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

LUPRON DEPOT-PED GUIDE FOR NURSES

An in-depth educational resource made specifically for nurses. Use this brochure to further understand Central Precocious Puberty (CPP) and the role of LUPRON DEPOT-PED in preparation for conversations with caregivers of children who have CPP. When speaking with caregivers, use the appropriate LUPRON DEPOT-PED resource to enhance your discussion.

What's inside:

INDICATION

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).

SAFETY CONSIDERATIONS

• LUPRON DEPOT-PED is contraindicated in patients who are hypersensitive to gonadotropin-releasing hormone (GnRH), GnRH agonists, or any of the product excipients or in females who are or may become pregnant during treatment, as LUPRON DEPOT-PED may cause fetal harm. • Increased clinical signs and symptoms of puberty, including vaginal bleeding, may occur during the first weeks of drug therapy or after subsequent doses. • Psychiatric events have been reported in patients taking GnRH agonists, including LUPRON DEPOT-PED. Postmarketing reports include symptoms of emotional lability, such as crying, irritability, impatience, anger, and aggression. Monitor for development or worsening of psychiatric symptoms during treatment. • Convulsions have been observed postmarketing in patients taking GnRH agonists, including LUPRON DEPOT-PED, with or without a history of seizures, epilepsy, cerebrovascular disorders, central nervous system anomalies or tumors, and in patients on concomitant medications that have been associated with convulsions, such as bupropion and selective serotonin reuptake inhibitors (SSRIs). Convulsions have also been reported in patients in the absence of any of the conditions mentioned above. • 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. • Diagnostic tests of pituitary gonadotropic and gonadal functions may be affected when conducted during treatment and up to 6 months after discontinuation.

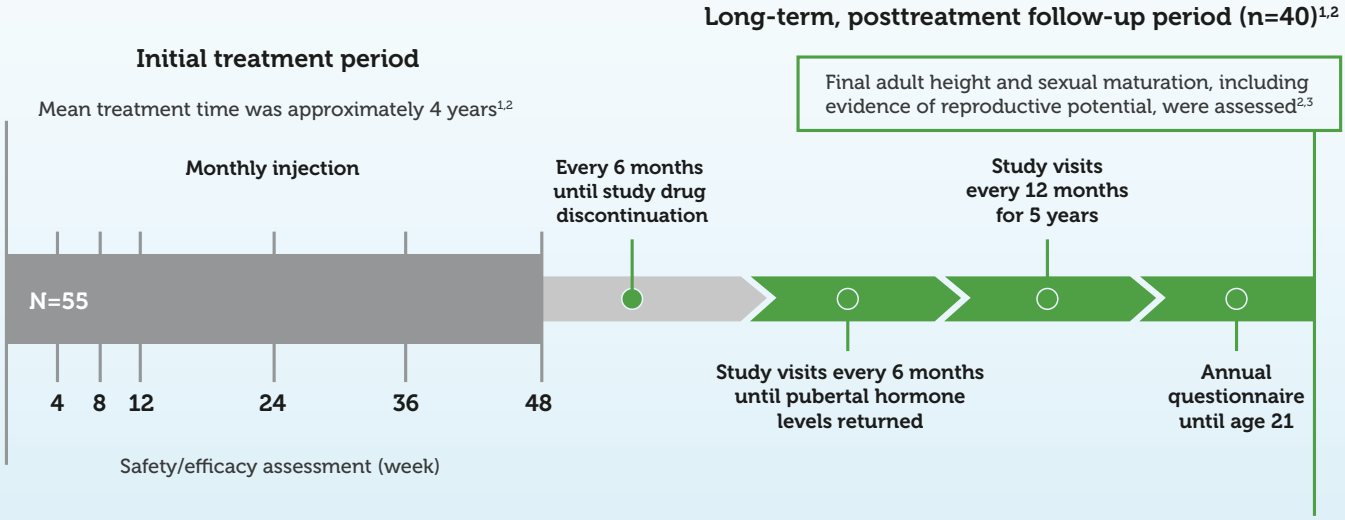
Please see Important Safety Information throughout.

Please see accompanying full Prescribing Information or visit https://www.rxabbvie.com/pdf/lupronpediatric.pdf.

