

MEDICATION GUIDE
Tranlycypromine Sulfate Tablets, USP
(TRAN-il-SIP-roe-meen suhl-feyt)

What is the most important information I should know about Tranlycypromine Sulfate tablets?

Tranlycypromine Sulfate tablets can cause serious side effects including:

• **Increase in suicidal thoughts or actions** in some children, teenagers, and young adults within the first few months of treatment and when the Tranlycypromine Sulfate dose is changed. Depression and other serious mental illnesses are the most important causes of suicidal thoughts and actions. Some people may have a particularly high risk of having suicidal thoughts or actions. These include people who have, or have a family history of, bipolar illness (also called manic-depressive illness) or suicidal thoughts or actions. **Tranlycypromine Sulfate is not for use in children.**

How can I watch for and try to prevent suicidal thoughts and actions?

- Pay close attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings. This is very important when an antidepressant medicine is started or when the dose is changed.
- Call the healthcare provider right away to report new or sudden changes in mood, behavior, thoughts, or feelings.
- Keep all follow-up visits with your healthcare provider as scheduled. Call the healthcare provider between visits as needed, especially if you have concerns about symptoms.

Call a healthcare provider right away if you have any of the following symptoms, especially if they are new, worse, or worry you:

- thoughts about suicide or dying
- new or worse depression
- feeling agitated, restless, angry or irritable
- trouble sleeping
- acting aggressive, being angry or violent
- an extreme increase in activity or talking (mania)
- attempts to commit suicide
- new or worse anxiety
- panic attacks
- new or worse irritability
- acting on dangerous impulses
- other unusual changes in behavior or mood

• **A sudden, severe increase in blood pressure (hypertensive crisis).**

A hypertensive crisis can happen when you eat certain foods and drink certain beverages during or after Tranlycypromine Sulfate treatment. A hypertensive crisis can lead to stroke and death. People who have thyroid problems (hyperthyroidism) may have a higher chance of having a hypertensive crisis. Symptoms of a hypertensive crisis may include:

- sudden, severe headache
- vomiting
- a fast heartbeat (palpitations) or a change in the way your heart beats
- the pupils in your eyes increase in size
- fast or slow heart beat with chest pain
- nausea
- stiff or sore neck
- excessive sweating, sometimes with fever or cold, clammy skin
- light bothers your eyes
- bleeding in your brain

A hypertensive crisis can also happen if you take Tranlycypromine Sulfate with certain other medicines. See, "Who should not take Tranlycypromine Sulfate?"

Avoid foods and drinks with a lot of tyramine while taking Tranlycypromine Sulfate and for 2 weeks after you stop taking it.

For a list of some of the foods and drinks you should avoid during treatment with Tranlycypromine Sulfate see, "What should I avoid while taking Tranlycypromine Sulfate?"

What is Tranlycypromine Sulfate?

Tranlycypromine Sulfate is a prescription medicine used to treat adults with a certain type of depression called major depressive disorder (MDD) who have not responded well to treatment with other medicines used to treat depression (antidepressants). Tranlycypromine Sulfate belongs to a class of medicines called monoamine oxidase inhibitors (MAOIs).

- It is important to talk with your healthcare provider about the risks of treating depression and the risk of not treating it. Talk with your healthcare provider about all your treatment choices.
- Tranlycypromine Sulfate is not for use as the first medicine to treat MDD.

- It is not known if Tranlycypromine Sulfate is safe and effective for use in children.

Who should not take Tranlycypromine Sulfate?

Taking Tranlycypromine Sulfate with certain antidepressants and certain pain, allergy symptom, and cold and cough symptom medicines may cause a potentially life-threatening hypertensive crisis or a problem called serotonin syndrome. See, "What is the most important information I should know about Tranlycypromine Sulfate?" and "What are the possible side effects of Tranlycypromine Sulfate?"

