BYSANTI™
(milsaperidone) tablets

For Bipolar I Disorder in Adults

Introducing BYSANTI™: a prescription medicine used for the acute treatment of manic or mixed episodes associated with bipolar I disorder in adults.

Elderly patients with psychosis related to dementia (having lost touch with reality due to memory loss and experiencing a decline in day-to-day functioning) who are treated with antipsychotic medications are at an increased risk of death compared to patients treated with a placebo. BYSANTI™ is not approved for use in people with dementia-related psychosis.

Please see Important Safety Information including BOXED WARNING on pages 8-11.
Please see full Prescribing Information inside pocket.

Enter BYSANTI™

Important Safety Information

Elderly patients with psychosis related to dementia (having lost touch with reality due to memory loss and experiencing a decline in day-to-day functioning) who are treated with antipsychotic medications are at an increased risk of death compared to patients treated with a placebo. BYSANTI™ is not approved for use in people with dementia-related psychosis.

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Bipolar I disorder is a treatable medical condition that can cause extreme shifts in mood, thoughts, energy, and behavior. Its impact can reach beyond those living with it, affecting loved ones, too.

It is called bipolar disorder because a person's mood can shift between the two "poles" of bipolar I disorder: mania, characterized by elevated or irritable mood and increased energy, and depression. These episodes can last anywhere from days to months.

During manic episodes, elevated or irritable mood and increased energy levels can significantly interfere with a person's physical, cognitive, and social functioning, making bipolar I disorder especially challenging to manage.

Bipolar disorder does not have a single known cause. Research suggests that brain chemistry, biology, and environment may play a role.

For additional Important Safety Information, see pages 8-11.

This brochure isn't meant to take the place of your healthcare professional's instructions. Read this and all medication information carefully before you take BYSANTI™ (milsaperidone) tablets. Talk to your healthcare professional if you have any questions or if there is anything you do not understand.

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It's important to know:

While no one fully understands why some people experience bipolar mania—9.6 million Americans do—you are not alone. Support and treatment options are available.

Symptoms:

Symptoms of a manic episode include inflated self-esteem, decreased need for sleep, pressured speech, racing thoughts, distractibility, psychomotor agitation, and risky behavior.

Treatment:

Right now, there is no cure for bipolar I disorder, but it is treatable. Many people successfully manage the disease through a combination of medications, counseling, and a support system.

BYSANTI™ may be the medication you've been looking for.

BYSANTI™ is proven to treat the symptoms of bipolar mania. Talk with your healthcare professional about whether BYSANTI™ may be right for you.

BYSANTI™ is a prescription medicine used for the acute treatment of manic or mixed episodes associated with bipolar I disorder in adults.

INDICATIONS AND IMPORTANT SAFETY INFORMATION

BYSANTI™ (milsaperidone) is a prescription medication used for the treatment of schizophrenia and the acute treatment of manic or mixed episodes associated with bipolar I disorder in adults.

Elderly patients with psychosis related to dementia (having lost touch with reality due to memory loss and experiencing a decline in day-to-day functioning) who are treated with antipsychotic medications are at an increased risk of death compared to patients treated with a placebo. BYSANTI™ is not approved for use in people with dementia-related psychosis.

Patients should not use BYSANTI™ if they have a known allergy to BYSANTI™ or its ingredients. Allergic reactions, including anaphylaxis, rapid swelling of the skin (angioedema) and other symptoms of allergy (e.g., throat tightness; swelling of the throat, face, lips, mouth and tongue; hives; rash and itching) have been reported.

WARNINGS AND PRECAUTIONS

- An increased risk of stroke has been reported in clinical studies of elderly people with dementia-related psychosis. BYSANTI™ is not approved for use in people with dementia-related psychosis.
- BYSANTI™ may change your heart rhythm (meaning there is more time between heartbeats). Heart rhythm changes have occurred in patients taking BYSANTI™ and are a risk factor for serious, even life-threatening medical issues. You should tell your healthcare provider if you have or have had heart problems. Contact your healthcare provider right away if you feel faint or have unpleasant feelings of irregular or forceful heartbeats as any of these feelings could be a sign of a rare, but serious side effect that could be fatal. You should not use BYSANTI™ with other drugs that are known to cause these same heart rhythm issues.
- Tell your healthcare provider if you have some or all of the following symptoms:

For additional Important Safety Information, see pages 8-11.

very high fever, rigid muscles, shaking, confusion, sweating or increased heart rate and blood pressure. These may be signs of a condition called neuroleptic malignant syndrome (NMS), a rare but serious side effect that could be fatal. This may happen with BYSANTI™ or drugs like it.

