RxCrossroads An AbbVie HUB Service

REFERRAL FORM

LuproNDepot® (leuprolide acetate for depot suspension) 3.75 mg/ -3 Month 11.25 mg

Lupaneta Pack™ leuprolide acetate for depot suspension and norethindrone acetate tablets

SIGN AND FAX THIS FORM TO 1-866-867-0465. FOR QUESTIONS, PLEASE CALL 1-855-587-7663.

To be completed by patient or legally authorized person:

PATIENT INFORMATION

First Name: _____ MI: _____

Last Name: _____

DOB: _____ Sex: Female

Address: _____

City/State/Zip: _____

Primary Phone: _____ Cell ☐

Alternate Phone: _____ Cell ☐

Drug Allergies: _____

INSURANCE

Primary Insurance: _____

Phone: _____

Cardholder ID: _____ Group#: _____

PCN: _____ BIN: _____

Policy Holder Name: _____ DOB: _____

Secondary Insurance: _____

Phone: _____

Cardholder ID: _____ Group#: _____

PCN: _____ BIN: _____

Policy Holder Name: _____ DOB: _____

PRESCRIBER INFORMATION

Prescriber Name: _____

Specialty: ☑ GYN ☐ Other: _____

NPI: _____

State License Number: _____

Tax ID Number: _____

Office Name: _____

Address: _____

City/State/Zip: _____

Phone: _____

Fax: _____

OFFICE CONTACT INFORMATION

Office Contact Name: _____

Office Contact Phone Number: _____

Office Contact Extension: _____

Office Contact Fax Number: _____

Address: _____

City/State/Zip: _____

The categories of personal information collected in this Enrollment Form include contact, insurance, prescription, and medical history information. The personal information collected will be used to provide and manage Hub Services and to perform research and analytics on a de-identified basis. For more information about the categories of personal information collected by AbbVie and the purposes for which AbbVie uses personal information, visit www.abbvie.com/privacy.html.

AbbVie, its affiliates, collaborators, and agents will use the information collected about you and your patient to provide the patient support and perform research and analytics, on a de-identified basis, for management of the program. For more information about the categories of personal information collected by AbbVie and the purposes for which AbbVie uses personal information, visit www.abbvie.com/privacy.html. Please share this information with your patient.

Please click for accompanying full Prescribing Information for LUPRON DEPOT or LUPANETA PACK.

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REFERRAL FORM

LupronDepot® (leuprolide acetate for depot suspension) 3.75 mg/ -3 Month 11.25 mg

Lupaneta Pack™ leuprolide acetate for depot suspension and norethindrone acetate tablets

DIAGNOSIS FOR WHICH LUPRON DEPOT IS BEING PRESCRIBED

Date of Diagnosis: _____

☐ Endometriosis ICD-10: _____

☐ Fibroids ICD-10: _____

☐ Other: _____ ICD-10: _____

LUPRON DEPOT/LUPANETA PACK PRESCRIPTION

☐ New ☐ Restart ☐ Continuing (Start Date: _____)

SHIPPING PREFERENCE

Date Needed: _____ ☐ Deliver medication to prescriber ☐ Deliver medication to patient

ENDOMETRIOSIS AND/OR UTERINE FIBROIDS

☐ LUPRON DEPOT 3.75 mg (1-month supply)	Sig: Administer IM once a month	#1 kit	Refills: _____
☐ LUPRON DEPOT 11.25 mg (3-month supply)	Sig: Administer IM once every 3 months	#1 kit	Refills: _____

ENDOMETRIOSIS ONLY

☐ LUPANETA PACK 3.75 mg (1-month supply)	Sig: Administer LUPRON DEPOT once a month, take one norethindrone acetate tablet by mouth daily	#1 kit	Refills: _____
☐ LUPANETA PACK 11.25 mg (3-month supply)	Sig: Administer LUPRON DEPOT once every 3 months, take one norethindrone acetate tablet by mouth daily	#1 kit	Refills: _____

ADD-BACK THERAPY (For LUPRON DEPOT - endometriosis only) **In states not permitting dual prescriptions, please fax a separate prescription.**

☐ Norethindrone acetate 5 mg tablet	Sig: Take one tablet by mouth daily	Qty: ☐ 30 ☐ 90	Other: _____	Refills: _____
☐ Norethindrone acetate 5 mg tablet	Sig: _____	Qty: _____		Refills: _____

PLEASE VERIFY THE FOLLOWING BENEFITS:

☐ Patient's coverage through pharmacy benefits ☐ Patient's coverage through medical benefits ☐ Patient's coverage through Buy/Bill

☐ I DO NOT WANT LUPRON DEPOT OR LUPANETA PACK DISPENSED AT THIS TIME.

