In clinical trials, four cases of a symptom complex involving hallucinations developed in the first month of treatment. Of these cases, three were reported within the first six months with a p-value* of 0.008 and one in the second year with a p-value* of <0.001. In two 3-month trials, patients with documented episodes of hallucinations developed in the first month of treatment. The data of more than 400 patients have confirmed that over a wide range of dosages, the p-value* was not less than 0.0001.

In TASMAR clinical trials, orthostatic hypotension was documented at least once in 3% of patients treated with placebo, 100 mg tid, and 200 mg tid, and 0% of patients treated with 100 mg TASMAR. Falling asleep while engaged in activities that require active participation, such as carbidopa levodopa products alone or with other dopaminergic medications have reported to have stopped when the dose was reduced or the medication was discontinued. In TASMAR clinical trials, drowsiness or episodes of falling asleep during activities that require active participation were documented at least once in 3% of patients treated with placebo, 100 mg tid, and 200 mg tid, and 0% of patients treated with 100 mg TASMAR. These patients were also on concomitant dopamine agonists (pergolide or bromocriptine) and the time of its occurrence (T_{max}) was 3 months long, and the primary outcome was a comparison between treatments in terms of the change from baseline in the amount of time spent “On” (a period of relatively good motor function). The data of more than 400 patients have confirmed that over a wide range of dosages, the p-value* was not less than 0.0001.
In vitro experiments have been performed to assess the potential for... make a meaningful estimate of the proportion of patients with Parkinson's disease who experience adverse reactions of a certain kind. Patients who develop evidence of hepatocellular injury while on TASMAR and are... present, generally occurred with a time lag of more than 7 days. The relationship of these hepatic reactions to tolcapone therapy has not been established, and the... increased SGPT/ALT or SGOT/AST values greater than the upper limit of normal... when used with and without levodopa/carbidopa co-administration. This was in a 1-week study in... 

### Common Side Effects

#### Acute Reactions
- Dizziness
- Nausea
- Headache
- Fever
- Rhabdomyolysis

#### Other Adverse Events Observed During All Trials in Patients With Parkinson's Disease:
- Anosmia
- Anorexia
- Asthenia
- Bradycardia
- Deafness
- Diaphoresis
- Dysarthria
- Dysphagia
- Dysuria
- Edema
- Epigastric pain
- Erythema multiforme
- Flushing
- Frequent urination
- Hallucination
- Hyperkinesia
- Flatulence
- Dyspnea
- Hypertonia

#### Infrequent Side Effects

- Body as a Whole — frequent:
  - Fatigue
- Blood Vessels — frequent:
  - Hypotension
- Cardiovascular System — frequent:
  - Chest discomfort
- Central Nervous System — frequent:
  - Emotional lability
  - Insomnia
  - Nervousness
  - Somnolence
  - Anxiety
  - Depression
  - Mania
  - Dizziness
  - Restlessness
  - Vertigo
- Gastrointestinal System — frequent:
  - Cholestasis
  - Pancreatitis
  - Vomiting
- Genitourinary System — frequent:
  - Enuresis
  - Hematuria
- Hematologic System — frequent:
  - Anemia
  - Hemoglobin decrease
  - Leukopenia
- Metabolism and Nutrition — frequent:
  - Increased appetite
  - Fluid retention
  - Weight increased
- Musculoskeletal System — frequent:
  - Arthralgia
  - Muscular weakness
- Respiratory System — frequent:
  - Dyspnea
  - Rhinitis
- Visual Disturbances — frequent:
  - Blurred vision

#### Rare Side Effects

- Body as a Whole — rare:
  - Alopecia
  - Constipation
  - Dysphagia
  - Fatigue
  - Flu symptoms
  - Hypertension
  - Hypotension
  - Palpitation
  - Mouth sores
  - Nausea
  - Headache
  - Migraine
  - Rash
- Cardiovascular System — rare:
  - Hypertension
- Central Nervous System — rare:
  - Coma
  - Hallucinations
  - Headache
  - Nervousness
  - Somnolence
  - Vertigo
- Dermatologic System — rare:
  - Acne
  - Dermatitis
  - Pruritus
  - Pustulation
  - Rash
- Gastrointestinal System — rare:
  - Acute esophagitis
  - Cholelithiasis
  - Colitis
  - Tongue disorder
  - Rectal disorder
- Hematologic System — rare:
  - Anemia
  - Leukopenia
  - Thrombocytopenia
  - Thrombocytosis
- Metabolic and Endocrine System — rare:
  - Decreased appetite
  - Flu symptoms
  - Hypoglycemia
  - Hyperglycemia
- Musculoskeletal System — rare:
  - Arthralgia
  - Arthritis
  - Myalgia
  - Myopathy
  - Osteopathy
- Respiratory System — rare:
  - Asthma
  - Airway edema
- Visual Disturbances — rare:
  - Blurred vision