- Abnormal or uncontrollable movements of the face, tongue or other parts of the body may be signs of a serious condition called tardive dyskinesia (TD), which could become permanent. The chance of this condition going away decreases, depending on how long and how much medication has been taken. Tell your healthcare provider if you have body movements you can't control.
- BYSANTI™ and medicines like it have been associated with metabolic changes (high blood sugar, high cholesterol and triglycerides, and weight gain) that can increase cardiovascular/cerebrovascular risks. Increases in blood sugar levels (hyperglycemia), which in some cases can be serious and associated with coma or death, have been reported in patients taking BYSANTI™ and medicines like it. Changes in cholesterol and triglycerides have been seen in patients taking BYSANTI™ and medicines like it. Some patients may gain weight while taking BYSANTI™. Your healthcare provider should check your blood sugar, fat levels and weight before you start and regularly while you take BYSANTI™.
- Light-headedness or faintness caused by a sudden change in heart rate and blood pressure when rising quickly from a sitting or lying position (orthostatic hypotension) has been reported with BYSANTI™. This condition is most common when you start therapy, when restarting treatment or when the dose of BYSANTI™ is increased. You should consult your healthcare provider if you have or have had heart problems or conditions that lead to these sudden changes since BYSANTI™ should be used with caution in these patients.
- BYSANTI™ may increase the risk of falls, which could cause fractures or other injuries.
- Tell your healthcare provider if you have a history of or have a condition that may increase your risk for seizures before you begin taking BYSANTI™.

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INDICATIONS AND IMPORTANT SAFETY INFORMATION (CONTINUED)

- Decreases in infection-fighting white blood cells (WBCs) have been reported in some patients taking antipsychotic agents. Patients with a preexisting history of low WBC count or who have experienced a low WBC count due to drug therapy should have their blood tested and monitored during the first few months of therapy. Some (including fatal) cases of agranulocytosis, a serious decrease in specific types of WBCs called neutrophils or granulocytes, have been reported in drugs like BYSANTI™.
- BYSANTI™ can increase the level of the hormone prolactin. Tell your healthcare provider if you experience breast enlargement, breast pain or breast discharge, abnormal menstrual cycles in females or impotence in males. If elevated levels of prolactin persist, this may lead to bone loss.
- Medicines like BYSANTI™ can impact your body's ability to reduce your body temperature. You should avoid overheating and dehydration.
- BYSANTI™ and medicines like it have been associated with swallowing problems (dysphagia). If you have or have had swallowing problems, you should tell your healthcare provider.
- For males, in the rare event you have a painful or prolonged erection (priapism) lasting 4 or more hours, stop using BYSANTI™ and seek immediate medical attention.
- BYSANTI™ and medicines like it can affect your judgment, thinking or motor skills. You should not drive or operate hazardous machinery, including automobiles, until you know how BYSANTI™ affects you.
- A condition called intraoperative floppy iris syndrome has been observed in some patients taking drugs like BYSANTI™. Please tell your healthcare provider if you take or have taken BYSANTI™ before cataract or other eye surgeries.

The most common side effects for BYSANTI™ versus placebo in patients with schizophrenia were dizziness, dry mouth, feeling unusually tired or sleepy, stuffy nose, feeling faint/light-headed when standing quickly, racing heartbeat and weight gain. The most common side effects for BYSANTI™ versus placebo in a clinical study of patients with bipolar I disorder were racing heartbeat, dizziness, dry mouth, increase in liver enzymes, stuffy nose, weight gain, low blood pressure and feeling unusually tired or sleepy. Compared to placebo, the average weight gain in clinical studies in schizophrenia lasting 4 to 6 weeks was 6 pounds and in a clinical study of patients with bipolar I disorder over 4 weeks was 7 pounds. If you experience any of these symptoms, talk with your healthcare provider.