PRESCRIBER SIGNATURE: Prescriber must manually sign (rubber stamps, signature by other office personnel for the prescriber and computer-generated signatures will not be accepted).

SIGN

Dispense as written / Do not substitute Date Substitution permitted / Brand exchange permitted Date

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.

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.

For states requiring handwritten expressions of Product Selection, use this area (e.g., medically necessary, may not substitute, dispense as written, etc.)

Please click for accompanying full Prescribing Information for LUPRON DEPOT or LUPANETA PACK.

Indications and Important Safety Information for LUPRON DEPOT® (leuprolide acetate for depot suspension)[1]

LupronDepot®
(leuprolide acetate for depot suspension)
3.75 mg/ -3 Month 11.25 mg

INDICATIONS

ENDOMETRIOSIS

Monotherapy

LUPRON DEPOT® (leuprolide acetate for depot suspension) 3.75 mg or 11.25 mg is indicated for management of endometriosis, including pain relief and reduction of endometriotic lesions.

In Combination with Norethindrone Acetate

LUPRON DEPOT 3.75 mg or 11.25 mg in combination with norethindrone acetate is indicated for initial management of the painful symptoms of endometriosis and for management of recurrence of symptoms.

Use of norethindrone acetate in combination with LUPRON DEPOT 3.75 mg or 11.25 mg is referred to as add-back therapy and is intended to reduce the loss of bone mineral density (BMD) and reduce vasomotor symptoms associated with use of LUPRON DEPOT 3.75 mg or 11.25 mg.

Limitations of Use:

The total duration of therapy with LUPRON DEPOT 3.75 mg or 11.25 mg plus add-back therapy should not exceed 12 months due to concerns about adverse impact on bone mineral density.

UTERINE LEIOMYOMATA (FIBROIDS)

LUPRON DEPOT 3.75 mg or 11.25 mg used concomitantly with iron therapy is indicated for the preoperative hematologic improvement of women with anemia caused by fibroids for whom three months of hormonal suppression is deemed necessary.

Consider a one-month trial period on 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 indicated for combination use with norethindrone acetate add-back therapy for the preoperative hematologic improvement of women with anemia caused by heavy menstrual bleeding due to fibroids.

IMPORTANT SAFETY INFORMATION[1]

CONTRAINDICATIONS

- LUPRON DEPOT 3.75 mg or 11.25 mg is contraindicated in patients who are hypersensitive to gonadotropin-releasing hormone (GnRH), GnRH agonist analogs including leuprolide acetate, or any of the excipients in LUPRON DEPOT; in patients with undiagnosed abnormal uterine bleeding; and in pregnancy.
- When norethindrone acetate is administered with LUPRON DEPOT 3.75 mg or 11.25 mg, the contraindications to the use of norethindrone acetate also apply to this combination regimen. Refer to the norethindrone acetate prescribing information for a list of contraindications for norethindrone acetate.

WARNINGS AND PRECAUTIONS

Loss of Bone Mineral Density

- LUPRON DEPOT 3.75 mg or 11.25 mg induces a hypoestrogenic state that results in loss of bone mineral density (BMD), some of which may not be reversible after stopping treatment. In women with major risk factors for decreased BMD, such as chronic alcohol use (>3 units per day), tobacco use, strong family history of osteoporosis, or chronic use of drugs that can decrease BMD, such as anticonvulsants or corticosteroids, use of LUPRON DEPOT may pose an additional risk. Carefully weigh the risks and benefits of LUPRON DEPOT use in these populations.
- The duration of LUPRON DEPOT 3.75 mg or 11.25 mg treatment is limited by the risk of loss of BMD.
- When using LUPRON DEPOT 3.75 mg or 11.25 mg for the management of endometriosis, combination use of norethindrone acetate (add-back therapy) is effective in reducing the loss of BMD that occurs with leuprolide acetate. Do not retreat with LUPRON DEPOT 3.75 mg or 11.25 mg without combination norethindrone acetate. Assess BMD before retreatment.

