pharmacy | SOLUTIONS

Address: 1 North Waukegan Road,
AP5 NE, D-LP90
North Chicago, IL 60064
Phone: 888-857-0668
Fax: 800-266-2065

Bringing you LUPRON DEPOT® (leuprolide acetate for depot suspension) and LUPANETA PACK™ (leuprolide acetate for depot suspension and norethindrone acetate tablets)

THIS FORM CAN BE USED TO REQUEST THE FOLLOWING SERVICES:

BENEFIT VERIFICATION • DISPENSING MEDICATION • FINANCIAL ASSISTANCE RESEARCH

Pharmacy Solutions, a specialty pharmacy service brought to you by AbbVie, provides expanded patient support and gives patients more options for accessing LUPRON DEPOT® (leuprolide acetate for depot suspension) and LUPANETA PACK™ (leuprolide acetate for depot suspension and norethindrone acetate tablets) by providing the personalized support they need.

Insurance Support Services

- o Benefit verification and prior authorization assistance

Pharmacy Services

- o Medication dispensing and delivery coordination
- o Forwarding of the prescription to an in-network specialty pharmacy or patient-preferred pharmacy if Pharmacy Solutions is not in-network to dispense

Financial Assistance Research

- o AbbVie-sponsored co-pay card eligibility
- o Referrals to independent co-pay foundations or the AbbVie Patient Assistance Foundation

CHECKLIST FOR SUBMITTING FORM

1. Check the appropriate box above the Prescriber Signature section on the form if you do not want LUPRON DEPOT or LUPANETA PACK to be dispensed at this time and are requesting benefit verification services.
2. Complete all sections of the form. Fax form to 800-266-2065.
3. Provide front and back copies of all insurance/prescription card(s).
4. Prescriber should sign in the designated area if writing a prescription for dispensing.
5. If your state requires a prescription to be written on an official state prescription form (e.g., New York, New Jersey), please fax the prescription along with the LUPRON DEPOT/LUPANETA PACK Referral Form.
6. If you wish to prescribe norethindrone acetate (for endometriosis patients), and you live in a state that does not permit multiple prescriptions on one blank, please fax a prescription for norethindrone acetate along with the LUPRON DEPOT/LUPANETA PACK Referral Form.

Please provide complete information to ensure timely processing.

For more information, or to be connected with a dedicated Pharmacy Solutions Partner for your office, please call us at 888-857-0668.

Product support services are available regardless of where the prescription is filled.

Please see Indications and Important Safety Information on next two pages.
Please click here for full Prescribing Information.

An AbbVie Company

Indications for LUPRON DEPOT® (leuprolide acetate for depot suspension)[1]

Uterine Leiomyomata (Fibroids)

LUPRON DEPOT® (leuprolide acetate for depot suspension) 3.75 mg for 1-month and 11.25 mg for 3-month administration concomitantly with iron therapy are indicated for the preoperative hematologic improvement of patients with anemia caused by uterine leiomyomata. The clinician may wish to consider a one-month trial period on iron alone inasmuch as some of the patients will respond to iron alone. LUPRON DEPOT may be added if the response to iron alone is considered inadequate. Recommended duration of therapy with LUPRON DEPOT 3.75 mg is up to three months. The 3-month 11.25 mg dosage form is indicated only for women for whom three months of hormonal suppression is deemed necessary. Experience with LUPRON DEPOT in females has been limited to women 18 years of age and older.

Endometriosis

LUPRON DEPOT® (leuprolide acetate for depot suspension) 3.75 mg for 1-month and 11.25 mg for 3-month administration are indicated for the management of endometriosis, including pain relief and reduction of endometriotic lesions. LUPRON DEPOT with daily norethindrone acetate 5 mg is also indicated for initial management of endometriosis and for management of recurrence of symptoms. Duration of initial treatment or retreatment should be limited to 6 months.

Important Safety Information[1]

LUPRON DEPOT 3.75 mg for 1-month and 11.25 mg for 3-month administration are contraindicated in:

- patients who are hypersensitive to gonadotropin releasing hormone (GnRH), GnRH agonist analogs or any of the excipients in LUPRON DEPOT.
- undiagnosed abnormal vaginal bleeding.
- females who are or may become pregnant while receiving the drug. LUPRON DEPOT may cause fetal harm when administered to pregnant women. If used during pregnancy, the patient should be apprised of the potential hazard to a fetus, and that spontaneous abortion may occur. Before starting treatment with LUPRON DEPOT, pregnancy must be excluded.
- women who are breast-feeding.

Norethindrone acetate as add-back therapy in endometriosis is contraindicated in women with thrombophlebitis, thromboembolic disorders, cerebral apoplexy, or a past history of these conditions; markedly impaired liver function or liver disease; and known or suspected carcinoma of the breast.

Assessment and management of risk factors for cardiovascular disease is recommended prior to initiation of add-back therapy with norethindrone acetate. Norethindrone acetate should be used with caution in women with risk factors, including lipid abnormalities or cigarette smoking.

Used at the recommended dose, LUPRON DEPOT usually inhibits ovulation and stops menstruation. Patients should use non-hormonal methods of contraception.

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 will dissipate with continued therapy.

LUPRON DEPOT plus norethindrone acetate treatment should be discontinued if there is a sudden partial or complete loss of vision or if there is sudden onset of proptosis, diplopia, or migraine. If examination reveals papilledema or retinal vascular lesions, medication should be withdrawn.

Patients should be counseled on the possibility of the development or worsening of depression and the occurrence of memory disorders. Patients who have a history of depression should be carefully observed during treatment.

