

Patient Information

SYMBYAX™ (SIM-bee-ax)
(olanzapine and fluoxetine HCl capsules)

Read the Patient Information that comes with SYMBYAX before you start using it and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or treatment. It is important to stay under a doctor's care while taking SYMBYAX. **Do not change or stop treatment without first talking with your doctor.** Talk to your doctor or pharmacist if you have any questions about SYMBYAX.

What is SYMBYAX?

SYMBYAX is a prescription medicine used to treat adults who have depression with bipolar disorder. SYMBYAX contains two medicines, olanzapine and fluoxetine hydrochloride. Olanzapine is also the active ingredient in Zyprexa® and Zyprexa Zydis®. Fluoxetine hydrochloride is also the active ingredient in Prozac®, Prozac Weekly™, and Sarafem®.

SYMBYAX has not been studied in children.

What is bipolar disorder?

Bipolar disorder, once called manic-depressive illness, is a brain disorder that causes unusual changes in a person's mood, energy level, and ability to function. Bipolar disorder is a long-term illness that can be treated with medicines, but it usually requires life-long treatment.

Who should not take SYMBYAX?**Do not take SYMBYAX if you are:**

- **Taking a medicine known as a monoamine oxidase inhibitor (MAOI) or have stopped taking a MAOI within the last 2 weeks.** An MAOI is a medicine sometimes used for depression and other mental problems. Examples of MAOI medicines are Nardil® (phenylzine sulfate) and Parnate® (tranylcypromine sulfate). Taking SYMBYAX with a MAOI may cause serious side effects that can be life threatening. Do not take a MAOI for at least 5 weeks after you stop taking SYMBYAX.
- **Taking Mellaril® (thioridazine) for mental problems or stopped taking it within the last 5 weeks.** Mellaril® (thioridazine) can cause a heart problem (prolongation of the QTc interval) **that can cause death.** SYMBYAX with Mellaril® (thioridazine) can increase your chances of having this serious and life-threatening heart problem.
- **Allergic to SYMBYAX or any of its ingredients.** The active ingredients are olanzapine and fluoxetine hydrochloride. See the end of this leaflet for a complete list of ingredients in SYMBYAX.

What should I tell my doctor before taking SYMBYAX?

- **Tell your doctor if you are taking fluoxetine, Prozac, Prozac Weekly, Sarafem, olanzapine, Zyprexa, or Zyprexa Zydis.** These medicines each contain an active ingredient that is also found in SYMBYAX.

- **Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements. SYMBYAX can interact with many other medicines, causing serious or life-threatening side effects.** Your doctor will decide if you can take SYMBYAX with your other medicines, or if your dose should be adjusted. Keep a list of your medicines with you and show it to your doctor and pharmacist every time you are prescribed a new medicine or start a new non-prescription medicine, vitamin, or herbal supplement.
- **Tell your doctor if you are taking SYMBYAX and are taking or plan to take nonsteroidal anti-inflammatory drugs or aspirin** since combined use of these drug products has been associated with an increased risk of bleeding.
- **Before taking SYMBYAX, tell your doctor if you have or had the following medical conditions:**
 - **Are pregnant or plan to become pregnant.** It is not known if SYMBYAX can harm your unborn baby. You and your doctor should decide if SYMBYAX is right for you during pregnancy.
 - **Are breast-feeding or plan to breast-feed.** SYMBYAX may pass into your milk and may harm your baby. You should choose either to breast-feed or take SYMBYAX, but not both.
 - **Are older than age 65 and have a mental problem called dementia** (slow loss of mental function)
 - **High blood sugar, diabetes or family history of diabetes**
 - **Liver problems.** You may need a lower dose of SYMBYAX.
 - **Seizures** (convulsions or fits)
 - **Low blood pressure.** SYMBYAX may cause dizziness or fainting in people with low blood pressure.
 - **Heart problems including heart attacks**
 - **Strokes, or mini-strokes called transient ischemic attacks (TIA)**
 - **High blood pressure**
 - **An enlarged prostate** (men)
 - **An eye problem called narrow angle glaucoma**
 - **A stomach problem called a paralytic ileus**
- **Also, tell your doctor if you**
 - **Currently smoke**
 - **Drink alcohol**, especially if you drink a lot
 - **Exercise a lot** or are often in **hot places**

How should I take SYMBYAX?