When taking BYSANTI™, you should avoid drinking alcohol and you should not breastfeed.

You should notify your healthcare provider if you become pregnant or intend to become pregnant while taking BYSANTI™.

Tell your healthcare provider about any medical conditions that you have, including problems with your liver. BYSANTI™ is not recommended for patients with severe liver problems.

Tell your healthcare provider about all prescription and non-prescription medicines and supplements you are taking. Some medications may interact with BYSANTI™.

Your healthcare provider may recommend a genetic test before starting BYSANTI™ to see how your body processes the medication, as this can affect the right dose for you. People who process it slowly (poor metabolizers) may need a different dosing schedule.

If you take certain other medications that can affect how BYSANTI™ works in your body (such as strong inhibitors of CYP2D6 or CYP3A4), your healthcare provider may need to lower your dose. Always tell your healthcare provider about all medicines you're taking to avoid interactions.

To access the full Prescribing Information, including BOXED WARNING, visit www.bysanti.com.

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.

Important things to know:

Your healthcare professional will consider several factors when deciding if a medication is right for you, including your symptoms, current health conditions, and other medications you may be taking.

Side effects can vary from person to person, so it's important to work with your healthcare professional.

Common side effects for BYSANTI™ in people with bipolar I disorder include:

- Racing heartbeat
- Dizziness
- Dry mouth
- Liver enzyme increase
- Stuffy nose
- Weight gain
- Low blood pressure
- Sleepiness



Important things to know (continued):

- In a study of iloperidone that supported the approval of BYSANTI™ in adults with bipolar I disorder, most did not have clinically significant weight gain.
- In a study of iloperidone that supported the approval of BYSANTI™ in adults with bipolar I disorder, patients reported occurrence of EPS (extrapyramidal symptoms, i.e. uncontrollable facial or body twitching) and akathisia (extreme restlessness) at low rates.
- BYSANTI™ and medicines like it have been associated with metabolic changes (high blood sugar, high cholesterol and triglycerides, and weight gain) that can increase cardiovascular/cerebrovascular risks. Your healthcare professional should check your metabolic levels before you start and regularly while you take BYSANTI™.
- Abnormal or uncontrollable movements of the face, tongue, or other parts of the body may be signs of a serious condition called tardive dyskinesia (TD), which could become permanent. The chance of this condition going away decreases, depending on how long and how much medication has been taken. Tell your healthcare professional if you have body movements you can't control.

Iloperidone and milsaperidone (the active ingredient in BYSANTI™) rapidly convert into one another in the body.

If you experience any side effects that concern you, talk to your healthcare professional right away.

Starting BYSANTI™:

With your healthcare professional's guidance, you will start BYSANTI™ at a lower dose and gradually increase it over a few days to help your body adjust.

Starting low and increasing your dose slowly may help avoid lightheadedness or faintness. Lightheadedness or faintness may occur when standing up or getting up too quickly due to changes in heart rate and blood pressure (orthostatic hypotension).

How to take BYSANTI™:

- Take 1 tablet in the morning and 1 tablet in the evening.
- Swallow the tablets whole, with or without food.
- Keep taking BYSANTI™ as prescribed, even if you start to feel better, unless your healthcare professional tells you otherwise.

For additional Important Safety Information, see pages 8-11.

Important Safety Information:

Light-headedness or faintness caused by a sudden change in heart rate and blood pressure when rising quickly from a sitting or lying position (orthostatic hypotension) has been reported with BYSANTI™. This condition is most common when you start therapy, when re-starting treatment, or when the dose of BYSANTI™ is increased. You should consult your healthcare professional if you have or have had heart problems or conditions that lead to these sudden changes since BYSANTI™ should be used with caution in these patients.

BYSANTI™ Starter Package:

Titration packs are available to help you follow the recommended dosing schedule when starting treatment with BYSANTI™. Be sure to start taking BYSANTI™ exactly as your healthcare professional prescribes.