1-MONTH LUPRON DEPOT-PED DEMONSTRATED SUSTAINED, REVERSIBLE SUPPRESSION AND IS THE ONLY CPP TREATMENT WITH FOLLOW-UP DATA INTO ADULTHOOD[1-3]

Study design for LUPRON DEPOT-PED 1-month administration

The 1-month LUPRON DEPOT-PED study was a prospective, multicenter, longitudinal study from 1991 to 2009 divided into 2 key phases: the open-label treatment period and the long-term, posttreatment follow-up period.[2]



Primary Endpoint: Percentage of patients with suppression of clinical/physical signs of puberty at Week 4 and yearly over five years.[1,3]

Secondary Endpoints: Mean gonadotropin levels (LH and FSH), mean sex hormone levels (basal estradiol/testosterones), mean ratio of bone age to chronological age, growth rate[4]

BA=bone age; CA=chronological age.

IMPORTANT SAFETY INFORMATION

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.

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.

Please see additional Important Safety Information throughout.

Please see accompanying full Prescribing Information or visit https://www.rxabbvie.com/pdf/lupronpediatric.pdf.

1-MONTH ADMINISTRATION STUDY

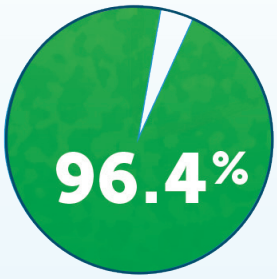
THE CLINICAL SIGNS OF PUBERTY WERE SUPPRESSED DURING THE FIRST 5 YEARS OF TREATMENT IN MOST PATIENTS[1]

During 5 years of treatment:

- **66.7% to 90.6%** of females had suppression of breast development[1]
- **60% to 100%** of males had suppression of genitalia development[1]

At 6 months posttreatment:

- In females (n=35), Tanner breast stage 5 was achieved in:[3]
  - **78% within the first 3 years**
  - **100% within 5 years**
- 4 of 5 males showed Tanner genital stage advancement[3]



BY WEEK 4,
96.4% of patients achieved LH suppression of <1.75 IU/L.[1]

Sustained suppression of mean peak LH, with hormone levels usually restored within 6 months of stopping treatment.[3]

LUPRON-DEPOT PED was also studied with 3-month and 6-month dosing schedules and provided control, pausing early puberty as early as 4 weeks.[1] See pages 6-7 for study details.

SAFETY PROFILE FOR 1-MONTH LUPRON DEPOT-PED

Adverse reactions occurring in ≥2% of pediatric patients with CPP receiving LUPRON DEPOT-PED 1-month:[1]

- Injection site reactions including abscess:† 9%
- Emotional lability: 5%
- Headache: 3%
- General pain: 3%
- Acne/seborrhea: 3%
- Rash including erythema multiforme: 3%
- Vaginitis/vaginal bleeding/vaginal discharge: 3%
- Vasodilation: 2%

†Most events were mild or moderate in severity.

TIP FOR TALKING WITH CAREGIVERS

When talking with caregivers about LH suppression, let them know that this means puberty is slowing down or pausing.[1] Use pages 8 and 9 of Caregiver Journey Brochure.

LH=luteinizing hormone.

IMPORTANT SAFETY INFORMATION (cont'd)

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.

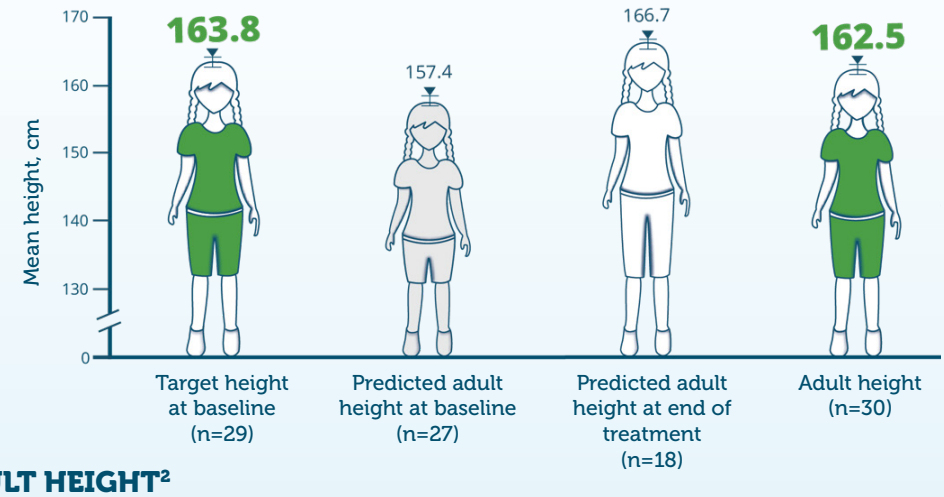
Please see additional Important Safety Information throughout.

Please see accompanying full Prescribing Information or visit https://www.rxabbvie.com/pdf/lupronpediatric.pdf.