Embryo-Fetal Toxicity

- Based on animal reproduction studies and the drug's mechanism of action, LUPRON DEPOT 3.75 mg or 11.25 mg may cause fetal harm if administered to a pregnant woman and is contraindicated in pregnant women. Exclude pregnancy prior to initiating treatment with LUPRON DEPOT 3.75 mg or 11.25 mg, if clinically indicated. Discontinue LUPRON DEPOT 3.75 mg or 11.25 mg if the woman becomes pregnant during treatment and inform the woman of potential risk to the fetus. Advise women to notify their healthcare provider if they believe they may be pregnant.

PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION ON NEXT PAGE.

- When used at the recommended dose and dosing interval, LUPRON DEPOT 11.25 mg usually inhibits ovulation and stops menstruation. Contraception, however, is not ensured by taking LUPRON DEPOT 11.25 mg. If contraception is indicated, advise women to use non-hormonal methods of contraception while on treatment with LUPRON DEPOT 3.75 mg or 11.25 mg.

Hypersensitivity Reactions

- Hypersensitivity reactions, including anaphylaxis, have been reported with LUPRON DEPOT use. LUPRON DEPOT 3.75 mg or 11.25 mg is contraindicated in women with a history of hypersensitivity to gonadotropin-releasing hormone (GnRH) or GnRH agonist analogs.
- In clinical trials of LUPRON DEPOT 3.75 mg or 11.25 mg, adverse events of asthma were reported in women with pre-existing histories of asthma, sinusitis, and environmental or drug allergies. Symptoms consistent with an anaphylactoid or asthmatic process have been reported postmarketing.

Initial Flare of Symptoms

- Following the first dose of LUPRON DEPOT 3.75 mg or 11.25 mg, sex steroids temporarily rise above baseline because of the physiologic effect of the drug. Therefore, an increase in symptoms may be observed during the initial days of therapy, but these should dissipate with continued therapy.

Convulsions

- There have been postmarketing reports of convulsions in women on GnRH agonists, including leuprolide acetate. These included women with and without concurrent medications and comorbid conditions.

Clinical Depression

- Depression may occur or worsen during treatment with GnRH agonists including LUPRON DEPOT 3.75 mg or 11.25 mg. Carefully observe women for depression, especially those with a history of depression, and consider whether the risks of continuing LUPRON DEPOT 3.75 mg or 11.25 mg outweigh the benefits. Women with new or worsening depression should be referred to a mental health professional, as appropriate.

Risks Associated with Norethindrone Combination Treatment

- If LUPRON DEPOT 3.75 mg or 11.25 mg is administered with norethindrone acetate, the warnings and precautions for norethindrone acetate apply to this regimen. Refer to the norethindrone acetate prescribing information for a full list of the warnings and precautions for norethindrone acetate.

ADVERSE REACTIONS

- Most common adverse reactions (>10%) in clinical trials were hot flashes/sweats, headache/migraine, vaginitis, depression/emotional lability, general pain, weight gain/loss, nausea/vomiting, decreased libido, and dizziness.

These are not all the possible side effects of LUPRON DEPOT 3.75 mg or 11.25 mg.

- Safety and effectiveness of LUPRON DEPOT 3.75 mg or 11.25 mg for management of endometriosis and the preoperative hematologic improvement of women with anemia caused by fibroids have been established in females of reproductive age. Efficacy is expected to be the same for postpubertal adolescents under the age of 18 as for users 18 years and older. The safety and effectiveness of LUPRON DEPOT 3.75 mg or 11.25 mg for these indications have not been established in premenarcheal pediatric patients.
- LUPRON DEPOT 3.75 mg or 11.25 mg is not indicated in postmenopausal women and has not been studied in this population.

Please see full Prescribing Information.

