2.1 General Dosing Considerations

Dosage and Administration (2.2)

Pramipexole dihydrochloride extended-release tablets are a non-ergot dopamine agonist indicated for the treatment of Parkinson's disease (PD) (2.2).

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The pharmacokinetics of pramipexole are markedly influenced by renal function. The renal clearance, which is approximately 30% lower in women than in men, can be accounted for by the metabolic conversion of pramipexole to metabolites with increased plasma clearance in women compared with men. The renally eliminated metabolites are mainly recovered in the urine as glucuronide and/or sulfate conjugates.

In healthy volunteers (N=11), metoprolol clearance did not influence the pharmacokinetics of pramipexole. This indicates that the plasma pharmacokinetics of pramipexole are not affected by the concomitant use of renally eliminated drugs.

The use of the renal creatinine clearance calculator as a tool for the calculation of renal function is recommended when determining the appropriate pramipexole dose in patients with renal impairment. The use of this calculator can help in the decision of dosage adjustments in patients with renal impairment.

16.2 Storage and Handling
Pramipexole extended-release tablets can be stored at room temperature, with or without light. Store pramipexole dihydrochloride extended-release tablets in a cool place away from direct light, but not in the refrigerator.

16.3 Disposition
Pramipexole is metabolized in the liver by cytochrome P450 3A4 (CYP3A4) and by other CYP enzymes. The metabolic pathways include hydroxylation, glucuronidation, and sulfation. The major metabolites are identified as pramipexole-N-oxide and pramipexole-glucuronide. The pharmacokinetics of pramipexole are significantly influenced by renal function, as pramipexole is renally eliminated. The renal clearance of pramipexole is lower in women than in men, and this difference can be explained by the metabolic conversion of pramipexole to metabolites with increased plasma clearance in women compared with men.

17 List of Drugs Eliminated Via Renal Secretion

17.1 Drugs Eliminated Via Organic Anion Transporters

17.2 Drugs Eliminated Via Organic Cation Transporters

17.3 Drugs Eliminated Via Loss of Function of Organic Solutes Transporters

17.4 Other Drugs Eliminated Via Renal Secretion

18 Interactions

18.1 Drug Interactions

18.2 Hereditary Enzyme Defects

18.3 Laboratory Tests

19.7 Indications

20.4 Administration

20.5 Dosage and Administration

20.6 Monitoring

21.2 Pediatric Use

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22.2 Lactation

22.3 Pediatric Use

22.5 Other Side Effects

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25.6 Warnings and Precautions

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26.2 Additional Information

26.3 Additional Warnings and Precautions

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27.3 Pharmacokinetics

27.4 Pharmacodynamics

28.1 Standard Sulfonylurea Hypoglycemic Agents and Metformin

28.2 Thiazolidinediones

28.3 Dipeptidyl Peptidase-4 Inhibitors

28.4 Glucagon-like Peptide-1 Receptor Agonists

29.1 Preclinical Pharmacology

29.2 Safety and Tolerability

29.3 Adverse Reactions

29.4 Postmarketing Experience

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29.6 Other Warnings and Precautions

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