In the presence of pheochromocytoma, diovascular disease, hypertension, or history of headache, the following drugs should be avoided: MAO inhibitors or dibenzazepine derivatives; sympathomimetics, including amphetamines, which may be found in many herbal preparations, coca leaves, and other sympathomimetic-containing products; and tranylcypromine sulfate. In addition, patients should be advised to minimize or avoid use of all alcoholic beverages and foods that cause a release of tyramine, such as aged cheeses, red wine, and sauerkraut. The combination of MAO inhibitors and dextromethorphan has been reported to cause brief episodes of psychosis or bizarre behavior. The concurrent administration of an MAO inhibitor and bupropion hydrochloride is not approved for use in pediatric patients. See WARNINGS for Pediatric Use.}

In general, the physician should be on the lookout for the possibility of a rebound reaction when pheochromocytoma is surgically removed. Withdrawal of a sympathomimetic agent is recommended in these cases, with an MAO inhibitor initiated at a lower dosage than is usually given. In situations where pheochromocytoma is not suspected but severe hypertension is present, the blood pressure should be lowered as an emergency measure, with the patient being started on an MAOI, some MAO inhibitors, and other sympathomimetics should be withdrawn if there is a possibility of a rebound reaction.

The effectiveness of tranylcypromine sulfate in patients who meet the criteria for a diagnosis of Major Depressive Episode implies a prominent and relatively persistent loss of interest in usual activities or decrease in sexual drive, increased fatigability, feelings of worthlessness, slowed thinking, or impaired concentration. Diagnosis of Major Depressive Episode Without Melancholia. As described in the non-melancholic depression mentioned above, features of hypomania and mania, have been reported in adult and pediatric patients being treated with antidepressants for any indication. Such symptoms include: increased energy, agitation, pressure to keep busy, flight of ideas, and distractibility. Treatment of hypomania and mania, have been reported in adult and pediatric patients being treated with antidepressants for any indication.

In combination with sympathomimetics, Tyramine occurs naturally in some foods or may occur from the bacterial breakdown of protein. It is not usually harmful unless a high tyramine diet is taken by patients who have a monoamine oxidase (MAO) inhibitor or who are taking agents that interfere with tyramine metabolism. Tyramine formation from the bacterial breakdown of protein is enhanced in patients with protein malnutrition, diarrhea, and in patients taking MAO inhibitors or other drugs that interfere with tyramine metabolism. The combination of MAO inhibitors with tyramine-containing foods may cause a hypertensive crisis with severe headache, flushing, and syncope. Certain tyramine-containing foods may cause a hypertensive crisis. The combination of tyramine-containing foods with MAO inhibitors may precipitate hypertension, headache, and syncope. Certain tyramine-containing foods may cause a hypertensive crisis. The combination of tyramine-containing foods with MAO inhibitors may precipitate hypertension, headache, and syncope. It is important to avoid these foods in patients taking MAO inhibitors.

10. In combination with cheese or other foods with a high tyramine content

1. In patients with cardiovascular defects or cardiovascular disorders

18 to 24 5 additional cases

>65 6 fewer cases

per 1,000 Patients Treated

No suicides occurred in any of the pediatric trials. There were suicides in adult trials, but the number was too small to reach any conclusion about drug effect on suicide. It is unclear whether the observed increase in suicidal ideation or behavior was due to drug effects, a worsening of a pre-existing condition, or the natural course of the illness.

Case reports indicate the possibility of a rebound reaction when pheochromocytoma is surgically removed. Withdrawal of a sympathomimetic agent is recommended in these cases, with an MAO inhibitor initiated at a lower dosage than is usually given. In situations where pheochromocytoma is not suspected but severe hypertension is present, the blood pressure should be lowered as an emergency measure, with the patient being started on an MAOI, some MAO inhibitors, and other sympathomimetics should be withdrawn if there is a possibility of a rebound reaction.

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Drugs which lower the seizure threshold, including MAO inhibitors, should not have been reported: restlessness, anxiety, depression, confusion, hallucinations, had a history of previous substance abuse. The following withdrawal symptoms are spontaneously reported adverse reactions:

There have been reports of drug dependency in patients using doses of tranylcypromine sulfate. Symptoms of postural hypotension are seen most commonly but may be relieved by having the patient lie down until blood pressure returns to normal. Frequent headaches during therapy with tranylcypromine sulfate. These signs may be prodromal of a hypertensive crisis.

Significant adverse reactions observed in patients treated with tranylcypromine sulfate include:

- Hypertensive Crisis: The most important reaction associated with tranylcypromine sulfate is an episode of hypertension or malignant hyperthermia. Older patients have been reported to have an increased incidence of hyperpyrexia. In a study by Trombok et al., hyperpyrexia occurred in 12 patients with malignant hyperthermia. The patient should be treated with external cooling if hyperpyrexia occurs. Barbiturates have been reported to help relieve myoclonic reactions, but frequency of administration must be determined by the treating physician.

- Localized scleroderma, flare-up of cystic acne, ataxia, confusion, disorientation, impaired water excretion compatible with the syndrome of inappropriate secretion of antidiuretic hormone have each been reported.

- Tachycardia, significant anxiety, agitation, and psychiatric symptoms are frequently encountered in clinical trials. The following have been reported in patients treated with tranylcypromine sulfate:

**WARNINGS TO PHYSICIANS**

- Depression and other serious mental illnesses are the most important cause of suicidal thoughts and actions. Some people may have a particularly high risk of thinking about suicide or taking actions to harm themselves. Patients should be advised to report any new or unusual symptoms, especially if they are new, worse, or worry you:

  - Feelings of depression, suicidality, agitation, anxiety, confusion, mood swings
  - Changes in weight (weight gain or loss)
  - New-onset or worsening sleep problems
  - New-onset or worsening anxiety or agitation
  - Agitation and hostility
  - Hypomania or mania
  - Suicide-related thinking and behaviors
  - Increased use of alcohol or increase use of prescription or street drugs
  - Other unusual symptoms, i.e., palpitation and/or tachycardia, a sense of constriction, numbness, paresthesia, or muscle weakness

In a single study, rats given high intraperitoneal doses of tranylcypromine sulfate and disulfiram produced no adverse interaction.

Other unusual symptoms, i.e., palpitation and/or tachycardia, a sense of constriction, numbness, paresthesia, or muscle weakness have been reported. The patient should be advised to report the presence or onset of suicidal thoughts or actions, whether or not they are new, worse, or worry you. Patients should be advised to contact their prescriber if these occur while taking tranylcypromine sulfate.

**ADVERSE REACTIONS**

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