Induced hypoestrogenic state results in bone loss over the course of treatment, some of which may not be reversible. In controlled clinical trials in patients with endometriosis, at the end of 6 months of therapy with LUPRON DEPOT, vertebral bone density decreased by an average of 3.2% compared with the pretreatment values. In controlled clinical trials in patients with fibroids, after 3 months of therapy, vertebral bone density decreased by an average of 2.7% compared with the pretreatment value.

In patients with major risk factors for loss of bone mineral content, risks and benefits of LUPRON DEPOT alone must be weighed carefully before therapy is instituted, and concomitant treatment with daily norethindrone acetate 5 mg should be considered. Treatment with LUPRON DEPOT beyond an initial 6-month course is not advisable in these patients. In patients that are candidates for retreatment, it is recommended that bone density be assessed before retreatment. Retreatment with LUPRON DEPOT alone is not recommended.

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

Due to suppression of the pituitary-gonadal system by LUPRON DEPOT, diagnostic tests of pituitary gonadotropic and gonadal functions conducted during treatment, and for up to 3 months after discontinuation of LUPRON DEPOT, may be affected.

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

In controlled clinical trials of endometriosis patients, with or without add-back therapy with norethindrone acetate, adverse events occurring in >20% of patients were headache, vasomotor flushes, depression/emotional lability, vaginitis, pain, nausea/vomiting, and insomnia/sleep disorder. In controlled clinical trials of fibroid patients adverse events occurring in >10% of patients were headache, vasomotor flushes, depression/emotional lability and vaginitis.

LUPRON DEPOT plus norethindrone acetate-treated patients had significantly decreased HDL levels and significantly increased LDL/HDL ratios in clinical trials. After discontinuation of treatment, mean serum lipid levels in clinical trial patients with follow-up data returned to pretreatment values. In controlled clinical trials of fibroid patients, mean changes in cholesterol, LDL, HDL and the LDL/HDL ratios were observed.

Reference: 1. LUPRON DEPOT [package insert].

Please click here for full Prescribing Information.

Indication for LUPANETA PACK™ (leuprolide acetate for depot suspension and norethindrone acetate tablets)[2]

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[2]

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.

Reference: 2. LUPANETA PACK [package insert].

Please click here for full Prescribing Information.

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LUPRON DEPOT® (leuprolide acetate for depot suspension) and LUPANETA PACK™ (leuprolide acetate for depot suspension and norethindrone acetate tablets) REFERRAL FORM. SIGN AND FAX THIS FORM TO 800-266-2065. FOR QUESTIONS PLEASE CALL 888-857-0668.

REFERRAL TYPE

REFERRAL TYPE

☐ Dispense – Rx will be filled or forwarded

☐ Non-dispense – Only a benefit verification will be performed

COVERAGE TO INVESTIGATE (please select one)

☐ Patient's prescription drug benefits

☐ Physician buy-and-bill benefits

PATIENT AND PRESCRIBER INFORMATION

PATIENT INFORMATION SSN (Last 4 ONLY) ____ | ____ | ____ | ____

First Name: _____ MI: _____

Last Name: _____

DOB: _____ Weight (lbs): _____ Sex: Female

Address: _____

City/State/Zip: _____

Primary Phone: _____ ☐ H ☐ W ☐ M

Alternate Phone: _____ ☐ H ☐ W ☐ M

Drug Allergies: _____

PRESCRIBER INFORMATION ☐ MD ☐ DO ☐ Other: _____

Prescriber Name: _____

Specialty: ☐ Gyn ☐ Other: _____

NPI/Provider #: _____ State License #: _____

Office Name: _____

Contact: _____

Address: _____

City/State/Zip: _____

Phone: _____ Fax: _____

INSURANCE INFORMATION

Fax a copy of the front and back of prescription insurance card(s) or fill in the information below

Primary Insurance: _____

Phone: _____

Cardholder ID #: _____ Group #: _____

PCN: _____ BIN: _____

Policyholder Name: _____ DOB: _____

Secondary Insurance: _____

Phone: _____

Cardholder ID #: _____ Group #: _____

PCN: _____ BIN: _____

Policyholder Name: _____ DOB: _____

CLINICAL AND PRESCRIPTION INFORMATION

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 the patient ☐ Deliver medication to the prescriber

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: _____

☐ Other _____ Sig: _____ Qty: _____ Refills: _____

Endometriosis ONLY

☐ LUPANETA PACK 3.75 mg (1-month supply) Includes norethindrone acetate 5 mg tablets #30 Sig: Administer Lupron IM once a month; take one norethindrone acetate tablet by mouth daily #1 kit Refills: _____

☐ LUPANETA PACK 11.25 mg (3-month supply) Includes norethindrone acetate 5 mg tablets #90 Sig: Administer Lupron IM 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: _____

PRESCRIBER SIGNATURE: PRESCRIBER MUST MANUALLY SIGN (RUBBER STAMPS, SIGNATURE BY OTHER OFFICE PERSONNEL FOR THE PRESCRIBER, AND COMPUTER-GENERATED SIGNATURES WILL NOT BE ACCEPTED), OR SEND AN ELECTRONIC PRESCRIPTION TO PHARMACY SOLUTIONS, AN ABBVIE COMPANY.

☐ **Dispense as written/Do not substitute** **Date**

☐ **Substitution permitted/Brand exchange permitted** **Date**

I authorize Pharmacy Solutions and its employees to serve as my agent for the sole purpose of obtaining patient benefit information and the necessary prior authorization forms when dealing with Health Plans and Pharmacy Benefits Managers (PBMs), if the plan or PBM requires such authorization.

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

Please see Indications and Important Safety Information on previous two pages.

Please click here for full Prescribing Information.