- Take SYMBYAX exactly as instructed by your doctor. Your doctor will usually start you on a low dose of SYMBYAX. Your dose may be adjusted depending on your body's response to

SYMBYAX. Your dose will also depend on certain medical problems you have. **Do not stop taking SYMBYAX or change your dose even if you feel better, without talking with your doctor.**

- SYMBYAX is usually taken once a day in the evening. Take SYMBYAX at the same time each day. SYMBYAX may be taken with or without food.
- If you miss a dose, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and take only your regularly scheduled dose. Do not take more than your doctor has prescribed for you.
- Tell your doctor if your depression does not get better while taking SYMBYAX. Your doctor may adjust your dose or give you a different medicine.
- If you take too much SYMBYAX or overdose, call your doctor or poison control center right away, or go to the nearest emergency room.

What should I avoid while taking SYMBYAX?

- Do not drive or operate other dangerous machinery until you know how SYMBYAX affects you. SYMBYAX can impair your judgment, thinking, and motor skills.
- Do not take medicines, including prescription and non-prescription medicines, vitamins and herbal supplements unless you have talked to your doctor about them.
- Do not get pregnant.
- Do not breast-feed.
- Do not drink alcohol.
- Do not get over-heated or dehydrated (loss of body fluids) during hot weather or exercise, or when using a hot tub.
- Do not take a MAOI medicine for **at least 5 weeks** after you stop taking SYMBYAX.

What are the possible side effects of SYMBYAX?

All medicines may cause side effects in some patients. Serious side effects reported by patients treated with SYMBYAX follow below:

- **Severe allergic reactions** that cause hives, swelling of your face, eyes, mouth, or tongue, trouble breathing or a rash with fever and joint pain. Tell your doctor right away if you get these symptoms. Your doctor may stop SYMBYAX and prescribe medicines to treat your allergic reaction.
- **Strokes and "mini-strokes" called transient ischemic attacks (TIAs).** These are more common in elderly patients with dementia. As with other mental health drugs, SYMBYAX should be used with caution in elderly patients with dementia. SYMBYAX is not approved for the treatment of elderly patients with dementia.
- **High blood sugar or diabetes.** Patients who already have diabetes should have their blood sugar checked regularly during treatment with SYMBYAX. Patients at risk for diabetes (for example, those who are overweight or have a family history of diabetes) who are starting treatment with SYMBYAX should undergo blood sugar testing on an empty stomach at the beginning of treatment and regularly during treatment. Any patient treated

with SYMBYAX should be monitored for signs of high blood sugar including being thirsty, going to the bathroom a lot, eating a lot, and feeling weak. Patients who develop signs of high blood sugar during treatment with SYMBYAX should undergo blood sugar testing on an empty stomach. In some cases, high blood sugar has gone away when SYMBYAX was stopped; however, some patients had to keep taking medicine for diabetes even though they stopped taking SYMBYAX.

