

## **Understanding Your Treatment UTERINE FIBROIDS**

#### USE<sup>1</sup>

#### **Uterine Fibroids**

LUPRON DEPOT<sup>®</sup> (leuprolide acetate for depot suspension) 3.75 mg or 11.25 mg with iron therapy is used before fibroid surgery to improve anemia due to vaginal bleeding from fibroids for patients in whom 3 months of hormonal suppression is deemed necessary. The duration of therapy with LUPRON DEPOT is limited to 3 months. The symptoms associated with fibroids will return after stopping therapy.

Your doctor may consider a 1-month trial of iron alone, as some women will respond to iron alone. LUPRON DEPOT 3.75 mg or 11.25 mg may be added if the response to iron alone is considered inadequate.

#### Limitations of Use

LUPRON DEPOT 3.75 mg or 11.25 mg is not used in combination with norethindrone acetate add-back therapy before fibroid surgery to improve anemia due to vaginal bleeding from fibroids.

#### SAFETY CONSIDERATIONS<sup>1</sup>

You should not receive LUPRON DEPOT if you are pregnant, think you may be pregnant, or are planning to become pregnant during treatment with LUPRON DEPOT; have undiagnosed uterine bleeding; or have experienced any type of allergic reaction to LUPRON DEPOT or similar drugs • Thinning of your bones can occur and may not be completely reversible after stopping treatment; do not exceed the prescribed duration of treatment • LUPRON DEPOT may cause harm to your unborn child
A condom, a diaphragm with contraceptive jelly, or a copper IUD is required to prevent pregnancy • Serious allergic reactions can occur
Fibroid symptoms, such as abdominal bloating or pelvic pain or pressure, may increase during the first days of therapy • Convulsions have occurred in patients taking LUPRON DEPOT • Development or worsening of depression has occurred

Please see Use and Important Safety Information on page 7.

Please see accompanying full Prescribing Information for LUPRON DEPOT 3.75 mg, or visit: <u>https://www.rxabbvie.com/pdf/</u> lupron3\_75mg.pdf

Please see accompanying full Prescribing Information for LUPRON DEPOT 11.25 mg, or visit:

https://www.rxabbvie.com/ pdf/lupron3month11\_25mg.pdf **Lupron**Depot<sup>®</sup> (leuprolide acetate for depot suspension)

3.75 mg/ -3 Month 11.25 mg

### LEARNING ABOUT FIBROIDS

### WHAT ARE FIBROIDS?

If you have uterine fibroids, you are not alone...

outof

About **one** in **four** women with uterine fibroids suffers from symptoms that affect daily life.<sup>2</sup>

### The good news is that there are treatment options for fibroids.

This brochure can help you learn more about fibroids, the symptoms they can cause, and treatment considerations to discuss with your doctor.



Uterine fibroids are growths (or tumors) that develop in the muscular wall of the uterus.

They may also be called myomas or leiomyomas. Fibroids are generally benign—that is, they are **not** cancerous (malignant). **Fibroids are the most common kind of growths of the uterus.** A woman may have just 1 fibroid or several.

Uterine fibroids can range in size from as small as a pea (less than 1 inch) up to several inches in diameter.

They may remain very small for a long time, then grow suddenly and rapidly—or they may grow slowly over a number of years.<sup>3</sup>

### TYPES OF FIBROIDS

### SYMPTOMS OF FIBROIDS

Uterine fibroids can appear inside the uterus, on its outer surface or within its wall, or attached to the uterus by a stem-like structure.<sup>3</sup>



- Fibroid appears within the uterine wall (intramural fibroid)
- Fibroid appears within the outside layer of the uterine wall **(subserosal fibroid)**
- Fibroid appears within the inside layer
   of the uterine wall (submucosal fibroid)
- Fibroid is attached by a stem within the outside layer of the uterine wall (pedunculated subserosal fibroid)
- 5 Fibroid is attached by a stem within the inside layer of the uterine wall (pedunculated submucosal fibroid)

# Some possible symptoms associated with fibroids

- Heavy or abnormal menstrual bleeding
- Bleeding between periods
- Anemia
- Pelvic pain or feeling of pressure
- Pain during intercourse or when going to the bathroom
- Enlarged uterus and abdomen
- Miscarriages
- Infertility

It's important to discuss all symptoms – or if your symptoms change or worsen in any way – with your doctor.