LUPRON DEPOT-PED 1-MONTH IS THE ONLY GnRHa WITH AN 18-YEAR STUDY WITH LONG-TERM TREATMENT AND FOLLOW-UP[2]

NORMALIZATION OF GROWTH RATE AND BONE MATURATION OCCURRED IN PATIENTS TREATED WITH 1-MONTH LUPRON DEPOT-PED[2]

Height outcomes for females[2]



24 of 29
patients reached target height range

ADULT HEIGHT[2]

- 4.0 cm mean adult height increase (n=30) over baseline predicted adult height
- Patients essentially reached the mean height of the normal population by adulthood (mean height standard deviation score was -0.1 at adult height)
- Adult height includes data from patients whose height was collected at adulthood (after age 18). For patients who were missing adulthood height data, adult height was established when their growth velocity was <1 cm/year or BA was ≥14 years during the follow-up period

GROWTH RATE THROUGHOUT TREATMENT

- The advance in BA was delayed with LUPRON DEPOT-PED treatment. The mean ratio of BA to CA was 1.5 at baseline. After 1 year of treatment, mean ΔBA/ΔCA was 0.7 and was not more than 0.6 during the next 3 years of treatment[1,2]*
- Mean incremental growth rate was greatly reduced from 10.6 cm/year at baseline to approximately 5-6 cm/year during the first 72 weeks of therapy and then 4-4.5 cm/year from week 72 to week 192[2]

TIP FOR TALKING WITH CAREGIVERS

When talking with caregivers about height outcomes, let them know that, on average, children on LUPRON DEPOT-PED grew taller than the height predicted for them when they were first diagnosed with CPP.[1,2] Use page 11 of Caregiver Journey Brochure.

*Mean age was 7.3 ± 1.9. GnRHa=gonadotropin-releasing hormone agonist.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

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.

Please see additional Important Safety Information throughout.

Please see accompanying full Prescribing Information or visit https://www.rxabbvie.com/pdf/lupronpediatric.pdf.

PATIENTS WHO WERE TREATED WITH LUPRON DEPOT-PED WERE FOLLOWED INTO ADULTHOOD (AGE 21)[3]

AFTER TREATMENT, THE REPRODUCTIVE DEVELOPMENT OF 20 PATIENTS AGED 18–26 WAS EVALUATED[3]

12 PREGNANCIES
in 7 patients (including multiple pregnancies in 4 patients)

80% (16/20)
Reported normal menstrual cycles
- 7 of 20 women reported use of birth control

4 OF 4 WOMEN
who tried to get pregnant did

TIP FOR TALKING WITH CAREGIVERS

When talking with caregivers about long-term data, be sure to mention that LUPRON DEPOT-PED is the only CPP treatment that has an 18+ year safety study and has been prescribed for 30 years to treat CPP.[2,5]

Use page 10 of Caregiver Journey Brochure.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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.

Please see additional Important Safety Information throughout.

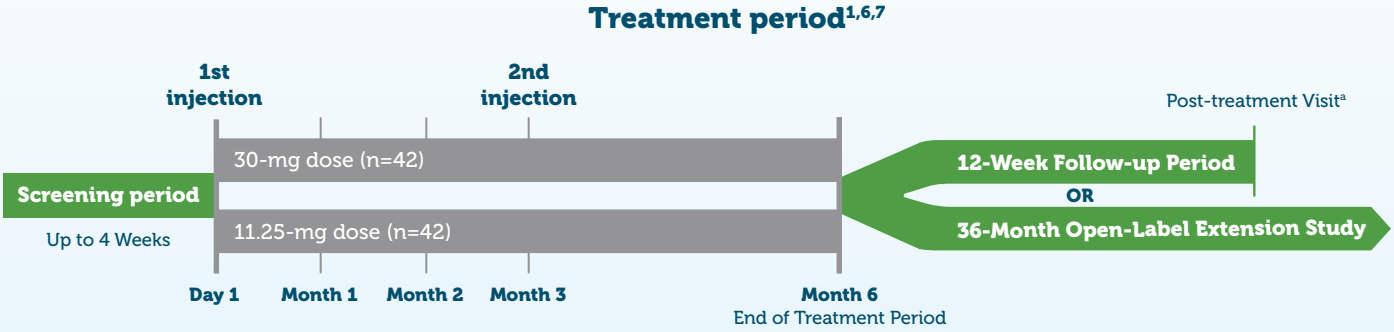
Please see accompanying full Prescribing Information or visit https://www.rxabbvie.com/pdf/lupronpediatric.pdf.