#### Organ System Involved

- Dose of the day of levodopa/carbidopa, and the subsequent doses of TASMAR were given... failure has occurred but they may do so only after significant damage, that... is reintroduced. These patients should not ordinarily be considered for retreatment... it and be especially aware of persistent nausea, fatigue, lethargy, decreased... may not be appropriate for these patients. TASMAR therapy should not be initiated in any... “New Food and Drug Administration (FDA) WARNINGS and PRECAUTIONS” for tolcapone, which may be obtained... body weight, in 60 kg or more, we consider this patient at increased risk. If the... of hepatic enzymes, including the cytochrome P450 isoenzymes, may be involved in tolcapone metabolism, which may influence the... other highly protein-bound drugs from their binding sites at therapeutic concentrations. Therefore, caution should be exercised when desipramine is administered to Parkinson’s disease patients for treatment of levodopa-induced dyskinesia, although desipramine is a... of these adverse reactions. TASMAR therapy should be avoided in patients with hepatic impairment. Instead, therapy with... (males) or 1.7 (females) times the human exposure. Minimal-to-marked damage to the renal... (males) or 1.7, 11.8 and 26.4 times the human exposure in... cell damage and sustained repair, but this relationship has not been established, and the... and potentially serious adverse drug reactions should be considered when they are co-administered with tolcapone. This... should be noted that tolcapone is a structurally distinct monamine oxidase B inhibitor, which may... the safety as it relates to advancing age, three subgroups were identified: less than 65 years, 65 to 75 years, and greater than 75 years. There were generally no consistent age-related differences detected in the clinical trials. For the tolcapone groups, the mean age of patients in tolcapone clinical trials was 60 to 65 years. To investigate... is caused by a substance that has the potential to alter a patient’s mental state (e.g., alcohol, drugs, or stress) but does not cause damage to the brain. 

### Summary

TASMAR therapy should not be initiated in any patient at increased risk. If a patient fails to show the expected incremental benefit on the 200-mg dose after a total of 3 weeks of treatment (regardless of dose), TASMAR therapy should be discontinued and not reinstituted. Patients who develop evidence of hepatocellular injury while on TASMAR and are considered clinically well should be monitored as described in the “ADVERSE REACTIONS” section, and the dose should be decreased or TASMAR therapy should be discontinued. These patients should not ordinarily be considered for retreatment. Patients who develop evidence of hepatocellular injury while on TASMAR and are considered clinically ill should be monitored as described in the “ADVERSE REACTIONS” section, and the dose should be decreased or TASMAR therapy should be discontinued. Patients should not be considered for retreatment until they have shown evidence of clinical recovery. If a patient fails to show the expected incremental benefit on the 200-mg dose after a total of 3 weeks of treatment (regardless of dose), TASMAR therapy should be discontinued and not reinstituted. Patients who develop evidence of hepatocellular injury while on TASMAR and are considered clinically well should be monitored as described in the “ADVERSE REACTIONS” section, and the dose should be decreased or TASMAR therapy should be discontinued. These patients should not ordinarily be considered for retreatment. Patients who develop evidence of hepatocellular injury while on TASMAR and are considered clinically ill should be monitored as described in the “ADVERSE REACTIONS” section, and the dose should be decreased or TASMAR therapy should be discontinued. Patients should not be considered for retreatment until they have shown evidence of clinical recovery. If a patient fails to show the expected incremental benefit on the 200-mg dose after a total of 3 weeks of treatment (regardless of dose), TASMAR therapy should be discontinued and not reinstituted. Patients who develop evidence of hepatocellular injury while on TASMAR and are considered clinically well should be monitored as described in the “ADVERSE REACTIONS” section, and the dose should be decreased or TASMAR therapy should be discontinued. These patients should not ordinarily be considered for retreatment. Patients who develop evidence of hepatocellular injury while on TASMAR and are considered clinically ill should be monitored as described in the “ADVERSE REACTIONS” section, and the dose should be decreased or TASMAR therapy should be discontinued. Patients should not be considered for retreatment until they have shown evidence of clinical recovery.