cerebri, including headache, papilledema, blurred vision, diplopia, loss of vision, pain behind the eye or pain with eye movement, tinnitus, dizziness, and nausea.

ADVERSE REACTIONS

- The most common (≥2%) adverse reactions in clinical studies with LUPRON DEPOT-PED 7.5 mg, 11.25 mg, and 15 mg for 1-month administration were: injection site reactions including abscess, emotional lability, acne/seborrhea, vaginitis/vaginal bleeding/vaginal discharge, pain, rash including erythema multiforme, headache, and vasodilation.
- The most common ≥2%) adverse reactions in clinical studies with LUPRON DEPOT-PED 11.25 mg and 30 mg for 3-month administration were: injection site pain, increased weight, headache, altered mood, and injection site swelling.
- The most common (≥4%) adverse reactions in clinical studies with LUPRON DEPOT-PED 45 mg for 6-month administration were: injection site reactions, headache, psychiatric events, abdominal pain, diarrhea, hemorrhage, nausea and vomiting, pyrexia, pruritus, pain in extremities, rash, back pain, ligament sprain, increased weight, fracture, breast tenderness, insomnia, chest pain, and hyperhidrosis.
- Diagnostic tests of pituitary gonadotropic and gonadal functions conducted during treatment and up to 6 months after discontinuation may be affected.
- The safety and effectiveness of LUPRON DEPOT-PED have not been established in pediatric patients less than 1 year old.
- LUPRON DEPOT-PED must be administered by a healthcare professional.

Reference: 1. LUPRON DEPOT-PED [package insert]. North Chicago, IL: AbbVie Inc.

LUPRON DEPOT-PED®

(leuprolide acetate for depot suspension)

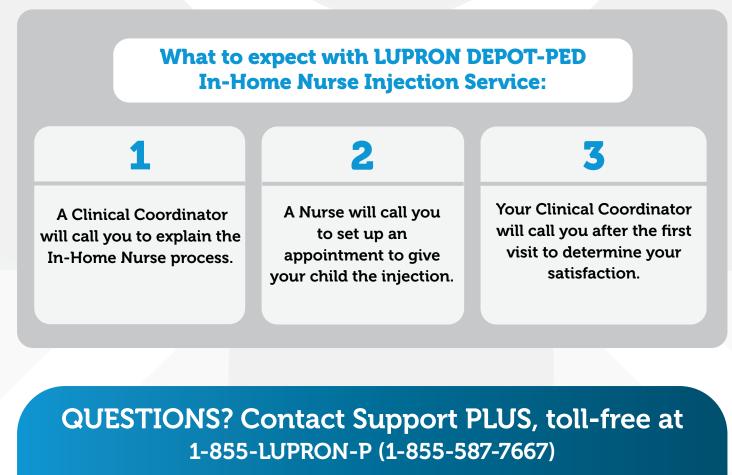
Please click here for full <u>Prescribing Information</u>.



Welcome to the LUPRON DEPOT-PED® Support PLUS In-Home Nurse* Injection Service

Designed for your child—and you

We are committed to helping you and your child receive the LUPRON DEPOT-PED Injection and supporting you throughout your child's treatment.



Monday through Friday: 7 AM - 7 PM CT.

*Support PLUS is provided by AbbVie and nurses under the Support PLUS program do not work under the direction of your healthcare professional (HCP) or give medical advice. Nurses are trained to direct patients to their HCP for treatment-related advice, including further referrals.

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Please see Use and Important Safety Information on page 6.

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USE AND IMPORTANT SAFETY INFORMATION

Use for LUPRON DEPOT-PED® (leuprolide acetate for depot suspension)

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It is not known if LUPRON DEPOT-PED is safe and effective in children less than 1 year old.

Important Safety Information for LUPRON DEPOT-PED

What is the most important information I should know about LUPRON DEPOT-PED?

- During the first 2 to 4 weeks of treatment, LUPRON DEPOT-PED can cause an increase in some hormones. During this time, you may notice more signs of puberty in your child, including vaginal bleeding. Call your child's doctor if these signs continue after the second month of treatment with LUPRON DEPOT-PED.
- Some people taking gonadotropin-releasing hormone (GnRH) agonists like LUPRON DEPOT-PED have had new or worsened mental (psychiatric) problems. Mental (psychiatric) problems may include emotional symptoms such as:
 - Crying Anger
 - Irritability Acting aggressive
 - Restlessness (impatience)

Call your child's doctor right away if your child has any new or worsening mental symptoms or problems while taking LUPRON DEPOT-PED.

