

PATIENT INFORMATION
ON
TREATMENT WITH
LUPRON DEPOT
– 3 Month 11.25 mg
(leuprolide acetate for
depot suspension)

DRUGS-ABOUT.COM

LUPRON DEPOT[®]
-3 Month 11.25 mg

LEUPROLIDE ACETATE
FOR DEPOT SUSPENSION

This is combined labeling. Examples of different colors and fonts appear below.

- General Information
- Information on Endometriosis
- Information on Uterine Fibroids

This patient education booklet provides information on the use of LUPRON DEPOT[®] –3 Month 11.25 mg (leuprolide acetate for depot suspension) for two different medical conditions:

1. Endometriosis
2. Anemia due to vaginal bleeding from fibroids

Your health care provider will direct you to the section that will discuss your condition.

This booklet is not intended to be a substitute for information provided to you by your health care provider. You should discuss with your health care provider any questions you have about your diagnosis and treatment, and you may ask your health care provider for a copy of the information provided to him or her by TAP Pharmaceuticals Inc.

LUPRON DEPOT–3 Month 11.25 mg is given to decrease the production of estrogen by your ovaries. The information provided describes the drug's action in the treatment of either condition described in this booklet.

HOW IS LUPRON GIVEN?

LUPRON DEPOT–3 Month 11.25 mg is a prescription drug that is prescribed by your health care provider. Once every three months you will receive an injection of LUPRON DEPOT–3 Month 11.25 mg.

You should get your injections on time. The recommended initial treatment is no more than two injections for endometriosis and one injection for uterine fibroids. If you need retreatment for endometriosis, it should be limited to 6 months.

WHAT SHOULD I EXPECT?

At first, your estrogen level will increase for one or two weeks. During that time, you may notice an increase in your current symptoms. Then your estrogen level will decline, as it does in menopause.

The common side effects of LUPRON DEPOT –3 Month 11.25 mg include, but are not limited to, hot flashes, vaginal dryness, headaches, changes in mood,

and a decreased interest in sex. You should also know there is a possibility of the development or worsening of depression and/or the occurrence of forgetfulness.

Your menstrual periods will probably become less regular and the flow may be heavier or lighter. After a few months of therapy your periods may stop completely.

WHAT IS THE MOST IMPORTANT RISK OF TAKING LUPRON?

When you take LUPRON DEPOT–3 Month 11.25 mg, your estrogen level is decreased to menopausal levels or lower. This low level can result in thinning of the bones, which may not be completely reversible in some patients. There are certain conditions that may increase the possibility of the thinning of your bones when you take a drug such as LUPRON DEPOT–3 Month 11.25 mg. They are:

- Excessive use of alcohol;
- Smoking;
- Family history of osteoporosis (thinning of the bones with fractures);
- Taking other medications that can cause thinning of the bones.

You should discuss the possibility of osteoporosis or thinning of the bones with your health care provider before starting LUPRON DEPOT–3 Month 11.25 mg. You should also be aware that repeat treatment with LUPRON DEPOT–3 Month 11.25 mg alone is not advisable, particularly if you have the above conditions.

WHO SHOULD NOT USE LUPRON DEPOT –3 Month 11.25 mg?

If you answer YES to any of the following questions, you should **not** use LUPRON DEPOT–3 Month 11.25 mg.

- Are you pregnant?
- Are you breast-feeding?
- Do you have any abnormal vaginal bleeding that has not been evaluated by your health care provider?
- Have you experienced any type of allergic reaction to a drug like Lupron?

Remember, always ask your health care provider about any concerns you might have regarding this or any medication.

WHAT SHOULD I KNOW IF I AM RECEIVING CO-TREATMENT WITH LUPRON DEPOT - 3 Month 11.25 mg AND NORETHINDRONE ACETATE?

Norethindrone acetate is related to the hormone progesterone and is used in some birth control pills. Your health care provider may recommend co-treatment

with LUPRON DEPOT - 3 Month 11.25 mg and norethindrone acetate to reduce the risk of bone loss. This may also reduce some of the menopausal symptoms like hot flashes. To reduce bone loss, norethindrone acetate should be started with the first injection of LUPRON DEPOT - 3 Month 11.25 mg. This drug will not interfere with the desired effects of LUPRON DEPOT - 3 Month 11.25 mg in treating endometriosis.

LUPRON DEPOT - 3 Month 11.25 mg given with norethindrone acetate may lower your HDL-cholesterol level (the “good” cholesterol). Whether this change increases your long-term risk of heart disease is not known. Your health care provider should assess your risk of heart disease prior to starting this co-treatment.

You should not use co-treatment with norethindrone acetate if you have had or have any of the following conditions:

- Blood clots in your legs (phlebitis), heart disease, or stroke;
- Liver disease;
- Breast cancer.

If you have had any of the following conditions or if any of the following apply to you, tell your health care provider before beginning norethindrone acetate co-treatment:

- High levels of cholesterol;
- Migraine headaches;
- Epilepsy;
- Depression;
- Smoking.

After beginning co-treatment, notify your health care provider IMMEDIATELY if sudden loss of vision, double vision, or migraine headaches occur. In addition, you should notify your health care provider if any of the following conditions occur:

- Fluid retention;
- Epilepsy;
- Asthma or worsening asthmatic symptoms;
- Heart or kidney problems.

If your symptoms return after treatment is finished and repeat treatment is desired, you will need co-treatment with LUPRON DEPOT–3 Month 11.25 mg and norethindrone acetate. Your health care provider should assess your bone density at this time. Be sure to discuss this with your health care provider.

Co-treatment with LUPRON DEPOT–3 Month 11.25 mg and norethindrone acetate has not been studied for treatment of fibroids.

