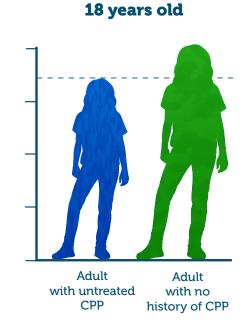


# —— UNTREATED CPP CAN ——— HAVE LASTING COMPLICATIONS

# CHILDREN WITH CPP MAY BE SIGNIFICANTLY TALLER THAN THEIR PEERS BUT WHEN IT COMES TO CPP, TALL NOW DOESN'T MEAN TALL LATER

Children with CPP may go through an early growth spurt and be taller than their peers at first because their bones mature quicker than normal. Once the growth plates close, children stop growing, which may lead to shorter adult height.

# Child without CPP



For illustrative purposes only.



# How children are affected by their condition

Children with CPP may face a series of struggles because they look older than they are. Everyday situations and interactions with their peers can become big challenges for them.

# TREATING EARLY MAY HELP PREVENT COMPLICATIONS

# THE GOAL OF TREATMENT IS TO DELAY EARLY PUBERTY



A gonadotropin-releasing hormone agonist (GnRHa) helps the pituitary gland ignore signals from the brain. This, in turn, stops the release of sex hormones that cause puberty.

While on a GnRHa, your child's signs of early puberty should slow or stop, and your child's growth rate should be more like that of other children their age.

THE SOONER YOUR CHILD STARTS TREATMENT,
THE SOONER EARLY PUBERTY MAY
SLOW DOWN OR STOP

LEARN ABOUT THE #1\* PRESCRIBED GNRHA TREATMENT FOR CPP ON THE NEXT PAGE



<sup>\*</sup>Data sourced as of February 2023.

# WHAT TO EXPECT FROM TREATMENT

LUPRON DEPOT-PED provides control, pausing early puberty within 4 weeks.



**96.4% of children taking 1-month LUPRON DEPOT-PED achieved suppression of a reproductive hormone.** Suppression means either pausing early puberty with no changes or reversing the signs of early puberty.



While on LUPRON DEPOT-PED, your child's early puberty should be paused.

**Your child's growth rate will be normalized**, so they can reach their full height potential at an appropriate age. Genital and breast development, as well as menses, should stop or reverse.



In nearly 9 out of 10 children taking 1-month LUPRON DEPOT-PED, reproductive hormones returned to puberty levels within 6 months of stopping treatment.

LUPRON DEPOT-PED was clinically studied as 6-month, 3-month, and 1-month dosing schedules. All treatment schedules provided control, pausing early puberty within 4 weeks.

# **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.

# WHAT TO EXPECT AFTER TREATMENT



Patients who were treated with 1-month **LUPRON DEPOT-PED were followed into adulthood (age 21).** 



On average, **children on LUPRON DEPOT-PED grew taller than the height predicted for them** when they were first diagnosed with CPP.

After treatment, the **reproductive development** of 20 patients aged 18 to 26 was evaluated:



**80%** (16 of 20) reported normal menstrual cycles\*



in 7 patients (including multiple pregnancies in 4 patients)



who tried to become pregnant did

Please see Important Safety Information throughout.

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

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

<sup>\*</sup>According to the Office on Women's Health, this is similar to women in the United States, with up to 86% having regular bleeding during their childbearing years.

## **IMPORTANT SAFETY INFORMATION FOR LUPRON DEPOT-PED (cont'd)**

What is the most important information I should know about LUPRON DEPOT-PED? (cont'd)

• 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– Restlessness (impatience)– Acting aggressive

IrritabilityAnger

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 gonadotropinreleasing 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
 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
- 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.

# Please see Important Safety Information throughout.

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# 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

- Bleeding

- 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

• The most common side effects of LUPRON DEPOT-PED received every 6 months include:

- Weight gain - Injection site reactions such Nausea and vomiting as pain, swelling, and abscess Fever Fracture - Headache - Itchina Breast tenderness - Mood changes Pain in extremities Difficulty sleeping - Upper stomach pain - Chest pain Rash - Diarrhea Back pain 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.

Ligament sprain

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 <a href="https://www.fda.gov/medwatch">www.fda.gov/medwatch</a> 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.



# **DON'T WAIT-ACT NOW!**

# When it comes to CPP, timely treatment is important.

You can help control your child's Central Precocious Puberty (CPP) with the #1\* prescribed treatment for CPP, trusted by parents and doctors for over 30 years.



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