- Some people taking GnRH agonists like LUPRON DEPOT-PED 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 LUPRON DEPOT-PED.

- Increased pressure in the fluid around the brain can happen in children taking gonadotropin-releasing hormone (GnRH) agonist medicines, including LUPRON DEPOT-PED. Call your child's doctor right away if your child has any of the following symptoms during treatment with LUPRON DEPOT-PED:
 - Headache
 - Eye problems including blurred vision, double vision, and decreased eyesight
 - Eye pain
 - Ringing in the ears
 - Dizziness
 - Nausea

LUPRON DEPOT-PED should not be taken if your child is:

- Allergic to GnRH, GnRH agonist medicines, or any ingredients in LUPRON DEPOT-PED. See the end of the Medication Guide for a complete list of ingredients in LUPRON DEPOT-PED.
- Pregnant or becomes pregnant. LUPRON DEPOT-PED can cause birth defects or loss of the baby. If your child becomes pregnant, call your child's doctor.

Before your child receives LUPRON DEPOT-PED, tell their doctor about all of your child's medical conditions, including if they:

- · Have a history of mental (psychiatric) problems
- · Have a history of seizures

Please click here for <u>Consumer Brief Summary</u> or visit https://www.rxabbvie.com/pdf/lupronpediatric.pdf for full Prescribing Information.

- 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)
- Are breastfeeding or plan to breastfeed. It is not known if LUPRON DEPOT-PED passes into the breast milk

Tell your child's doctor about all the medicines your child takes, including prescription and over-the-counter medicines, vitamins, and herbal supplements. **How will your child receive LUPRON DEPOT-PED?**

Your child's doctor should do tests to make sure your child has CPP before

- Your child's doctor should do tests to make sure your child has CPP before treating them with LUPRON DEPOT-PED.
- LUPRON DEPOT-PED is given as a single-dose injection into your child's muscle each month, every 3 months, or every 6 months by a doctor or trained nurse. Your child's doctor will decide how often your child will receive the injection.
- Keep all scheduled visits to the doctor. If a scheduled dose is missed, your child
 may start having signs of puberty again. The doctor will do regular exams and
 blood tests to check for signs of puberty.

What are the possible side effects of LUPRON DEPOT-PED?

LUPRON DEPOT-PED may cause serious side effects. See "What is the most important information I should know about LUPRON DEPOT-PED?"

- The most common side effects of LUPRON DEPOT-PED received 1 time each month include:
- Injection site reactions such as pain, swelling, and abscess
- Weight gain
- Pain throughout body
- Headache

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- Acne or red, itchy rash and white scales (seborrhea)
- Serious skin rash (erythema multiforme)
- Mood changes
- Swelling of vagina (vaginitis), vaginal bleeding, and vaginal discharge
- The most common side effects of LUPRON DEPOT-PED received every 3 months include:
- Injection site reactions such as pain and swelling
- Weight gain Headache Mood changes
- The most common side effects of LUPRON DEPOT-PED received every 6 months include:
- Injection site reactions such as pain, swelling, and abscess
- Headache Fever Weight gain
 - Mood changes Itching Fracture
- Upper stomach pain
 Pain in extremities
 Breast tenderness
 Diarrhea
 Rash
 Difficulty sleeping
 Bleeding
 Back pain
 Chest pain
- Nausea and vomiting Ligament sprain Excessive sweating

These are not all the possible side effects of LUPRON DEPOT-PED. Call your child's doctor for medical advice about side effects.

This is the most important information to know about LUPRON DEPOT-PED. For more information, talk to your child's doctor or healthcare provider. You are encouraged to report negative side effects of prescription drugs to

the FDA. Visit <u>www.fda.gov/medwatch</u> or call 1-800-FDA-1088.

If you are having difficulty paying for your medicine, AbbVie may be able to help. Visit <u>AbbVie.com/myAbbVieAssist</u> to learn more.

The LUPRON Support PLUS **In-Home Nurse Injection Service*** requires a physician recommendation and a signed Parent/Legal Guardian Authorization to begin the process. Please fax signed form to 1-866-866-0325. For questions, call toll-free at 1-855-587-7667.

TO BE COMPLETED BY PARENT/LEGAL GUARDIAN

Your child's doctor has prescribed LUPRON DEPOT-PED® therapy and recommended the In-Home Nurse Injection Service.