COULD YOU GET PREGNANT?

LUPRON DEPOT–3 Month 11.25 mg is not a contraceptive. Even though you may not have periods, unprotected intercourse could result in pregnancy. Therefore, you should use non-hormonal birth control such as condoms or a diaphragm with contraceptive gel/cream or an IUD. If you think that you may be pregnant while receiving LUPRON DEPOT–3 Month 11.25 mg contact your health care provider immediately.

CONDITION DESCRIPTIONS

Endometriosis is a condition in which the endometrium, the tissue that lines the uterus (womb) is found outside of the uterus. Common sites for such “endometrial implants” can be the ovaries, the fallopian tubes, the outer surface of the uterus, and the bowel. Such implants can bleed just like the normal endometrium does during your menstrual cycle, but the blood is trapped so the implants can cause pain and irritation to surrounding tissues. As a reaction to this irritation, the body sometimes forms scar tissue around and near the implants. Scar tissues that bind organs together are called adhesions.

Fibroids are not cancer. They are non-cancerous growths of the body of the uterus and they are very common in women. (They occur in about 20% to 25% of all women and are most common in women aged 30 to 40.) A woman may have only one fibroid or many. They may occur on the outer surface of the uterus, totally within the walls of the uterus, or on the inside surface. Many women who have fibroids are not aware of them because they do not cause problems.

Fibroids can cause problems due to their size, number and location, but a major problem is excessive menstrual bleeding. LUPRON DEPOT–3 Month 11.25 mg is used with iron for the improvement of anemia due to heavy menstrual bleeding because of fibroids. Like any growth, fibroids should be checked by a health care provider. Fibroids are also called myomas or leiomyomas.

SIGNS AND SYMPTOMS

Endometriosis can be the cause of severe menstrual cramps just before or during your menstrual cycle as well as pelvic pain or pressure and/or pain during intercourse.

Fibroids may cause you to have unusually heavy menstrual periods, bleeding between periods, sudden or long-lasting pain or a feeling of pressure in the lower abdomen. Excessive bleeding may lead to anemia from a shortage of iron in the blood and can make you feel tired or sick.

HOW DOES LUPRON DEPOT–3 Month 11.25 mg WORK?

LUPRON DEPOT–3 Month 11.25 mg interrupts the normal menstrual cycle and the production of estrogen and this may slow the growth of endometrial implants. As a result, pain and other symptoms resulting from endometriosis can be eased during treatment. In about 50% to 60% of the women treated during clinical studies, LUPRON DEPOT 3.75 mg (monthly depot) afforded relief from symptoms. Some of the symptoms were more responsive to treatment than others. The list below shows the percent of patients with specific symptoms who found relief at the end of treatment.

| | |
|-----------------------------|-----|
| Menstrual pain/cramping | 96% |
| Pelvic pain | 53% |
| Pain with intercourse | 56% |
| Pelvic tenderness | 66% |
| Thickening of pelvic tissue | 71% |

Many of the original patients were followed up to 1 year after treatment with LUPRON DEPOT 3.75 mg was stopped to determine when symptoms of endometriosis recurred. In these patients, some of the symptoms reappeared faster than others.

Fibroids that do not cause symptoms or occur in women nearing menopause often will not require treatment. However, if you have heavy bleeding as a result of your fibroids, you may also be anemic. LUPRON DEPOT–3 Month 11.25 mg together with iron may stop the bleeding and allow your blood count to build up to a normal level. The uterine and fibroid volume will decrease and you may also experience relief from abdominal bloating, pelvic pain and pressure if you have suffered from these symptoms because of your fibroids.

Your health care provider may consider a one month trial of iron alone as some patient's anemia will improve with iron alone.

WHAT HAPPENS AFTER THERAPY IS FINISHED?

Once you have finished your course of treatment with LUPRON DEPOT–3 Month 11.25 mg alone or co-treatment with LUPRON DEPOT and norethindrone acetate, your periods will return and the menopausal symptoms you experienced will usually disappear within twenty-four weeks from the day of your last injection. In some patients, thinning of the bone structure may not be completely reversible.

CAN I GET PREGNANT AFTER THERAPY IS FINISHED?

Once you have finished your course of treatment with LUPRON DEPOT–3 Month 11.25 mg your health care provider may schedule you for surgery. You may be able to get pregnant after your surgery if only your fibroids are removed. You will not be able to get pregnant if your uterus is removed during surgery. Fibroids may develop again even after their removal. If they do, 20% to

40% of patients may require more surgery. Your health care provider will help you to make decisions about any need for more surgery.

This patient education brochure is not intended to be a substitute for information provided to you by your health care provider or provided to your health care provider by TAP Pharmaceuticals Inc.

You should discuss with your health care provider any questions you have about the diagnosis and treatment of your condition.

This information is provided as a service of TAP Pharmaceuticals Inc.

GLOSSARY

Adhesions – scar tissue.

Anemia – low blood count.

Aygestin® – brand name of norethindrone acetate.

Diaphragm – barrier type birth control device that covers the cervical opening between the vagina and the uterus.

Estrogen – female hormone produced by the ovaries.

Fallopian tube – a tube that transports eggs from each ovary to the uterus.

Fibroids – non-cancerous growths of the body of the uterus.

Implants – endometrial tissue that fixes itself outside the uterine cavity.

IUD – birth control device temporarily implanted in the uterus.

Menopause – the end of a woman's reproductive years.

Norethindrone acetate – a drug related to the hormone progesterone.

Osteoporosis – a thinning of the bone structure that is most often found in women after menopause.

Uterus – the womb; muscular organ in which a fertilized egg embeds and is nourished.



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