Do not take Tranlycypromine Sulfate if you:

- **take certain medicines, including:**
 - antidepressants, such as:
 - other monoamine oxidase inhibitors (MAOIs)
 - selective serotonin reuptake inhibitors (SSRIs) and serotonin and norepinephrine reuptake inhibitors (SNRIs)
 - tricyclic antidepressants
 - other antidepressants, such as amoxapine, bupropion, maprotiline, nefazodone, trazodone, vilazodone, vortioxetine
 - amphetamines and methylphenidates
 - medicines that can raise blood pressure (sympathomimetic medicine), such as pseudoephedrine, phenylephrine and ephedrine. These medicines are in some cold, hay fever or weight-loss medicines.
 - sympathomimetic herbal medicines or dietary supplements
 - antihistamines (allergy medicines)
 - triptans
 - carbamazepine
 - dopamine
 - levodopa and methyl dopa
 - rasagiline
 - s-adenosyl-L-methionine (SAM-e)
 - tapentadol
 - tetrabenazine
 - buspirone
 - dextromethorphan
 - hydroxytryptophan and tryptophan
 - meperidine
 - reserpine

Ask your healthcare provider or pharmacist if you are not sure if you take any of these medicines.

- **have a tumor on your adrenal gland called a pheochromocytoma or a type of tumor called a paraganglioma.**

Before taking Tranlycypromine Sulfate, tell your healthcare provider about all your medical conditions, including if you:

- have high or low blood pressure
- have heart problems
- have cerebrovascular problems or have had a stroke
- have headaches
- have, or have a family history of, bipolar disorder, mania or hypomania
- plan to have surgery
- have liver or thyroid problems
- have or have had seizures or convulsions
- have diabetes
- are pregnant or plan to become pregnant. Tranlycypromine Sulfate may harm your unborn baby.
- are breastfeeding or plan to breastfeed. Tranlycypromine Sulfate passes into your breast milk. Do not breastfeed during treatment with Tranlycypromine Sulfate. Talk to your healthcare provider about the best way to feed your baby while taking Tranlycypromine Sulfate.

Tell your healthcare provider about all medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Tranlycypromine Sulfate and some other medicines may affect each other causing serious side effects. Tranlycypromine Sulfate may affect the way other medicines work, and other medicines may affect how Tranlycypromine Sulfate works.

Some medicines need to be stopped for a period of time before you can start taking Tranlycypromine Sulfate and for a period of time after you stop taking Tranlycypromine Sulfate.

Know the medicines you take. Keep a list of them to show your healthcare providers, pharmacist, and dentist when you get a new medicine.

How should I take Tranlycypromine Sulfate tablets?

- Take Tranlycypromine Sulfate tablets exactly as your healthcare provider tells you to take it.
- Your healthcare provider may need to change your dose of Tranlycypromine Sulfate tablets until it is the right dose for you.
- Do not stop taking Tranlycypromine Sulfate tablets without first talking to your healthcare provider. Stopping Tranlycypromine Sulfate suddenly

may cause withdrawal symptoms. See, "What are the possible side effects of Tranylcypromine Sulfate tablets?"

- Tell your healthcare provider if you think your condition has gotten worse during treatment with Tranylcypromine Sulfate tablets.
- If you take too much Tranylcypromine Sulfate tablets (overdose) call your healthcare provider or poison control, or go to the nearest hospital emergency room right away.

What should I avoid while taking Tranylcypromine Sulfate tablets?

- Do not eat foods or have drinks that have high amounts of tyramine while taking Tranylcypromine Sulfate tablets or for 2 weeks after you stop taking Tranylcypromine Sulfate tablets.
 - All foods you eat should be fresh or properly frozen.
 - Avoid foods when you do not know how those foods should be stored.
 - Ask your healthcare provider if you are not sure if certain foods and drinks contain tyramine.

The table below lists some of the foods and drinks you should avoid while you take Tranylcypromine Sulfate tablets.

Type of Food and Drink that contain Tyramine	
Meat, Poultry, and Fish	<ul style="list-style-type: none">• air dried, aged and fermented meats, sausages, and salamis• pickled herring• any spoiled or improperly stored meat, poultry, and fish. These foods have a change in color, odor, or are moldy.• spoiled or improperly stored animal livers
Vegetables	<ul style="list-style-type: none">• broad bean pods (fava bean pods)
Dairy (milk products)	<ul style="list-style-type: none">• aged cheeses
Drinks	<ul style="list-style-type: none">• all tap beers and other beers that have not been <u>pasteurized</u>
Other	<ul style="list-style-type: none">• concentrated yeast extract (such as Marmite)• most soybean products (including soy sauce and tofu)• sauerkraut• over-the-counter supplements containing tyramine

- Do not drive, operate heavy machinery, or do other dangerous activities until you know how Tranylcypromine Sulfate tablets affects you.
- You should not drink alcohol while taking Tranylcypromine Sulfate tablets.

