PEXOPRAM™

Pramipexole Dihydrochloride

0.125 mg / 0.25 mg / 0.5 mg / 1.0 mg Tablets

CLASS :

Dopamine agonist of the non-ergoline class.

INDICATION :

Pexopram is indicated for the treatment of signs and symptoms of Parkinson's Disease and Restless Leg Syndrome .

MECHANISM OF ACTION :

Parkinson's Disease: The precise mechanism of action of Pexopram as a treatment for Parkinson's disease is unknown, although it is believed to be related to its ability to stimulate dopamine receptors in the striatum. This conclusion is supported by electrophysiologic studies in animals that have demonstrated that pramipexole influences striatal neuronal firing rates via activation of dopamine receptors in the striatum and the substantia nigra, the site of neurons that send projections to the striatum. The relevance of D3 receptor binding in Parkinson's disease is unknown.

R**estless Legs Syndrome (RLS):** The precise mechanism of action of Pexopram tablets as a treatment for Restless Legs Syndrome (RLS) is unknown. Although the pathophysiology of RLS is largely unknown, neuropharmacological evidence suggests primary dopaminergic system involvement. Positron Emission Tomographic (PET) studies suggest that a mild striatal presynaptic dopaminergic dysfunction may be involved in the pathogenesis of RLS.

DOSAGE :

Parkinsonism – Initially – 0.125mg thrice daily; max 1.5mg thrice daily; Gradual increase in dosage after 5-7 days.

Restless Leg Syndrome – Initially- 0.125mg once daily 2-3hrs before bedtime; max 0.5mg/day; If needed double dose every 4-7days.

Presentation – Pexopram is available in strengths of 0.125mg, 0.25mg, 0.5mg and 1 mg Uncoated Coated Tablets.

“ Move as You Like”

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BACKGROUND :

PARKINSON'S DISEASE

A disease that affect nerve cells in the brain and causes tremors, poor coordination and problems walking and moving

CAUSE & RISK FACTORS

Both sexes & all races are affected

Parkinson's commonly develops after age 50

Scientist have identified abnormal genes that may lead to parkinson's in some people, but there is no solid proof to show it is always inherited

Men are more likely to develop parkinson's disease because they're more likely to experience head injury or exposure to toxins

SYMPTOMS OF PARKINSON'S

- Slow blinking
- No facial expression
- Drooling
- Difficulty swallowing

- Shaking, tremors
- Loss of small or fine hand movements

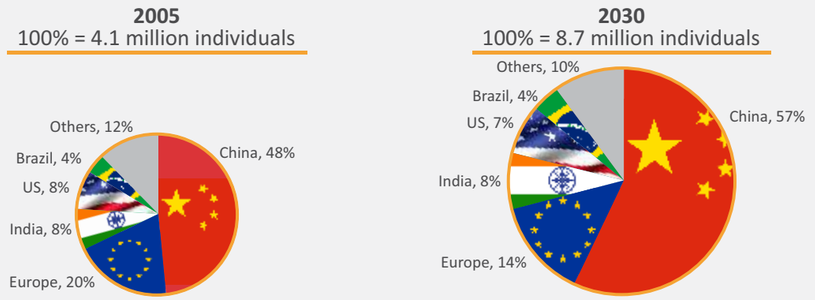
- Memory loss, dementia
- Anxiety, depression
- Hallucinations

- Stooped posture
- Aches and pains
- Constipation
- Problems with balance or walking

PREVALENCE :

The burden of Parkinson's disease and other neurodegenerative conditions is growing

Distribution of individuals with Parkinson disease by country from 2005 to 2030*



*Among individuals over 50 in the world's ten most and western Europe's five most populous nations

Source: Neurology 2007, 68-384-6

CLINICAL EFFECTIVENESS :

1. Journal of Neurology, Neurosurgery, and Psychiatry: 2002

"Pramipexole in patients with Parkinson's disease and marked drug resistant tremor: a randomised, double blind, placebo controlled multicenter study"

Double blind, randomized, placebo controlled, multicentre study on 84 patients with early or advanced Parkinson's disease and marked, drug resistant tremor under a stable and optimised antiparkinsonian medication.

RESULTS :

- Outcome of study suggest that pramipexole is significantly superior to placebo with a difference between treatment groups in the mean absolute change in tremor score of -4.4 (95% confidence interval (95% CI) -6.2 to -2.5) (p<0.0001), corresponding to a difference in the mean percentage change of -34.7% in favor of pramipexole.

- Long term EMG registration as an objective measure shows a difference in mean absolute change in tremor occurrence of -15.2% (95%CI -21.4 to -9.0) (p<0.0001), and a difference in the mean percentage change of -45.7% in favour of pramipexole.

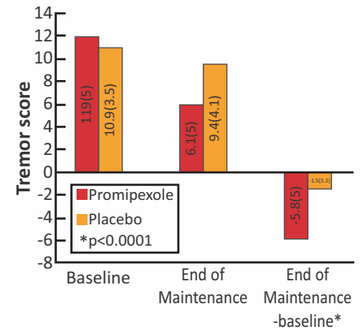


Figure 1: Mean itemor score (SD) at baseline (left) and end of maintenance (middle) of pramipexole (n=44) and placebo (n=39) group Right: mean change from baseline to end of maintenance.

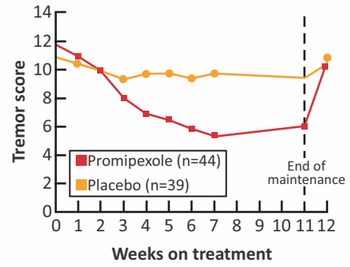


Figure 2: Development of the mean tremor score per week on treatment with pramipexole (ppx) and placebo (pbo) (intent ot treat last observation carried forward), at week 0 (baseline). weeks 1-7 (ascending dose interval), weeks 7-11 (maintenance period), week 11-12 (dose reduction).

CONCLUSION :

- The present study shows that pramipexole is not only an effective antiparkinsonian agent with respect to improvement in ADL or UPDRS motor scores as a whole, but also leads to a statistically significant reduction of parkinsonian tremor when added to a stable antiparkinsonian medication.

2. As per JAMA Neurology: 2004

"Pramipexole vs Levodopa as Initial Treatment for Parkinson Disease: 4-Year Randomized Controlled Trial"

- Multicenter, parallel-group, double-blind, randomized controlled trial on 301 patients with early Parkinson disease.

RESULT :

- Initial treatment with pramipexole result in a significant reduction in the risk of developing dyskinesias (24.5% vs 54%; hazard ratio, 0.37; 95% confidence interval [CI], 0.25-0.56; P<.001) and wearing off (47% vs 62.7%; hazard ratio, 0.68; 95% CI, 0.49-0.63; P = .02).

CONCLUSIONS :

- Initial treatment with pramipexole results in lower incidences of dyskinesias and wearing off in comparison to initial treatment with levodopa.