### CAUSES OF **FIBROIDS** AND WHO IS AT **RISK**

### Facts you should know

It is not clear what causes fibroids, but evidence suggests that their growth is related to estrogen and progesterone. **Fibroids are most common in women aged 30-40 years** but they can occur at any age.<sup>3</sup>

**Fibroids occur about 3 times more often in African-American women** than in Caucasian women.<sup>2</sup>

If you've been diagnosed with fibroids, talk to your doctor about treatment options that may be right for you.

African-American women have a

greater relative risk and prevalence<sup>2</sup>

### TREATMENT CONSIDERATIONS

The treatment your doctor recommends may depend on your symptoms, the number of fibroids you have, and their location in the body.

Surgical considerations may include a myomectomy or hysterectomy.

- Myomectomy involves the surgical removal of uterine fibroids without the removal of the uterus.
   Fibroids do not regrow after surgery, but new fibroids may develop and need further treatment.
- Hysterectomy is the removal of the uterus. The ovaries may or may not be removed. It might also be considered if the fibroids are causing serious complications or discomfort. A hysterectomy is a permanent procedure.

### Anemia related to fibroids

Excessive bleeding due to fibroids may lead to anemia, which can make you feel abnormally tired. People are considered anemic when they have a lower than normal amount of red blood cells in their blood.<sup>3</sup> To assess this, a routine blood test measures the hemoglobin and hematocrit levels.

Raising hemoglobin and hematocrit levels prior to surgery is a treatment consideration you should discuss with your doctor.

### PREPARING FOR SURGERY WITH LUPRON DEPOT

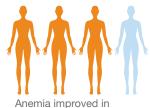
To help improve anemia from excessive bleeding due to fibroids and to prepare for surgery, your doctor may recommend LUPRON DEPOT along with an iron supplement for up to 3 months before vour procedure. The use of LUPRON DEPOT may reduce or stop the bleeding by decreasing your body's production of estrogen.

#### Clinical studies of 3 months of LUPRON DEPOT with daily iron therapy have shown<sup>1</sup>:

- Corrected anemia in 75% of patients as compared to 49% of patients with daily iron therapy alone
- Less excessive vaginal bleeding in 80% of patients
- Relieved symptoms of bloating, pelvic pain, and pressure

41% average reduction

in uterine volume



three out of four women.<sup>1,4</sup>

 37% average reduction in fibroid volume

#### SAFETY CONSIDERATIONS<sup>1</sup>

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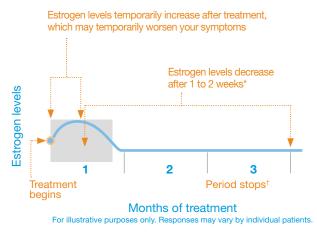
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Please see accompanying full Prescribing Information for LUPRON DEPOT 11.25 mg, or visit: https://www.rxabbvie.com/pdf/ lupron3month11 25mg.pdf

### LUPRON DEPOT THERAPY CONSIDERATIONS

### What to expect during a full 3-month course of LUPRON DEPOT therapy<sup>1</sup>



\*As a result of lower estrogen levels, you may experience symptoms such as hot flashes, headaches, and vaginal dryness during this time.

<sup>†</sup>If you don't get your period within 3 months after stopping LUPRON DEPOT therapy, talk to your doctor.

You should notify your doctor immediately if you develop any new or worsened symptoms after beginning LUPRON DEPOT.

### What you should know

There are a few reasons why a woman should not start or continue LUPRON DEPOT therapy. It should not be taken if you are:

- Pregnant or may become pregnant
- Experiencing undiagnosed abnormal vaginal bleeding
- Allergic to LUPRON DEPOT or similar drugs
- Breastfeeding if you are taking LUPRON DEPOT 3.75 mg



3.75 mg/ -3 Month 11.25 mg

### **Dosage and length of therapy**

LUPRON DEPOT is given in combination with iron therapy as a single injection lasting 3 months (3-month 11.25 mg), or single monthly injections (1-month 3.75 mg) for up to 3 months prior to surgery.

Your doctor may consider a 1-month trial of iron alone as some patients' anemia will improve with iron alone. It is recommended that LUPRON DEPOT not be used for more than 3 months in patients with fibroids. Experience with LUPRON DEPOT in females has been limited to women 18 years of age and older.