What are the possible side effects of Tranylcypromine Sulfate tablets? Tranylcypromine Sulfate tablets may cause serious side effects, including:

- See "What is the most important information I should know about Tranylcypromine Sulfate tablets?"
- **Serotonin Syndrome.** A potentially life-threatening problem called serotonin syndrome can happen when you take Tranylcypromine Sulfate tablets with certain other medicines. See, "Who should not take Tranylcypromine Sulfate?" Symptoms of serotonin syndrome may include:
 - agitation, confusion
 - coma
 - changes in blood pressure
 - sweating
 - high body temperature (hyperthermia)
 - seizures
 - becoming unstable
 - seeing or hearing things that are not real (hallucinations)
 - rapid pulse
 - dizziness
 - flushing
 - fever
 - tremors, stiff muscles, or muscle twitching
 - nausea, vomiting, diarrhea

If you have any of these symptoms, call your healthcare provider or go to the nearest hospital emergency room right away.

- **Mania or hypomania** (manic episodes) in people who have a history of bipolar disorder.
 - greatly increased energy
 - unusually grand ideas
 - severe problems sleeping
 - excessive happiness or irritability
 - racing thoughts
 - talking more or faster than usual
 - reckless behavior

- **Low blood pressure (hypotension)** including a drop in your blood pressure when you stand or sit up (postural hypotension). This can happen more often in people who have high blood pressure (hypertension) and

when the Tranylcypromine Sulfate tablets dose is changed. Postural hypotension may cause you to feel dizzy and faint (syncope).

- **Changes in your blood pressure (hypotension or hypertension) during surgery and during the time around surgery (perioperative).** Taking Tranylcypromine Sulfate tablets with certain medicines used for anesthesia can cause hypotension or hypertension. If you plan to have surgery, tell your surgeon or the healthcare provider who will give you anesthesia that you take Tranylcypromine Sulfate tablets. Your healthcare provider should stop Tranylcypromine Sulfate tablets at least 10 days before you have surgery.

- **Withdrawal symptoms.** Talk with your healthcare provider before you stop taking Tranylcypromine Sulfate tablets. Symptoms of withdrawal may include:

- dizziness
- anxiety
- changes in your mood
- nausea
- abnormal dreams
- hypomania
- diarrhea
- tiredness
- irritability and agitation
- confusion
- seizures
- problems sleeping
- electric shock sensation (paresthesia)
- headache
- sweating
- ringing in your ears (tinnitus)

• Liver problems

- **Seizures (convulsions).** Seizures have happened in people who take too much Tranylcypromine Sulfate tablets.

- **Low blood sugar (hypoglycemia).** Hypoglycemia has happened in people with diabetes who take medicines to lower blood sugar. Talk with your healthcare provider about checking your blood sugar during treatment with Tranylcypromine Sulfate tablets. Tell your healthcare provider if your blood sugar gets low.

- **Worsening of symptoms that can happen with depression,** such as anxiety and agitation.

The most common side effects of Tranylcypromine Sulfate tablets include:

- dry mouth
- headache
- shakiness (tremor)
- feeling sleepy
- blurry vision
- problems sleeping
- constipation
- dizziness
- overexcitement

These are not all the side effects of Tranylcypromine Sulfate.

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

How do I store Tranylcypromine Sulfate tablets?

- Store Tranylcypromine Sulfate tablets at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F). [See USP Controlled Room Temperature].
- Store Tranylcypromine Sulfate tablets in a tight, light resistant container.

Keep Tranylcypromine Sulfate tablets and all medicines out of the reach of children.

General information about the safe and effective use of Tranylcypromine Sulfate tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not take Tranylcypromine Sulfate tablets for a condition for which it was not prescribed. Do not give Tranylcypromine Sulfate tablets to other people, even if they have the same symptoms you have. It may harm them. You can ask your healthcare provider or pharmacist for information about Tranylcypromine Sulfate tablets that is written for health professionals.

What are the ingredients in Tranylcypromine Sulfate tablets?

Active Ingredient: tranylcypromine sulfate

Inactive Ingredients: colloidal silicon dioxide, croscarmellose sodium, dibasic calcium phosphate anhydrous, magnesium stearate, microcrystalline cellulose, talc, and Opadry® II pink 85F14289. Opadry pink is used for purposes of coating and contains the following: FD&C Red # 40, polyethylene glycol 3350, polyvinyl alcohol, talc, and titanium dioxide.

For Medication Guide, please visit www.parpharm.com.

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This Medication Guide has been approved by the U.S. Food and Drug Administration.

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