Reference: 1. LUPRON DEPOT GYN 3.75 mg and 3-month 11.25 mg [package insert]. North Chicago, IL: AbbVie Inc.

Indication and Important Safety Information[1]

Lupaneta Pack™
leuprolide acetate for depot suspension
and norethindrone acetate tablets

INDICATION[1]

LUPANETA PACK™ (leuprolide acetate for depot suspension and norethindrone acetate tablets) 1-Month 3.75 mg and 3-Month 11.25 mg are indicated for initial management of the painful symptoms of endometriosis and for management of recurrence of symptoms. The initial treatment course is limited to 6 months. If symptoms recur, a single treatment course of not more than 6 months may be administered. Use is not recommended longer than a total of 12 months due to concerns about adverse impact on bone mineral density.

IMPORTANT SAFETY INFORMATION[1]

LUPANETA PACK 1-Month 3.75 mg and 3-Month 11.25 mg are contraindicated in:

- Patients who are hypersensitive to gonadotropin-releasing hormone (GnRH), GnRH agonist analogs or any of the excipients in leuprolide acetate for depot suspension, or norethindrone acetate
- Undiagnosed abnormal uterine bleeding
- Known, suspected, or planned pregnancy during the course of therapy
- Lactating women
- Known, suspected, or history of breast cancer or other hormone-sensitive cancer
- Current or history of thrombotic or thromboembolic disorder
- Liver tumors or liver disease

Leuprolide acetate for depot suspension induces a hypoestrogenic state resulting in loss of bone mineral density (BMD), some of which may not be reversible. In patients that are candidates for retreatment, it is recommended that bone density be assessed before retreatment. Retreatment with leuprolide acetate for depot suspension alone is not recommended.

In patients with major risk factors for loss of bone mineral content, risks and benefits of LUPANETA PACK must be weighed carefully before therapy is instituted, as use in this population may pose additional risks.

Leuprolide acetate may cause fetal harm if administered to a pregnant woman. Exclude pregnancy before initiating treatment with LUPANETA PACK. Use at the recommended dose usually inhibits ovulation and stops menstruation. Patients should use non-hormonal methods of contraception. Discontinue LUPANETA PACK if a patient becomes pregnant during treatment and inform the patient of potential risk to the fetus.

Discontinue norethindrone acetate tablets, pending examination, if there is a sudden partial or complete loss of vision or sudden onset of proptosis, diplopia, or migraine. Discontinue LUPANETA PACK if examination reveals papilledema or retinal vascular lesions.

Depression may occur or worsen during treatment with LUPANETA PACK. Carefully observe patients with a history of clinical depression and discontinue if the depression recurs to a serious degree.

In clinical trials of LUPANETA PACK, adverse events of asthma were reported in women with pre-existing histories of asthma, sinusitis, and environmental or drug allergies. Postmarketing reports of symptoms consistent with an anaphylactoid or asthmatic process have been reported.

Assess and manage risk factors for cardiovascular disease before starting LUPANETA PACK. Closely monitor women on norethindrone acetate who have risk factors for arterial vascular disease (e.g., hypertension, diabetes mellitus, tobacco use, hypercholesterolemia, and obesity) and/or venous thromboembolism (VTE) (e.g., family history of VTE, obesity, and smoking).

An increase in clinical signs and symptoms may be observed during the initial days of therapy due to a temporary rise in sex steroids, but these should dissipate with continued therapy.

Norethindrone acetate may cause some degree of fluid retention; therefore, carefully observe women with conditions that might be influenced by this effect, such as epilepsy, migraines, or cardiac or renal dysfunctions.

Postmarketing reports of convulsions have been observed in patients on leuprolide acetate therapy, including patients with and without concurrent medications and comorbid conditions.

Experience with LUPANETA PACK for treatment of endometriosis has been limited to women 18 years of age and older.

In controlled clinical trials, adverse events occurring in >10% of patients were hot flashes/sweats, headache/migraine, depression/emotional lability, nausea/vomiting, nervousness/anxiety, insomnia, pain, acne, asthenia, vaginitis, weight gain, constipation/diarrhea.

Please see full Prescribing Information.

Reference: 1. LUPANETA PACK [package insert].