SUSTAINED SUPPRESSION WITH 3-MONTH ADMINISTRATION OF LUPRON DEPOT-PED[1]

STUDY DESIGN FOR LUPRON DEPOT-PED 3-MONTH ADMINISTRATION

The 3-month LUPRON DEPOT-PED study was a randomized, open-label clinical trial to assess the safety and efficacy of LUPRON DEPOT-PED 11.25 and 30 mg for 3-month administration in 84 subjects (76 females, 8 males) with CPP between 1 and 11 years of age.[1]

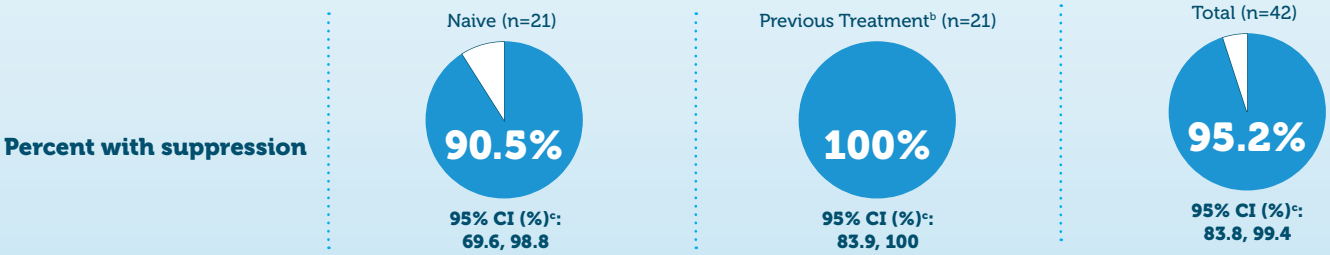
- Efficacy was measured as the suppression of peak stimulated LH to <4.0 mIU/mL, assessed at Months 2, 3, and 6[1]
- Both treatment groups had equal numbers of naïve and previously treated patients[1]



[a]Subjects entering the separate open-label extension study did not enter the follow-up period and did not participate in the follow-up visit of the study.

LH SUPPRESSION WAS ACHIEVED IN 95.2% OF PATIENTS[1]

Suppression of peak stimulated LH <4 mIU/mL from month 2 through month 6[a] with LUPRON DEPOT-PED 30 mg every 3 months[1]



[a]Primary endpoint.
[b]Previously treated with GnRHa for at least the 6 months prior to enrollment in the study.
[c]2-sided 95% CI.

GnRHa=gonadotropin-releasing hormone agonist; LH=luteinizing hormone.

Suppression of peak stimulated LH <4.0 mIU/mL from month 2 through month 6 with LUPRON DEPOT-PED 3-month 11.25 mg was 76.2% for treatment-naïve patients (n=21; 95% CI: 52.8, 91.8), 81% for previously treated patients (n=21; 95% CI: 58.1, 94.6), and 78.6% for the total number of patients (N=42; 95% CI: 63.2, 89.7).[1]

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS (cont'd)

- 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.

Please see additional Important Safety Information throughout.

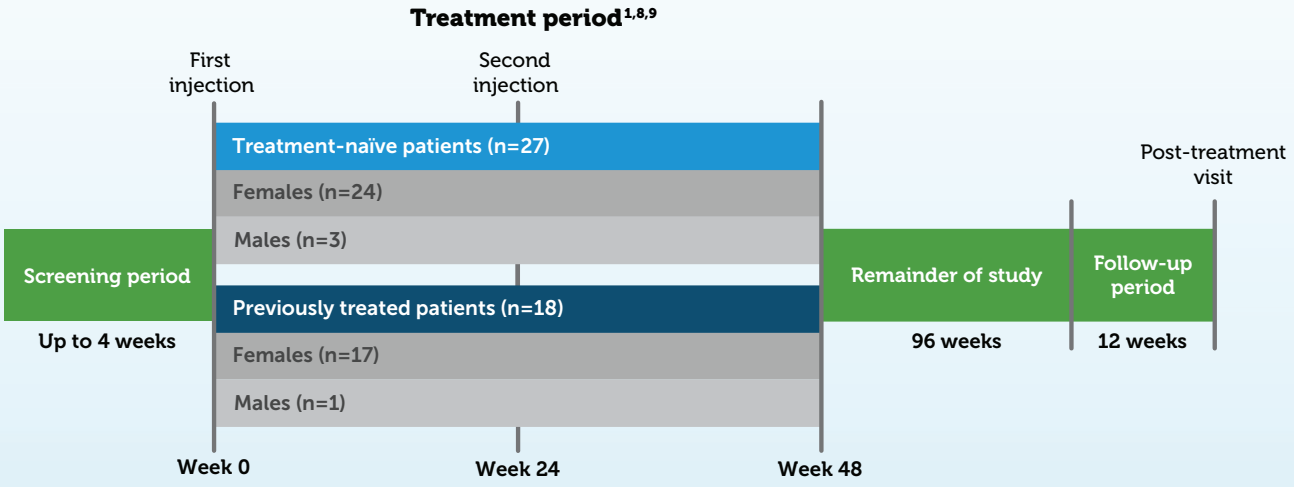
Please see accompanying full Prescribing Information or visit https://www.rxabbvie.com/pdf/lupronpediatric.pdf.

