MIRATOR

To be sold by retail on the prescription of a neurologist only

Abbreviated Prescribing information for Mirator (Pramipexole Dihydrochloride Tablets 0.125 mg/ 0.25 mg/ 0.5 mg / 1 mg / 1.5 mg) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Pramipexole is a non-ergot dopamine agonist with high relative *in vitro* specificity and full intrinsic activity at the D_2 subfamily of dopamine receptors, binding with higher affinity to D_3 than to D_2 or D_4 receptor subtypes and used in Parkinson's disease and Restless Legs Syndrome.

INDICATION: Mirator tablets are indicated for the treatment of the signs and symptoms of idiopathic Parkinson's disease and moderate-to-severe primary Restless Legs Syndrome (RLS).

DOSAGE AND ADMINISTRATION: Pramipexole tablets are taken orally, with or without food. If a significant interruption in therapy with Pramipexole tablets has occurred, re-titration of therapy may be warranted. For treatment of Parkinson's disease doses should be increased gradually from a starting dose of 0.375 mg/day given in three divided doses and should not be increased more frequently than every 5 to 7 days and for the treatment of restless leg syndrome the recommended starting dose of Pramipexole tablets is 0.125 mg taken once daily 2-3 hours before bedtime.

CONTRAINDICATION: None.

WARNINGS & PRECAUTIONS: Patients treated with Pramipexole have reported falling asleep while engaged in activities of daily living and Somnolence. Dopamine agonists, in clinical studies and clinical experience, appear to impair the systemic regulation of blood pressure, with resulting orthostatic hypotension, especially during dose escalation. Impulse Control/Compulsive Behavior is also reported, Rhabdomyolysis, retinal deterioration, Melanoma, Symptomatic Orthostatic Hypotension, Rebound and Augmentation in RLS, Fibrotic Complications, Hyperpyrexia and Confusion. Pramipexole tablets may potentiate the dopaminergic side effects of levodopa and may cause or exacerbate preexisting dyskinesia. Caution should be exercised when prescribing it to renal impaired patients.

DRUG INTERACTION: Since pramipexole is a dopamine agonist, it is possible that dopamine antagonists, such as the neuroleptics (phenothiazines, butyrophenones, and thioxanthenes) or metoclopramide, may diminish the effectiveness of Pramipexole tablets.

ADVERSE REACTIONS: Anemia, iron deficiency anemia, angina pectoris, deafness, ear pain, goiter, abdominal discomfort, chest discomfort, biliary colic, abscess, acute tonsillitis, drug hypersensitivity, accidental falls, drug toxicity epicondylitis, diabetes mellitus, gout, bone pain, fasciitis, abdominal neoplasm, adenocarcinoma, akinesia, aggression, agitation, amenorrhea, breast pain, apnea, aspiration, asthma, acne, alopecia, anticholinergic syndrome, abnormal dreams, nasal congestion, arthritis, and constipation, abnormal behavior, abnormal dreams, hypotension, inappropriate antidiuretic hormone secretion (SIADH), increased eating, libido disorders, pathological gambling, pruritus, syncope, vomiting, and weight increase.

MARKETED BY:

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IN/MIRATOR 0.125/0.25/ 0.5/1/1.5 mg /Jun-15/01/AbPI

(Additional information is available on request)