

FDA-Approved Medication Guide
MEDICATION GUIDE

Milnacipran Hydrochloride (mil-NA-si-pran HYE-droe-KLOR-ide) Tablets

Milnacipran hydrochloride tablets are not used to treat depression, but it acts like medicines that are used to treat depression (antidepressants) and other psychiatric disorders.

Read the Medication Guide that comes with milnacipran hydrochloride tablets before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or treatment. Talk with your healthcare provider if there is something you do not understand or want to learn more about.

What is the most important information I should know about milnacipran hydrochloride tablets?

Milnacipran hydrochloride tablets and antidepressant medicines may cause serious side effects, including:

1. Suicidal thoughts or actions:

- **Milnacipran hydrochloride tablets and antidepressant medicines may increase suicidal thoughts or actions in some children, teenagers, and young adults within the first few months of treatment or when the dose is changed.**
- Depression or other serious mental illnesses are the most important causes of suicidal thoughts or actions. Watch for these changes and call your healthcare provider right away if you notice:
 - New or sudden changes, in mood, behavior, thoughts, or feelings, especially if severe.
 - Pay particular attention to such changes when milnacipran hydrochloride tablets is started or when the dose is changed.
 - Keep all follow-up visits with your healthcare provider and call between visits if you are worried about symptoms.

Call your healthcare provider right away or go to the nearest hospital emergency room if you have any of the following symptoms, especially if they are new, worse, or worry you:

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| • attempts to commit suicide | • new or worse anxiety or panic attacks |
| • acting on dangerous impulses | • feeling agitated, restless, angry or irritable |
| • acting aggressive, being angry, or violent | • trouble sleeping (insomnia) |
| • thoughts about suicide or dying | • an increase in activity or talking more than what is normal for you |
| • new or worse depression | • other unusual changes in behavior or mood |

Call your healthcare provider right away or go to the nearest hospital emergency room if you have any symptoms of the serious side effects listed below:

2. Serotonin Syndrome. This condition can be life-threatening, symptoms may include:

- agitation, hallucinations, coma or other changes in mental status
- coordination problems or muscle twitching (overactive reflexes)
- sweating or fever
- diarrhea
- muscle rigidity

- dizziness
- tremor

Symptoms such as racing heartbeat, high or low blood pressure, nausea, vomiting, and flushing are common with milnacipran hydrochloride tablets. **Call your healthcare provider right away if you get these symptoms and they are severe or if they happen with any of the symptoms of serotonin syndrome listed above.**

3. Increase in blood pressure or heart rate: Milnacipran hydrochloride tablets may increase your blood pressure or heart rate. Check your blood pressure and heart rate before you start and during treatment with milnacipran hydrochloride tablets. Before taking milnacipran hydrochloride tablets, tell your healthcare provider if you have high blood pressure or problems with your heart or blood vessels (cardiovascular disease).

4. Seizures or convulsions.

5. Liver problems. Symptoms of liver problems may include:

- itching
- right upper abdominal pain
- dark urine
- yellowing of your skin or eyes
- enlarged liver
- increased liver enzymes

6. Low salt (sodium) levels in the blood. Elderly people may be at greater risk for this. Symptoms may include:

- headache
- weakness or feeling unsteady
- confusion, problems concentrating or thinking or memory problems

7. Abnormal bleeding: Milnacipran hydrochloride tablets and other similar medicines (antidepressants) may increase your risk of bleeding or bruising, especially if you take the blood thinner warfarin (Coumadin, Jantoven), a nonsteroidal anti-inflammatory drug (NSAID), or aspirin.

8. Manic episodes

- greatly increased energy
- severe trouble sleeping
- racing thoughts
- reckless behavior
- unusually grand ideas
- excessive happiness or irritability
- talking more or faster than usual

9. Problems with urination

- decreased urine flow
- unable to pass any urine

Men may be more likely to have these symptoms, and may develop pain in their testicles or have problems with ejaculation.

10. Visual problems

- eye pain
- changes in vision
- swelling or redness in or around eye

Only some people are at risk for these problems. You may want to undergo an eye examination to see if you are at risk and receive preventative treatment if you are.

11. Sexual problems (dysfunction). Taking serotonin and norepinephrine reuptake inhibitors (SNRIs), including milnacipran hydrochloride, may cause sexual problems.

Symptoms in males may include

- Delayed ejaculation or inability to have an ejaculation
- Decreased sex drive
- Problems getting or keeping an erection

Symptoms in females may include

- Decreased sex drive
- Delayed orgasm or inability to have an orgasm

Talk to your healthcare provider if you develop any changes in your sexual function or if you have any questions or concerns about sexual problems during treatment with milnacipran hydrochloride. There may be treatments your healthcare provider can suggest.

Do not stop milnacipran hydrochloride tablets without first talking to your healthcare provider. Stopping milnacipran hydrochloride tablets too quickly may cause symptoms, some serious, including:

- anxiety, irritability, or confusion
- feeling tired or problems sleeping
- headache, dizziness, seizures
- electric shock-like sensations, ringing in ears

What are milnacipran hydrochloride tablets?

Milnacipran hydrochloride tablets are prescription medicine used to manage fibromyalgia. It is important to talk with your healthcare provider about the risks of treating fibromyalgia and also the risks of not treating it. You should discuss all treatment choices with your healthcare provider. It is not known if milnacipran hydrochloride tablets are safe and effective in children.

Who should not take milnacipran hydrochloride tablets?

