Side Effects
Sleep disturbances, restlessness and agitation, and urinary retention in association with prostate hyper-trophy may occur uncommonly. Paranoid exog-enous psychoses accompanied by visual hallucina-tions may be triggered, particularly in predisposed elderly patients. Adverse reactions of this type may occur with greater frequency when PK-Merz is given in combination with other antiparkinsonian drugs (e.g. levodopa, bromocriptine) or memantine. The development of livedo reticularis (characterised by mottled skin), sometimes accompanied by edema in the lower leg and ankle, is uncommonly reported.

Nausea, dizziness, dry mouth, and orthostatic dys-regulation are observed common to uncommonly and blurred vision very rare to rarely.

There have been very rare reports of cardiac arrhythmias such as ventricular tachycardia, ventric-ular fibrillation, torsades de pointes, and QT prol-on-gation. Most of these cases occurred after overdos-age or in association with certain drugs or other risk factors for cardiac arrhythmias.

In very rare cases temporary loss of vision, increased photosensitivity, and heart rhythm disturbances with tachycardia have been reported. Epileptic fits have also been triggered in rare cases, usually after treat-ment in excess of the recommended dose.

There have been very rare reports of muscle twitch- es and disturbances of feeling in the limbs.

Precautions
Anticholinergics and dopaminomimetics can potenti ate the action.

Pregnancy and Lactation
Although the teratogenic risk may be regarded as low, amantadine should not be taken during the first three months of pregnancy. Amantadine, the active ingredient in PK-Merz, passes into the milk of breast-feeding mothers; risks to the infant’s health have not become known to date.
### Drug Interactions

The simultaneous use of amantadine and drugs known to cause prolongation of the QT interval is contraindicated. Examples are:

- certain class I A antiarrhythmics (e.g. quinidine, disopyramide, procainamide) and class III (e.g. amiodarone, sotalol),
- certain antipsychotics (e.g. thioridazine, chlorpromazine, haloperidol, pimozide),
- certain tricyclic and tetracyclic antidepressants (e.g. amitriptyline),
- certain antihistamines (e.g. astemizole, terfenadine),
- certain macrolide antibiotics (e.g. erythromycin, clarithromycin),
- certain gyrase inhibitors (e.g. sparfloxacin),
- azole antifungicals and other drugs such as busulfan, halofantrine, co-trimoxazole, pentamidine, cisapride, and bepridil.

This list may be in-exhaustive. Before commencing use of another drug concomitantly with amantadine, this summary of product characteristics should be thoroughly checked for potential interactions between the drug and amantadine caused by QT prolongation.

Use of PK-Merz in combination with other antiparkinsonian drugs is possible. To avoid side effects (such as psychotic reactions), it may be necessary to reduce the dosage of the other drug or of the combination.

There have been no specific studies on the occurrence of interactions after administration of PK-Merz concomitantly with other antiparkinsonian drugs (e.g. levodopa, bromocriptine, trihexyphenidyl, etc.) or memantine (take note of side effects).

Simultaneous treatment with PK-Merz and any of the drug types or active substances listed below may lead to the following interactions:

#### Anticholinergics:

The side effects (confusion and hallucinations) of anticholinergics (e.g. trihexyphenidyl, benztropine, scopolamine, biperiden, orphenadrine, etc.) may be intensified if they are administered concomitantly with PK-Merz.

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**Indirectly CNS-active sympathomimetics:**

Potentiation of the central effects of amantadine.

**Alcohol:**

Lowering of alcohol tolerance.

**Levodopa (Antiparkinsonian Drug):**

Mutual potentiation of the therapeutic action. Levodopa can therefore be given concomitantly PK-Merz.

**Memantine:**

Memantine can potentiate the effect and side effects of PK-Merz.

**Other Drugs:**

The simultaneous use of diuretics of the triamterene/hydrochlorothiazide type can result in a decrease in the plasma clearance of amantadine, leading to toxic plasma concentrations. Simultaneous use should therefore be avoided.

### Dosage and Administration

Two to three tablets daily for the first week then two to five tablets daily; see literature.