SUSTAINED SUPPRESSION WITH 6-MONTH ADMINISTRATION OF LUPRON DEPOT-PED[1]

STUDY DESIGN FOR LUPRON DEPOT-PED 6-MONTH ADMINISTRATION

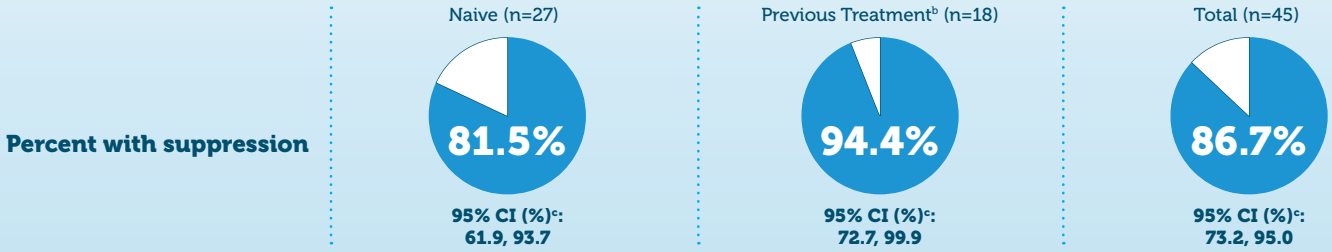
The 6-month LUPRON DEPOT-PED study was a single-arm, open-label clinical trial to assess the safety and efficacy of LUPRON DEPOT-PED 45 mg for 6-month administration in 27 pediatric patients with CPP (24 females, 3 males) naïve to previous GnRH agonist treatment and 18 pediatric patients with CPP (17 females, 1 male) previously treated with GnRH agonist therapy.[1]

- The primary efficacy endpoint was the percentage of patients with suppression of peak-stimulated LH to <4.0 mIU/mL at Week 24[1]



LH SUPPRESSION WAS ACHIEVED IN 86.7% OF PATIENTS AT WEEK 24[1]

Suppression of peak stimulated LH <4 mIU/mL at Week 24[a] with LUPRON DEPOT-PED 45 mg for 6-month administration[1]



[a]Primary endpoint.
[b]Previously treated with GnRHa for at least the 6 months prior to enrollment in the study.
[c]2-sided 95% CI.

GnRHa=gonadotropin-releasing hormone agonist; LH=luteinizing hormone.

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS (cont'd)

- 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.

Please see additional Important Safety Information throughout.

Please see accompanying full Prescribing Information or visit https://www.rxabbvie.com/pdf/lupronpediatric.pdf.

MULTIPLE DOSING OPTIONS

FLEXIBLE DOSING ALLOWS INDIVIDUALIZED TREATMENT WITH 1-, 3-, AND 6-MONTH DOSING OPTIONS[1]

6-MONTH DOSING OPTION

Product images for illustrative purposes only.

45 mg .....

3-MONTH DOSING OPTIONS

11.25 mg .....

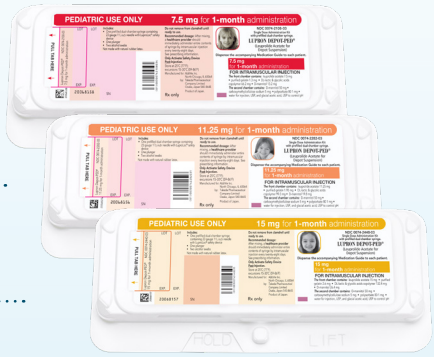
30 mg .....

1-MONTH DOSING OPTIONS

7.5 mg .....

11.25 mg .....

15 mg .....



TIP FOR TALKING WITH CAREGIVERS

When talking with caregivers about dosing and administration, mention that LUPRON DEPOT-PED is given in their child's doctor's office and that LUPRON DEPOT-PED is the only CPP treatment with 6-month, 3-month, and 1-month dosing options.[1,10]

Use pages 12 and 13 of Caregiver Journey Brochure.