Do not take milnacipran hydrochloride tablets if you:

- **take a Monoamine Oxidase Inhibitor (MAOI).** Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI, including the antibiotic linezolid.
 - Do not take an MAOI within 5 days of stopping milnacipran hydrochloride tablets unless your healthcare provider tells you to.
 - Do not start milnacipran hydrochloride tablets if you stopped taking an MAOI in the last 14 days unless your healthcare provider tells you to.
- **People who take milnacipran hydrochloride tablets close in time to an MAOI may have serious or even life-threatening side effects. Get medical help right away if you have any of these symptoms:**
 - high fever
 - uncontrolled muscle spasms
 - stiff muscles
 - rapid changes in heart rate or blood pressure
 - confusion
 - loss of consciousness (pass out)

**What should I tell my healthcare provider before taking milnacipran hydrochloride tablets?
Before starting milnacipran hydrochloride tablets, tell your healthcare provider if you:**

- have heart problems or high blood pressure
- have liver problems
- have kidney problems
- have or had seizures or convulsions
- have bipolar disorder or mania
- have low sodium levels in your blood
- have or had bleeding problems
- drink alcohol. Talk to your healthcare provider about how often and how much alcohol you drink.
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if milnacipran hydrochloride tablets will harm your unborn baby.
- are breastfeeding or plan to breastfeed. Milnacipran hydrochloride can pass into your breast milk and may harm your baby. Talk to your healthcare provider about the best way to feed your baby while taking milnacipran hydrochloride tablets.

Tell your healthcare provider about all the medicines that you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Milnacipran hydrochloride tablets and some medicines may interact with each other, may not work as well, or may cause serious side effects.

Especially tell your healthcare provider if you take:

- triptans used to treat migraine headache
- medicines used to treat mood, anxiety, psychotic or thought disorders, including tricyclics, lithium, buspirone, SSRIs, SNRIs or MAOIs
- tramadol, fentanyl, meperidine, methadone, or other opioids
- amphetamines
- the blood thinner warfarin (Coumadin, Jantoven)
- non-steroidal anti-inflammatory drug (NSAID) (like ibuprofen, naproxen or aspirin)
- over-the-counter supplements such as tryptophan or St. John's Wort

Ask your healthcare provider for a list of these medicines if you are not sure.

Your healthcare provider or pharmacist can tell you if it is safe to take milnacipran hydrochloride tablets with your other medicines. Do not start or stop any medicine while taking milnacipran hydrochloride tablets without talking to your healthcare provider first.

How should I take milnacipran hydrochloride tablets?

- Take milnacipran hydrochloride tablets exactly as your healthcare provider tells you.
- Your healthcare provider will slowly increase your dose to find the dose that is right for you.
 - On the first day of treatment, you will take 1 dose of milnacipran hydrochloride tablets as prescribed.
 - After your first dose, your healthcare provider will tell you how much milnacipran hydrochloride tablets to take and when to take it, usually 2 times each day.
- You may take milnacipran hydrochloride tablets with or without food. Taking milnacipran hydrochloride tablets with food may help you tolerate it better.
- If you miss a dose, skip the missed dose and take the next dose at your regular time.

- Tell your healthcare provider if you feel that your condition is not improving during treatment with milnacipran hydrochloride tablets.
- If you take too much milnacipran hydrochloride tablets, call your healthcare provider or go to the nearest hospital emergency room right away.

What should I avoid while taking milnacipran hydrochloride tablets?

- Do not drive or operate machinery until you know how milnacipran hydrochloride tablets affects you. Milnacipran hydrochloride tablets may make you less alert and affect your reaction time.

What are the possible side effects of milnacipran hydrochloride tablets?

Milnacipran hydrochloride tablets may cause side effects, some serious, including:

- See “**What is the most important information I should know about milnacipran hydrochloride tablets?**”

The most common side effects of milnacipran hydrochloride tablets include:

- nausea
- constipation
- dizziness
- trouble sleeping
- hot flush
- increased sweating
- vomiting
- headache
- irregular heartbeat (palpitations)
- heart rate increased
- dry mouth
- high blood pressure (hypertension)

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of milnacipran hydrochloride tablets. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store milnacipran hydrochloride tablets?

- Store at room temperature between 68°F to 77°F (20°C to 25°C).

Keep milnacipran hydrochloride tablets and all medicines out of the reach of children.

General information about the safe and effective use of milnacipran hydrochloride tablets

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use milnacipran hydrochloride tablets for a condition for which it was not prescribed. Do not give milnacipran hydrochloride tablets to other people, even if they have the same condition. It may harm them.

You may ask your healthcare provider or pharmacist for information about milnacipran hydrochloride tablets that is written for health professionals.

For more information, contact Breckenridge Pharmaceutical, Inc. at 1-800-367-3395.

What are the ingredients in milnacipran hydrochloride tablets?

Active ingredient: milnacipran hydrochloride

Inactive ingredients: Dibasic Calcium Phosphate Dihydrate (Di-Tab), Microcrystalline Cellulose (Avicel PH 112), Crospovidone (Kollidon CL), Colloidal Silicon Dioxide (Aerosil 200 Pharma), Magnesium Stearate (VG) and Purified water.

The film coat contains the inactive ingredients:

12.5 mg tablets: HPMC 2910/Hypromellose, Titanium Dioxide, Macrogol /PEG, FD&C Blue #1/Brilliant Blue FCF Aluminum Lake

25 mg tablets: HPMC 2910/Hypromellose, Titanium Dioxide, Macrogol /PEG

50 mg tablets: HPMC 2910/Hypromellose, Titanium Dioxide, Macrogol /PEG

100 mg tablets: HPMC 2910/Hypromellose, Titanium Dioxide, Macrogol /PEG, FD&C Red #40/Allura Red AC Aluminum Lake

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