- **Neuroleptic malignant syndrome (NMS).** NMS is a rare, but life-threatening reaction to certain medicines for mental problems, including SYMBYAX. Stop taking SYMBYAX and call your doctor right away if you get any of the following symptoms of NMS, such as a high fever, sweating, muscle stiffness, trouble thinking clearly, a change in mental functioning, sleepiness, or changes in your breathing, heartbeat, and blood pressure. NMS can cause death and must be treated in a hospital.
- **Tardive dyskinesia.** This is a condition caused by certain medicines for mental problems, including SYMBYAX. It causes body movements, mostly in your face or tongue, that keep happening and that you cannot control. It may start after you stop taking SYMBYAX. Tardive dyskinesia may not go away, even if you stop taking SYMBYAX. Tell your doctor if you get body movements that you can't control.
- **Low blood pressure.** SYMBYAX may cause low blood pressure in some patients. Low blood pressure is more likely in patients who have heart problems, who have brain problems such as strokes, who take certain medicines, or who drink alcohol. Signs of low blood pressure include dizziness, fast heartbeat, and fainting. To lower your chances of fainting while taking SYMBYAX, stand up slowly if you have been sitting or lying down.
- **Seizures.** SYMBYAX should be used cautiously in people who have had seizures in the past or who have conditions that increase their risk for seizures.
- **Impaired judgment, thinking, and motor skills**
- **Trouble swallowing**
- **Abnormal bleeding.** When SYMBYAX is used alone, and especially with certain other medicines that can increase bleeding risk (for example; ibuprofen or aspirin), your risk of bleeding can increase. If you notice increased or unusual bruising or other bleeding, contact your doctor.
- **Low salt levels in the blood.** SYMBYAX can cause a low salt level in the blood. Weakness, confusion, or trouble thinking can be caused by low salt levels in the blood. If you develop any of these symptoms, contact your doctor.
- **Body temperature problems.** SYMBYAX can cause problems in keeping your body temperature regular. Do not become overheated or dehydrated during hot weather or exercise, or when using a hot tub.

Common side effects of SYMBYAX are:

- Weight gain
- Sleepiness
- Diarrhea
- Dry mouth
- Increased appetite

- Feeling weak
- Swelling of your hands and feet
- Tremors (shakes)
- Sore throat
- Trouble concentrating
- SYMBYAX can cause problems in keeping your body temperature regulated.

Tell your doctor about any side effect that bothers you or won't go away. Your doctor may be able to help you manage the side effect.

These are not all the side effects of SYMBYAX. For more information ask your doctor or pharmacist.

Other important safety information about SYMBYAX

- The symptoms of bipolar disorder may include thoughts of harming yourself or others or committing suicide. Tell your doctor immediately or go to an emergency center if you have any of these thoughts.
- Symptoms of bipolar disorder may include mania. If you experience manic symptoms (for example: racing thoughts, poor sleep, irritability, mood swings, extra energy), contact your doctor.
- If your depression becomes worse, contact your doctor.
- Rarely, people taking medicines of this type have started to leak milk from their breasts, and women have missed periods or had irregular periods. If these symptoms occur, contact your doctor.
- If you gain weight while taking SYMBYAX, contact your doctor to discuss changes you can make in your activities or eating habits to help manage your weight.
- Problems with sexual functioning have commonly occurred in patients taking SYMBYAX. If these symptoms occur, contact your doctor.

How do I store SYMBYAX?

- Store SYMBYAX at room temperature, 59° to 86° F (15° to 30° C).
- Keep the container tightly closed and protect from moisture.
- **Keep SYMBYAX and all medicines away from children.**

General information about SYMBYAX

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not take SYMBYAX for a condition for which it was not prescribed. Do not give SYMBYAX to other people, even if they have the same symptoms that you have. It may harm them.

This leaflet summarizes important information about SYMBYAX. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information that is written for health professionals. You can also call 1-800-Lilly-Rx (1-800-545-5979) or visit our website at www.SYMBYAX.com.

What are the ingredients in SYMBYAX?

Active ingredients: olanzapine and fluoxetine hydrochloride

Inactive ingredients: pregelatinized starch, gelatin, dimethicone, titanium dioxide, sodium lauryl sulfate, edible black ink, red iron oxide, yellow iron oxide, and/or black iron oxide.

Rx Only

This patient information has been approved by the US Food and Drug Administration.

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www.SYMBYAX.com

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