Important Dosing Information[1]

- LUPRON DEPOT-PED must be administered by a healthcare professional
- Individualize the dose of LUPRON DEPOT-PED for each patient
- Select the appropriate LUPRON-DEPOT PED syringe for the intended dosing frequency and administer intramuscularly
- Each LUPRON DEPOT-PED strength and formulation has different release characteristics. Do not use partial syringes or a combination of syringes to achieve a particular dose
- In the case of inadequate suppression of pituitary gonadotropins and peripheral sex steroids with a maximal dosage, consider other available GnRH agonists indicated for the treatment of CPP
- Discontinue LUPRON DEPOT-PED at the appropriate age of onset of puberty

IMPORTANT SAFETY INFORMATION (cont'd)

- 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.

Please see additional Important Safety Information throughout.

Please see accompanying full Prescribing Information or visit https://www.rxabbvie.com/pdf/lupronpediatric.pdf.

LEARN ABOUT THE PREFILLED DUAL-CHAMBER SYRINGE WITH LUPROLOC® SAFETY DEVICE

KEY FEATURES

Fine 23-gauge 1.5" needle on all LUPRON DEPOT-PED doses[1]

LuproLoc® safety device[1]
- Integrated into the syringe to help reduce needlestick accidents

Prefilled dual-chamber syringe[1]
- No external mixing of ingredients required

Microsphere technology[1]
- Sterile lyophilized microspheres that become a suspension when mixed with diluent

Accompanying diluent[1,11]
- 1 mL for 1-month dosing
- 1.5 mL for 3- and 6-month dosing

Dosing strengths[1]

6-month:	3-month:	1-month:
45 mg	11.25 mg	7.5 mg
	30 mg	11.25 mg
		15 mg

2-hour window for injection[1]
If not used within 2 hours of mixing diluent, discard

No refrigeration required[1]

Injection site reactions, including abscess, injection site pain, and injection site swelling* occurred in ≥2% of patients with CPP in clinical trials.[1]

*Most events were mild or moderate in severity.

IMPORTANT SAFETY INFORMATION (cont'd)

CONTRAINDICATIONS (cont'd)

- 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.

Please see additional Important Safety Information throughout.

Please see accompanying full Prescribing Information or visit https://www.rxabbvie.com/pdf/lupronpediatric.pdf.

PREPARATION AND ADMINISTRATION[1]

PART 1: ASSEMBLE

Administration

- Administer LUPRON DEPOT-PED as a single-dose intramuscular injection into the gluteal area, anterior thigh, or shoulder
- Rotate injection sites within the same region from one injection to the next
- Inject immediately after reconstitution. Discard if not used within 2 hours

A

Visually inspect the LUPRON DEPOT-PED powder and diluent

- **DO NOT USE** the syringe if you see any clumping or caking
- A thin layer of powder on the wall of the syringe is considered normal prior to mixing with the diluent. The diluent should appear clear and free from particulate matter. Do not use the diluent if it is not clear or there is particulate matter.

B

Screw the plunger into the end stopper

- To prepare for injection, screw the white plunger into the end stopper until the stopper begins to turn

C

Slowly push the plunger for 6 to 8 seconds

- To help avoid needle tip leakage, hold the syringe **UPRIGHT**
- To release the diluent, **SLOWLY PUSH** the plunger for 6 to 8 seconds until the first stopper is at the blue line in the middle of the barrel
- Do not pull the plunger back (or downward) at any time during the mixing process. This will help prevent stopper separation

D

Mix the powder to form a uniform suspension

- Keep the syringe **UPRIGHT**. Thoroughly mix the powder by gently shaking the syringe until the powder forms a uniform suspension
- To help avoid leakage, do not shake the syringe too vigorously. The suspension should appear milky. If the powder adheres to the stopper or if you see caking or clumping, tap the syringe with your finger to disperse
- **DO NOT USE** the syringe if any of the powder has not gone into suspension

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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.

Please see additional Important Safety Information throughout.

Please see accompanying full Prescribing Information or visit https://www.rxabbvie.com/pdf/lupronpediatric.pdf.

PREPARATION AND ADMINISTRATION[1]

PART 1: ASSEMBLE (CONT'D)

E

Pull the needle cap upward without twisting

- Keep holding the syringe **UPRIGHT**
- With your other hand, pull the needle cap upward without twisting. This may help minimize the potential for product leakage

F

Advance the plunger to expel air from the syringe

- Keeping the syringe **UPRIGHT**, advance the plunger to expel the air from the syringe

Now the syringe is ready for injection!

