**WARNING AND PRECAUTIONS**

**Hallucinations and Psychotic-like Behavior:** May occur; risk increases with increasing dosage and duration of therapy. If hallucinations or other psychotic-like behavior (e.g., delusions, paranoia) occur, advise the patient to stop taking the medication until symptoms resolve. If symptoms recur, consider dose reduction or drug discontinuation. Patients with a history of psychiatric or neurological disorders should be observed closely during treatment with pramipexole dihydrochloride extended-release tablets.

**Pregnancy and Lactation:**

- Pregnancy Category C: Teratogenic effects have been observed when pramipexole dihydrochloride extended-release tablets were administered in rats and rabbits during organogenesis. Pregnant women should be advised of the potential risk to the fetus and should be carefully monitored for signs of embryolethality. When pramipexole dihydrochloride extended-release tablets are administered to pregnant women for treatment of Parkinson's disease, the risks and benefits of therapy should be considered. If pramipexole dihydrochloride extended-release tablets are administered to a woman who becomes pregnant while taking the drug, the patient should be advised to discontinue the medication and be referred to a physician experienced in the management of pramipexole dihydrochloride extended-release tablets. Women of childbearing potential should be advised to discontinue the drug at least 2 weeks before conception if the benefit of treatment outweighs the risk of drug exposure.

- Nursing Mothers: Pramipexole is excreted in human milk. It is not known whether pramipexole dihydrochloride extended-release tablets would occur in human milk or if pramipexole dihydrochloride extended-release tablets would cause harmful effects in the nursing child. The decision to use pramipexole dihydrochloride extended-release tablets in a nursing woman should be made with consideration of the potential benefits and risks to the nursing infant.

**Adverse Reactions**

- The most common adverse reactions (≥5% and more frequent than placebo) after 33 weeks of treatment with pramipexole dihydrochloride extended-release tablets were nausea (1%) and hallucination (1%).

**Drug Interactions**

- Concomitant use of pramipexole dihydrochloride extended-release tablets with MAO inhibitors or other drugs that increase the risk of serotonin syndrome, including selective serotonin reuptake inhibitors (SSRIs), selective serotonin/norepinephrine reuptake inhibitors (SNRIs), triptans, lithium, or tramadol, is contraindicated. When pramipexole dihydrochloride extended-release tablets are coadministered with a drug that is a CYP2D6 inhibitor, a dose reduction of pramipexole dihydrochloride extended-release tablets may be necessary to decrease the risk of adverse reactions. When pramipexole dihydrochloride extended-release tablets are coadministered with a drug that is a CYP2D6 inducer, the dose of pramipexole dihydrochloride extended-release tablets may need to be increased.

**Overdosage**

- In case of overdose, wash out the gastrointestinal tract by emesis or gastric lavage; monitor patient continuously for at least 24 hours; ensure adequate ventilation to prevent CNS depression; use correcting agents for hyperpyrexia; and provide supportive care. There is no experience with specific antidotes. Patients should be observed for signs of toxicity, especially in those who are taking multiple medications, as the effects of pramipexole dihydrochloride extended-release tablets may be additive with other drugs.

**Dosage and Administration**

- Patients should be assessed for therapeutic response and tolerability at a minimal interval of at least 1 week. If a patient’s condition worsens or the patient experiences new or worsening adverse reactions, dosage should be reduced. Patients should be monitored to determine if dosage adjustment is necessary.

**Examples**

- **Pramipexole Dihydrochloride Extended-Release Tablets**
  - 0.75 mg white to off-white round film-coated tablets engraved with “252” on one side and plain on the other side.

**Pharmaceutical Information**

- Pramipexole dihydrochloride extended-release tablets are a material aphrodisiac. Sexually inhibited males may experience increased hunger and weight gain during pramipexole dihydrochloride extended-release tablets treatment. Patients should be counseled about these effects and their impact on sexual function.

**Upcoming Clinical Trials**

- A clinical trial for the treatment of restless legs syndrome is ongoing. Patients with restless legs syndrome should be monitored for adverse reactions and therapeutic response.

**Future Research**

- Future research will focus on the long-term effects of pramipexole dihydrochloride extended-release tablets on cognition and behavior in patients with Parkinson's disease. The potential for pramipexole dihydrochloride extended-release tablets to improve quality of life and reduce the burden of disease will be evaluated in ongoing clinical trials.

**References**

- For a complete list of references,please see the full prescribing information for pramipexole dihydrochloride extended-release tablets.

**Appendix**

- For additional information, including full prescribing information,please see the full prescribing information for pramipexole dihydrochloride extended-release tablets.
Increase in systemic exposure of pramipexole following oral administration of 0.375 mg to 4.5 mg daily administration of immediate-release pramipexole tablets. From pramipexole dihydrochloride extended-release tablets with once-daily administration results in has not been systematically evaluated.

12.2 Pharmacodynamics

the substantia nigra, the site of neurons that send projections to the striatum. The relevance of D 3 conclusion is supported by electrophysiologic studies in animals that have demonstrated that prami-