Patient Name (last):	(first):	Date of Birth:	/ / month/date/year	Gender: 🗆 M	٦F
Address:	City/State/ZIP:				

Parent/Legal Guardian Name: _

__ Relationship to Patient: _____

Phone:

□ I agree to enroll my child identified above in the Support PLUS In-Home Nurse Injection Service*.

Please read and consent to full HIPAA Authorization disclosure on the next page.

For information on how we collect and process your personal data, including the categories we collect, purposes for their collection, and disclosures to third parties, visit <u>https://abbv.ie/PrivacyPatient</u>.

Through my submission of the LUPRON DEPOT-PED Support PLUS In-Home Nurse Injection Service Authorization Form, I consent to the collection, use, and disclosure of my personal health data, as described in the Privacy Notice above and in AbbVie's Privacy Notice in the "How <u>We May Disclose Personal Data</u>" section. My consent is required to process sensitive personal data under certain privacy laws, and I have the right to withdraw my consent by visiting "<u>Your Privacy Choices</u>" on AbbVie's website.

My signature certifies that I have read, understood, and agree to the release of my Protected Health Information pursuant to the Authorization on the next page.

*Support PLUS is provided by AbbVie and nurses under the Support PLUS program do not work under the direction of your healthcare professional (HCP) or give medical advice. Nurses are trained to direct patients to their HCP for treatment-related advice, including further referrals.

Parent/Legal Guardian Signature		Date
TO BE COMPLETED BY A HEALTHCARE PROFESSIONAL		
Practitioner Name (last):	_ (first):	
Address:		City/State/ZIP:
Office Contact Phone:		_ Office Contact Fax:

The patient above is at risk of abandoning the course of therapy I have prescribed without the use of the LUPRON DEPOT-PED In-Home Nurse Injection Service. Patient Case # _____

I, [Physician/Practitioner] _________, hereby authorize the patient to participate in the LUPRON DEPOT-PED In-Home Nurse Injection Service managed by Support PLUS. I understand that the intent of this Service is to provide intramuscular (IM) injections of LUPRON DEPOT-PED at the dose prescribed by me in my patient's home by a nurse trained in administering IM injections to ensure that my patient remains on the prescribed therapy. I acknowledge that I, or a healthcare professional operating under my supervision and at my direction, have administered or will administer to the patient the first injection of LUPRON DEPOT-PED prior to the patient's participation in the Service. I further acknowledge that the patient's participation in this Service is done at my request, and that the administration of the IM injection and overall Service is performed at all times under my supervision. I may terminate at any time my patient's participation in the Service by contacting Support PLUS at 1-855-587-7667. I further acknowledge that all treatment decisions regarding LUPRON DEPOT-PED (including my decision to prescribe LUPRON DEPOT-PED and/or to change the prescribed dose) are made based upon my independent clinical judgment. I further acknowledge that my participation in this Service is not intended to influence my prescribing decisions. I will not seek compensation or reimbursement of any kind for the services performed by or through the Service.

Physician Signature	Date	
THERAPY DETAILS AND PHARMACY INFORMATION*		

LUPRON DEPOT-PED PRESCRIPTION New Restart Continuing Date of last injection: ______ Injection site location: _____

Date to start In-Home Nurse Injection Service:

Important Information

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Please see Indication and Important Safety Information on page 8.

Please click here for full <u>Prescribing Information</u>.

HIPAA Authorization

I authorize my healthcare providers and staff, health plan, and pharmacies (collectively, my "Healthcare Providers") to disclose individually identifiable information about me, my health or condition(s), treatment and care that I have received, my insurance coverage, my payment information, and my medication history and prescriptions (collectively, "Protected Health Information") to AbbVie Inc. and/or its designated affiliates, agents, representatives, and service providers (collectively, "AbbVie") in order for AbbVie to (i) enroll me in, provide, operate, and administer the Support PLUS Program ("Program"); (ii) provide me with information concerning the Program; and (iii) develop, evaluate, and improve products, services, materials, and programs related to my condition or treatment. I understand that Protected Health Information disclosed to AbbVie under this Authorization will no longer be protected by HIPAA and may be subject to redisclosure by AbbVie. I understand that I am not required to sign this Authorization and that my Healthcare Providers will not otherwise condition my treatment, payment, health insurance enrollment, or eligibility for healthcare benefits to which I am otherwise entitled on whether I sign this Authorization. However, I understand that if I do not sign this Authorization, I cannot take part in the Program, I understand that this Authorization will expire once I am no longer participating in the Program, unless I cancel it sooner. I understand that I may cancel this Authorization at any time by making a data subject rights request at **https://abbviemetadata.my.site.com/AbbvieDSRM** or by writing to privacydsr@abbvie.com. However, I understand that if I cancel this Authorization, it will end my enrollment in the Program. I understand that canceling this Authorization will not affect any use or disclosure of my Protected Health Information that has already taken place in reliance on this Authorization.