PART 2: INJECT

G

Insert the needle at a 90-degree angle into the intramuscular injection site

- Clean the injection site with an alcohol swab and insert the needle at a 90-degree angle into the injection site
- Remember: Injection sites should be alternated between the gluteal area, anterior thigh, or shoulder
- Note that if a blood vessel is accidentally penetrated, you may see aspirated blood just below the Luer-lock connection, through the transparent LuproLoc® safety device. If this occurs, remove the needle immediately. Do not inject the medication

H

Immediately inject the contents of the syringe

- Inject the entire contents of the syringe intramuscularly immediately after reconstitution
- The suspension settles very quickly following reconstitution, so LUPRON DEPOT-PED should be mixed and used immediately

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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.

Please see additional Important Safety Information throughout.

Please see accompanying full Prescribing Information or visit https://www.rxabbvie.com/pdf/lupronpediatric.pdf.

PREPARATION AND ADMINISTRATION[1]

PART 3: DISCARD

I

Withdraw the needle and activate the LuproLoc®

- After the injection, withdraw the needle
- Immediately activate the LuproLoc® safety device by pushing the arrow on the lock upward toward the needle tip with your thumb or finger until the needle cover of the safety device is fully extended over the needle and you hear or feel a click
- Then dispose of the syringe according to applicable regulations or procedures

SEE THE LUPRON DEPOT-PED INJECTION VIDEO AT LUPRONPEDPRO.COM, AND THE FULL PRESCRIBING INFORMATION, FOR MORE INFORMATION

References: 1. LUPRON DEPOT-PED [package insert]. North Chicago, IL: AbbVie Inc. **2.** Lee PA, Neely EK, Fuqua J, et al. Efficacy of leuprolide acetate 1-month depot for central precocious puberty (CPP): growth outcomes during a prospective, longitudinal study. *Int J Pediatr Endocrinol.* 2011;2011(1):7. doi:10.1186/1687-9856-2011-7. **3.** Neely EK, Lee PA, Bloch CA, et al. Leuprolide acetate 1-month depot for central precocious puberty: hormonal suppression and recovery. *Int J Pediatr Endocrinol*. 2010;2010:398639. doi:10.1155/2010/398639. **4.** Data on File, AbbVie Inc. ABVRRTI62554. **5.** Drugs@FDA: FDA-approved drugs. US Food and Drug Administration. Accessed August 29, 2023. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=020263 **6.** Lee PA, Klein K, Mauras N, et al. Efficacy and safety of leuprolide acetate 3-month depot 11.25 milligrams or 30 milligrams for the treatment of central precocious puberty. J Clin Endocrinol Metab. 2012;97(5):1572-1580. doi:10.1210/jc.2011-2704 **7.** Lee PA, Klein K, Mauras N, Lev-Vaisler T, Bacher P. 36-month treatment experience of two doses of leuprolide acetate 3-month depot for children with central precocious puberty. *J Clin Endocrinol Metab.* 2014;99(9):3153-3159. doi:10.1210/jc.2013-4471 **8.** Klein KO, Mauras N, Nayak S, et al. Efficacy and safety of leuprolide acetate 6-month depot for the treatment of central precocious puberty: a phase 3 study. J Endocr Soc. 2023;7:1-11. doi:10.1210/jendso/bvad071 **9.** Data on file, AbbVie Inc. ABVRRTI75785. **10.** National Library of Medicine. DailyMed. Accessed October 17, 2023. https://dailymed.nim.nih.gov/dailymed/search.cfm?adv=1&labeltype=human&query=34067-9%3Acentral+precocious+puberty **11.** Data on file, AbbVie Inc. ABVRRTI75928. **12.** Data on file, AbbVie Inc. **13.** Data on file, AbbVie Inc. IQVIA NSP, 2023.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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.

Please see additional Important Safety Information throughout.

Please see accompanying full Prescribing Information or visit https://www.rxabbvie.com/pdf/lupronpediatric.pdf.

SUPPORT PLUS HELPS PATIENTS AND CAREGIVERS STAY ON TRACK WITH TREATMENT

SUPPORT FOR PATIENTS

- Help understanding their insurance coverage
- Potential ways to save on their LUPRON DEPOT-PED prescription
- Live nurse support hotline available to help with treatment-related questions Monday–Friday, 10 AM–7 PM CT

HELP YOUR PATIENTS GET STARTED ON SUPPORT PLUS

2 ways to enroll patients

- Download an enrollment form at LupronPedPro.com/support-plus-and-resources.html
- Use the enrollment form in your Support PLUS Welcome Kit

Questions?

Support PLUS representatives are available Monday–Friday, 7 AM–7 PM CT, at 1-855-LUPRON-P (1-855-587-7667) to help with any questions you may have.

Even if your patients are switched between the LUPRON DEPOT-PED 1-month, 3-month, and 6-month formulations, they will stay in the same support program they are already using, including access and reimbursement support.