Titration Pack B (4-Day)*



Titration Pack C (3-Day)†



*Titration Pack B follows recommended titration schedule for most adults with manic or mixed episodes associated with bipolar I disorder.

†Titration Pack C follows recommended titration schedule for adults with manic or mixed episodes associated with bipolar I disorder who are CYP2D6 poor metabolizers.

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Tips to help make sure you don't miss a dose:

- Link your medication to a daily routine and keep it somewhere visible to make it easy to remember.
- Set an alarm on your phone, clock or watch when it's time to take your dose.
- Mark a calendar or journal each time you take your medication so you always have a clear record.
- Use a pill organizer to see at a glance whether you've taken your dose for the day.
- Ask a family member or friend to check in with you daily and remind you when it's time to take your medication.
- Start each day with two rubber bands on your wrist and remove one after each dose, a simple visual cue to stay on track.

BYSANTI™ and other medicines:

While you are taking BYSANTI™, check with your healthcare professional before starting any new prescription or over-the-counter medicines you can get without a prescription, including any supplements.

Some medicines may be unsafe to use when taking BYSANTI™. Some medicines can affect how well BYSANTI™ works.

Who should NOT take BYSANTI™?

- People with a known allergy to BYSANTI™ or its ingredients.
- People with a history of significant cardiovascular illness.
- People with severe liver problems.

When taking BYSANTI™, you should avoid drinking alcohol, and you should not breastfeed.

Tell your healthcare professional if you become pregnant or intend to become pregnant while taking BYSANTI™. BYSANTI™ may cause extrapyramidal (abnormal involuntary movements) and/or withdrawal symptoms in newborn babies exposed to BYSANTI™ during the third trimester.

BYSANTI™ has not been studied in children and teenagers younger than 18 years.

For additional Important Safety Information, see pages 8-11.

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Tips for keeping track:

There's a lot of information to keep track of: medications, appointments, changes... Write them down in one place, such as a notebook or calendar, for when you talk to your healthcare professional.

- List all the medications (and dosages) you're supposed to take each day
- Together with your healthcare professional, set treatment goals. Write them down as a checklist to track your progress

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Caring for someone with bipolar disorder:

As difficult as it is to experience manic episodes, caring for someone you love with bipolar I disorder can be just as difficult, but in different ways.

And although everyone's situation is different, one thing all caregivers can do is to remember to take care of themselves, too, both physically and emotionally. Many caregivers have found valuable help by talking with people in similar situations at support groups.

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Caregivers have a lot to keep track of, too.

During a crisis, planning is vital. Keep a record of important information about the person you're caring for, including:

- The names and contact numbers of their healthcare professionals and support team
- A list of all medications (and dosages) they're taking
- A short history of their experience with the disease, including when diagnosed, and a record of episodes and how they were handled
- It's also helpful to decide ahead of time which medical center they prefer if hospitalization becomes necessary

The more decisions you discuss and agree on ahead of time, the easier it will be during a crisis.

Concerned about changes in mood or behavior? Contact their healthcare professional or go to the nearest emergency room or community mental health center.

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Resources:

This pamphlet summarizes important information about BYSANTI™.
If you want more information, talk to your healthcare professional.

If you have any questions, call Vanda Pharmaceuticals at:
1-844-468-2632, Monday-Friday, 8:30am - 5:00pm (EST)

NAMI (National Alliance on Mental Illness)

The National Alliance on Mental Illness (NAMI) provides support to people with mental illness and their families and friends.

www.nami.org 1-800-950-NAMI (6264)

NIMH (National Institute of Mental Health)

The National Institute of Mental Health (NIMH) offers information on mental illness and treatment options.

www.nimh.nih.gov 1-866-615-6464

MHA (Mental Health America)

Mental Health America is the country's oldest and largest nonprofit organization for mental health and mental illness.

www.mhanational.org 1-800-969-6642

DBSA (Depression and Bipolar Support Alliance)

The Depression and Bipolar Support Alliance (DBSA) is America's #1 provider of peer support and services, education, and wellness tools for people living with depression or bipolar disorder.

www.dbsalliance.org (312) 642-0049

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