# Important New Update to the MEDICATION GUIDE for ORILISSA® (elagolix) tablets, for oral use

In February 2021, the ORILISSA Prescribing information (PI) and MEDICATION GUIDE were updated. The following describes some of the changes in the ORILISSA MEDICATION GUIDE. Please refer to the full PI and MEDICATION GUIDE to review additional changes.

**The following items have been added to the MEDICATION GUIDE:**

**Do not take ORILISSA if you:**

- have had a serious allergic reaction to ORILISSA or any of the ingredients in ORILISSA. See the end of this Medication Guide for a complete list of ingredients in ORILISSA. Ask your healthcare provider if you are not sure.

**The following items have been updated in the MEDICATION GUIDE to read:**

**What is the most important information I should know about ORILISSA?**

**ORILISSA may cause serious side effects, including:**

- **bone loss (decreased bone mineral density)**
  - If you have bone loss on ORILISSA, your bone density may improve after you stop taking ORILISSA but complete recovery may not occur. It is unknown if these bone changes could increase your risk for broken bones as you age. For this reason, your healthcare provider may limit the length of time you take ORILISSA.
- **effects on pregnancy**
  - ORILISSA does not prevent pregnancy. You will need to use effective methods of birth control while taking ORILISSA and for 28 days after you stop taking ORILISSA. Examples of effective methods can include condoms or spermicide, which do not contain hormones.

**Do not take ORILISSA if you:**

- are taking medicines called organic anion transporting polypeptide (OATP) 1B1 inhibitors that are known or expected to significantly increase the blood levels of elagolix (the active ingredient in ORILISSA). Ask your healthcare provider if you are not sure if you are taking one of these medicines.

**Especially tell your healthcare provider if you take:**

- birth control that contains hormones. Your healthcare provider may advise you to change your method of birth control.

**This is not a complete list of all the changes made to the Prescribing Information and MEDICATION GUIDE for ORILISSA. Please refer to the full Prescribing Information and MEDICATION GUIDE for more details.**



**Please see Use and additional Important Safety Information on pages 2-3.**

**Please see accompanying full Prescribing Information including the Medication Guide for patients.**

## USE[1]

ORILISSA® (elagolix) is a prescription medicine used to treat moderate to severe pain associated with endometriosis. It is not known if ORILISSA is safe and effective in children.

## IMPORTANT SAFETY INFORMATION[1]

### What is the most important information I should know about ORILISSA?

**ORILISSA may cause serious side effects, including:**

- **Bone Loss (decreased Bone Mineral Density [BMD])**
  While you are taking ORILISSA, your estrogen levels will be low. This can lead to BMD loss. If you have bone loss on ORILISSA, your BMD may improve after stopping ORILISSA, but may not recover completely. It is unknown if these bone changes could increase your risk for broken bones as you age. For this reason, your healthcare provider (HCP) may limit the length of time you take ORILISSA. Your HCP may order a DXA scan to check your BMD.

- **Effects on Pregnancy**
  **Do not take** ORILISSA if you are trying to become or are pregnant, as your risk for early pregnancy loss may increase. **If you think you are pregnant**, stop taking ORILISSA right away and call your HCP. ORILISSA may change your menstrual periods (irregular bleeding or spotting, a decrease in menstrual bleeding, or no bleeding at all), making it hard to know if you are pregnant. Watch for other signs of pregnancy, such as breast tenderness, weight gain, and nausea. ORILISSA does not prevent pregnancy. You will need to use effective hormone-free birth control (such as condoms or spermicide) while taking ORILISSA and for 28 days after stopping ORILISSA. Birth control pills that contain estrogen may make ORILISSA less effective. It is unknown how well ORILISSA works while on progestin-only birth control.

### Do not take ORILISSA if you:

- Are pregnant, have osteoporosis, have severe liver disease, are taking medicines called organic anion transporting polypeptide (OATP) 1B1 inhibitors that are known or expected to significantly increase the blood levels of elagolix, the active ingredient in ORILISSA (ask your HCP if you are not sure if you are taking one of these medicines), or have had a serious allergic reaction to ORILISSA or any of the ingredients in ORILISSA. See the end of the Medication Guide for a complete list of ingredients in ORILISSA. Ask your HCP if you are not sure.

### What should I tell my HCP before taking ORILISSA?

**Tell your HCP about all of your medical conditions**, **including if you:**

- Have or have had broken bones or other conditions that may cause bone problems; have or have had depression, mood problems, or suicidal thoughts or behavior; have liver problems; think you may be pregnant; or are breastfeeding or plan to be. It is unknown if ORILISSA passes into breast milk. Talk to your HCP about the best way to feed your baby if you take ORILISSA.

**Tell your HCP about all of the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

**Especially tell your HCP if you take** birth control that contains hormones. Your HCP may advise you to change your method of birth control.

### What are the possible side effects of ORILISSA?

**ORILISSA can cause serious side effects including:**

- **Suicidal thoughts, actions, or behavior, and worsening of mood. Call your HCP or get emergency medical help right away if you have any of these symptoms, especially if they are new, worse, or bother you:** thoughts about suicide or dying, attempts to commit suicide, new or worse depression or anxiety, or other unusual changes in behavior or mood. You or your caregiver should pay attention to any changes, especially sudden changes in your mood, behaviors, thoughts, or feelings.
- **Abnormal liver tests. Call your HCP right away if you have any of these signs and symptoms of liver problems:** yellowing of the skin or the whites of the eyes (jaundice), dark amber-colored urine, feeling tired, nausea and vomiting, generalized swelling, right upper stomach area pain, or bruising easily.



**Please see accompanying full Prescribing Information including the Medication Guide for patients.**

**The most common side effects of ORILISSA include:** hot flashes and night sweats, headache, nausea, difficulty sleeping, absence of periods, anxiety, joint pain, depression, and mood changes.

These are not all of the possible side effects of ORILISSA. This is the most important information to know about ORILISSA. For more information, talk to your HCP.

Take ORILISSA exactly as your HCP tells you. Tell your HCP if you have any side effect that bothers you or that does not go away. Call your doctor for medical advice about side effects.

**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.**



**Please see accompanying full Prescribing Information including the Medication Guide for patients.**

**Reference: 1.** ORILISSA [package insert]. North Chicago, IL: AbbVie Inc.