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

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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.

Please see additional Important Safety Information throughout.

Please see accompanying full Prescribing Information or visit https://www.rxabbvie.com/pdf/lupronpediatric.pdf.

A SAVINGS CARD AND NURSE HOTLINE ARE PART OF SUPPORT PLUS

WITH THE INSTANT SAVINGS CARD, ELIGIBLE COMMERCIALLY INSURED PATIENTS* MAY PAY AS LITTLE AS $10 PER PRESCRIPTION OF LUPRON DEPOT-PED

Your patients can easily get their Instant Savings Card:

- Online at LupronPed.com
- By enrolling in Support PLUS (QR code at right)

This benefit can be redeemed at the pharmacy or by rebate.

NURSE SUPPORT HOTLINE

Your patients have access to live nurse support‡ via phone throughout therapy. Parents or caregivers can talk to a registered nurse about CPP or LUPRON DEPOT-PED therapy at no cost by calling 1-855-LUPRON-P (1-855-587-7667), Monday–Friday, 10 AM–7 PM CT

DID YOU KNOW? LUPRON DEPOT-PED HAS 98% COVERAGE ACROSS COMMERCIAL INSURANCE AND MEDICAID COMBINED FOR BOTH PHARMACY AND MEDICAL BENEFIT[12†]

*Eligibility: Available to patients with commercial insurance coverage for LUPRON DEPOT-PED® (leuprolide acetate for depot suspension) who meet eligibility criteria. This co-pay assistance program is not available to patients receiving prescription reimbursement under any federal, state, or government-funded insurance programs (for example Medicare [including Part D], Medicare Advantage, Medigap, Medicaid, TRICARE, Department of Defense, or Veteran's Affairs programs) or where prohibited by law. Offer subject to change or termination without notice. Restrictions, including monthly maximums, may apply. This is not health insurance. For full Terms and Conditions, visit lupronpedpro.com, or call 1-855-587-7667 for additional information. To learn about AbbVie's privacy practices and your privacy choices, visit https://privacy.abbvie.

†Source: MMIT, as of September 2023. Step edits, prior authorization, and other restrictions apply.

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

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS (cont'd)

- 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.

Please see additional Important Safety Information throughout.

Please see accompanying full Prescribing Information or visit https://www.rxabbvie.com/pdf/lupronpediatric.pdf.

THE SUPPORT PLUS IN-HOME NURSE INJECTION SERVICE OFFERS ADMINISTRATION OF LUPRON DEPOT-PED INJECTIONS FOR ELIGIBLE PATIENTS

Patients who are at risk of not completing their therapy, as determined by their physician, may be eligible for the In-Home Nurse Injection Service.*†

In-home treatment with flexible hours

- Trained nurses
- Available days, nights, and weekends

The nurse creates a supportive experience for pediatric patients

- Help support patients to stay on track with their prescribed therapy

Coordination with the doctor's office

- Welcome calls to your patients
- Nurse coordinators manage in-home nurse injection appointments
- Touchpoints with the doctor's office before and after each visit

If you've discussed the In-Home Nurse Injection Service with a physician and believe a patient would benefit from this program, call a Support PLUS representative at 1-855-LUPRON-P (1-855-587-7667) anytime Monday–Friday, 7 AM–7 PM CT, to enroll your patient

Note: Be sure to follow the treatment plan a physician prescribes and reinforce with parents/legal guardians that the program does not replace doctor visits to monitor progress between injections. HCPs can recommend that patients opt out of the program at any time.

*Qualifying cases include those patients who are needle phobic or who are experiencing challenges keeping office visits.

†If a patient is eligible for the In-Home Nurse Injection Service, be sure to have their parent/legal guardian read and sign the authorization.

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

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS (cont'd)

- 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.

Please see additional Important Safety Information throughout.

Please see accompanying full Prescribing Information or visit https://www.rxabbvie.com/pdf/lupronpediatric.pdf.

LUPRON DEPOT-PED CONTINUES TO BE THE #1* PRESCRIBED TREATMENT FOR CPP IN THE US[13]

Over 30 years
of proven efficacy and safety[1]

18+ year safety study

- LUPRON DEPOT-PED† is the only CPP treatment that has a long-term, 18-year safety study, including long-term follow-up data (1-month dosing)[2]

Support PLUS

- Provides your patients with the information and support they need throughout their treatment

*Data sourced as of February 2023.

†1-month dosing study.

IMPORTANT SAFETY INFORMATION

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.

Please see additional Important Safety Information throughout.

Please see accompanying full Prescribing Information or visit https://www.rxabbvie.com/pdf/lupronpediatric.pdf.

abbvie