Note: You have a right to receive a copy of this Authorization. You may print a copy of or save this Authorization and retain a copy for your records.

INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION¹

Central Precocious Puberty

LUPRON DEPOT-PED[®] (leuprolide acetate for depot suspension) 7.5 mg, 11.25 mg, and 15 mg for 1-month, 11.25 mg and 30 mg for 3-month, and 45 mg for 6-month administration are indicated for the treatment of pediatric patients with central precocious puberty (CPP).

IMPORTANT SAFETY INFORMATION¹

CONTRAINDICATIONS

- Hypersensitivity to gonadotropin-releasing hormone (GnRH), GnRH agonists, or any of the excipients in LUPRON DEPOT-PED. Anaphylactic reactions to synthetic GnRH or GnRH agonists have been reported.
- Pregnancy: LUPRON DEPOT-PED may cause fetal harm.

WARNINGS AND PRECAUTIONS

Initial Rise of Gonadotropins and Sex Steroid Levels

 During the early phase of therapy or after subsequent doses, gonadotropins and sex steroids may rise above baseline because of the initial stimulatory effect of the drug. Therefore, an increase in clinical signs and symptoms of puberty, including vaginal bleeding, may be observed during the first weeks of therapy or after subsequent doses.

Psychiatric Events

 Psychiatric events have been reported in patients taking GnRH agonists, including LUPRON DEPOT-PED. Postmarketing reports with this class of drugs include symptoms of emotional lability, such as crying, irritability, impatience, anger, and aggression. Monitor for development or worsening of psychiatric symptoms during treatment.

Convulsions

 Postmarketing reports of convulsions have been observed in patients receiving GnRH agonists, including LUPRON DEPOT-PED. These included patients with a history of seizures, epilepsy, cerebrovascular disorders, central nervous system anomalies or tumors, and patients on concomitant medications that have been associated with convulsions, such as bupropion and SSRIs. Convulsions have also been reported in patients in the absence of any of the conditions mentioned above.

Pseudotumor Cerebri (Idiopathic Intracranial Hypertension)

 Pseudotumor cerebri (idiopathic intracranial hypertension) have been reported in pediatric patients receiving GnRH agonists, including LUPRON DEPOT-PED. Monitor patients for signs and symptoms of pseudotumor cerebri, including headache, papilledema, blurred vision, diplopia, loss of vision, pain behind the eye or pain with eye movement, tinnitus, dizziness, and nausea.

ADVERSE REACTIONS

- The most common (≥2%) adverse reactions in clinical studies with LUPRON DEPOT-PED 7.5 mg, 11.25 mg, and 15 mg for 1-month administration were: injection site reactions including abscess, emotional lability, acne/seborrhea, vaginitis/vaginal bleeding/vaginal discharge, pain, rash including erythema multiforme, headache, and vasodilation.
- The most common (≥2%) adverse reactions in clinical studies with LUPRON DEPOT-PED 11.25 mg and 30 mg for 3-month administration were: injection site pain, increased weight, headache, altered mood, and injection site swelling.
- The most common (≥4%) adverse reactions in clinical studies with LUPRON DEPOT-PED 45 mg for 6-month administration were: injection site reactions, headache, psychiatric events, abdominal pain, diarrhea, hemorrhage, nausea and vomiting, pyrexia, pruritus, pain in extremities, rash, back pain, ligament sprain, increased weight, fracture, breast tenderness, insomnia, chest pain, and hyperhidrosis.
- Diagnostic tests of pituitary gonadotropic and gonadal functions conducted during treatment and up to 6 months after discontinuation may be affected.
- The safety and effectiveness of LUPRON DEPOT-PED have not been established in pediatric patients less than 1 year old.
- LUPRON DEPOT-PED must be administered by a healthcare professional.

Reference: 1. LUPRON DEPOT-PED [package insert]. North Chicago, IL: AbbVie Inc.





Please click here for full <u>Prescribing Information</u>.