

Policies Repository



Policy Title Selegiline HCl (Zelapar®)

Policy Number FS.CLIN.15

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This Pharmacy Policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety or FDA approval may have changed. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. This information may include new FDA approved indications, withdrawals or other FDA alerts. This type of information is relevant not only when considering whether this Policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Policy

Selegiline hydrochloride (HCl) (Zelapar®) is indicated as an adjunct therapy in the management of Parkinson's disease for individuals being treated with levodopa/carbidopa who exhibit deterioration in the quality of their response to this therapy. There is no evidence from controlled studies that selegiline HCl (Zelapar®) has any beneficial effect in the absence of concurrent levodopa therapy.

The use of selegiline HCl (Zelapar®) requires prior authorization (ie, clinical pharmacy and/or Medical Director review).

Policy Description

Selegiline HCl (Zelapar®) is best known as an irreversible inhibitor of monoamine oxidase (MAO). Selegiline HCl (Zelapar®) inhibits MAO by acting as a "suicide" substrate for the enzyme; that is, selegiline HCl (Zelapar®) is converted by MAO to an active moiety that combines irreversibly with the active site or with the enzyme's essential flavin adenine dinucleotide (FAD) cofactor. Because selegiline HCl (Zelapar®) has greater affinity for type B active sites than for type A active sites, it can serve as a selective inhibitor of MAO type B if it is administered at the recommended dose. Inhibition of MAO type B activity is generally considered to be of primary importance. In addition, there is evidence that selegiline HCl (Zelapar®) may act through other mechanisms by inhibiting the re-uptake of dopamine at the synapse to increase dopaminergic activity. Selegiline HCl (Zelapar®) is the orally disintegrating formulation of selegiline HCl and is designed to provide greater efficacy at lower doses of selegiline HCl.

Policy Guideline Inclusion

Selegiline hydrochloride (HCl) (Zelapar®) is approved when **all** of the following inclusion criteria are met:

- Documentation of Parkinson's disease

- Documentation of the trial and failure of, intolerance to, or contraindication to other oral non-disintegrating formulations of selegiline HCl

Policy Guideline Exclusion

Selegiline HCl (Zelapar®) is denied when **any** of the following exclusion criteria are present:

- No documentation of Parkinson's disease
- No documentation of the trial and failure of, intolerance to, or contraindication to other oral non-disintegrating formulations of selegiline HCl

Policy List of Applicable Drugs

Brand Name	Generic Name
Zelapar	selegiline hydrochloride

Dosing and Administration

Refer to the specific manufacturer's prescribing information for administration and dosage details for each specific agent.

Policy References

Micromedex. Zelapar® (selegiline HCl). [Micromedex Web site]. Available at: <http://www.micromedex.com> [via subscription only]. Accessed October 16, 2008.

Valeant Pharmaceuticals International. Zelapar® (selegiline HCl). [Valeant Pharmaceuticals Web site]. Available at: <http://www.zelapar.com/HTML-INF/index.html>. Accessed October 16, 2008.

Policy Link to Related Policies

Printed

11/11/2008 15:27:44

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