#### **SAFETY CONSIDERATIONS<sup>1</sup>**

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### To download your LUPRON DEPOT Savings Card\* now, visit: <u>LupronGyn.com</u>

#### If you have additional questions regarding savings and support, call: 1-855-587-7663

\*Eligibility: Available to patients with commercial insurance coverage for LUPRON DEPOT® (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 Veterans 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 <u>LUPRONDEPOTSavingscard.com</u> or call 1-855-587-7663 for additional information. To learn about AbbVie's privacy practices and your privacy choices, visit <u>https://privacy.abbvie</u>

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Learn more about treating anemia prior to uterine fibroids surgery with LUPRON DEPOT <u>here</u>.



3.75 mg/ -3 Month 11.25 mg

# Use and Important Safety Information for LUPRON DEPOT

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#### Limitations of Use

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#### **IMPORTANT SAFETY INFORMATION<sup>1</sup>**

#### **General Safety Information**

- Do not take LUPRON DEPOT 3.75 mg and 11.25 mg if you are or may be pregnant, have undiagnosed uterine bleeding, or if you have experienced any type of allergic reaction to LUPRON DEPOT or similar drugs.
- Thinning of the bones may occur during therapy with LUPRON DEPOT, which may not be completely reversible in some patients. Since some conditions may increase the possibility of bone thinning, you should tell your doctor if you smoke, use alcohol in excess, have a family history of osteoporosis (thinning of the bones with fractures), or are taking other medications that can cause thinning of the bones.
- LUPRON DEPOT may cause harm to your unborn child. LUPRON DEPOT is not a method of birth control. Even though you may not have periods, unprotected intercourse could result in pregnancy. You should use non-hormonal birth control, such as condoms, a diaphragm with contraceptive jelly, or a copper IUD, to prevent pregnancy. If you think you have become pregnant while on LUPRON DEPOT, talk to your doctor immediately.

#### **IMPORTANT SAFETY INFORMATION<sup>1</sup>** (contd.)

- Serious allergic reactions have been reported with LUPRON DEPOT use. Asthma was reported in women with a history of asthma, sinusitis, and environmental or drug allergies. Serious allergic reactions have also occurred.
- After beginning LUPRON DEPOT, your estrogen levels will increase during the first days of therapy. During this time, you may notice an increase in your current symptoms. You should notify your doctor if you develop any new or worsened symptoms after beginning LUPRON DEPOT treatment.
- Seizures have been observed in patients taking LUPRON DEPOT, including patients who have a history of seizures or conditions related to seizures or in patients who are taking medications that are connected to seizures. Seizures have also been reported in patients without any of these conditions.
- Depression may occur or worsen while taking LUPRON DEPOT, especially in patients who have a history of depression. Patients should be carefully observed during treatment. Immediately report thoughts and behaviors of concern to your doctor.
- The most common side effects of LUPRON DEPOT included hot flashes/sweats, headache/migraine, decreased libido (interest in sex), depression/emotional lability (changes in mood), dizziness, nausea/vomiting, pain, vaginitis, and weight gain. These are not all of the possible side effects of LUPRON DEPOT. Talk to your doctor for medical advice about side effects.
- LUPRON DEPOT for anemia associated with uterine fibroids has been limited to women 18 years of age and older. LUPRON DEPOT is not indicated in postmenopausal women.
- LUPRON DEPOT must be administered in your doctor's office.

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

# 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.

If you are having difficulty paying for your medicine, AbbVie may be able to help. Visit AbbVie.com/ myAbbVieAssist to learn more. References: 1. LUPRON DEPOT 3.75 mg and –3 Month 11.25 mg [package insert]. North Chicago, IL: AbbVie Inc. 2. Borah BJ, Nicholson WK, Bradley L, Stewart EA. The impact of uterine leiomyomas: a national survey of affected women. *Am J Obstet Gynecol.* 2013;209(4):319.e1-319.e20. 3. The American College of Obstetricians and Gynecologists. Frequently asked questions (FAQ074). Gynecologic problems: Uterine fibroids. https://www.acog.org/-/media/ For-Patients/faq074.pdf?dmc=1&ts=20160829T0938268934. Updated May 2011. Accessed August 29, 2016. 4. Stovall TG, Muneyyirci-Delale O, Summitt RL Jr, Scialli AR; Leuprolide Acetate Study Group. GnRH agonist and iron versus placebo and iron in the anemic patient before surgery for leiomyomas: a randomized controlled trial. *Obstet Gynecol.* 1995;86(1):65-71.

For prescription use only.

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.

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

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reupronue acetate for depot suspension,

3.75 mg/ -3 Month 11.25 mg

Look inside for valuable savings on LUPRON DEPOT.

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