

PRESCRIBING INFORMATION

PK-Merz® Tablets
(Amantadine Sulphate)

پی کے مرز ٹیبلٹس

COMPOSITION:

Each film coated tablet contains:
Amantadine Sulphate...Brookes Specs. 100mg
Mfg. Specs. Brookes

DESCRIPTION:

PK-Merz (Amantadine Sulphate) is (1-aminoadamantan) a tricyclic, symmetric amine with an antiviral activity against RNA & DNA viruses. Although exact mode of action of amantadine is not well understood, antiviral activity was found to be related to inhibition of viral uncoating and viral budding by interaction with the viral M2 protein which is a membrane protein. PK-Merz has established role in influenza and is also used in Parkinson's disease as an effective therapeutic agent having antagonistic action on NMDA-ion channel in basal ganglia which comprehensively improves the troublesome symptom of rigidity, tremor and hypokinesia, particularly the psychic brightening and the increased interest in surrounding.

PHARMACOKINETICS:

Absorption:

PK-Merz (Amantadine Sulphate) undergoes rapid and full absorption from the gastrointestinal tract after oral administration.

Plasma concentration:

Maximum plasma concentrations are reached about 2-8 hours (t-max) after administration of a single dose. At a dosage of 200mg/day a steady state is reached after 4-7 days, with plasma concentrations of 400-900ng/ml. After administration of 100 mg Amantadine Sulphate (C-max)0.15µg/ml.

Elimination:

The elimination half life is between 10 and 30 hours, on average about 15 hours, and is largely dependant on the age of the patient. In patients with kidney insufficiency the terminal plasma half life may be prolonged. Amantadine is bound to plasma protein at approximately 67%. Amantadine is excreted in urine almost completely unchanged, small amount being excreted in feces.

INDICATIONS:

- 1 As an adjunct in triple therapy of Hepatitis-C
- 1 As monotherapy in case of failed interferon response
- 1 In Hepatitis-C in which ribavirin is contraindicated
- 1 Parkinson's syndrome
- 1 Post-Zoster Neuralgia
- 1 Drug induced extra pyramidal syndrome

DOSAGE & ADMINISTRATION:

- 1 As an adjunct in triple therapy of Hepatitis-C
 - 1 tablet twice daily for 6-months with interferon and ribavirin
- 1 As monotherapy in case of failed interferon response
 - 1 tablet twice daily for 6-months
- 1 In Hepatitis-C in which ribavirin is contraindicated
 - 1 tablet twice daily for 6-months
- 1 For Parkinsonism
 - 1 tablet twice daily for 4 weeks
 - After 4 weeks 1 tablet three times a day
- 1 In advanced Parkinsonism
 - 5 tablet / day can be given.
- 1 For Post-Zoster Neuralgia and drug induced Parkinsonism
 - 1 tablet twice daily

PK-Merz Tablets may be combined with other anti-parkinsonism preparation. If given in combination, the dosage should be individually adjusted.

Treatment of patients with Parkinson's syndrome and drug-related movement disturbances should normally be introduced gradually, with the dose guided by the therapeutic effect. In elderly patients, treatment should be commenced at a lower dose.

The film-coated tablets are to be taken with a little liquid, preferably in the morning and after noon. The last daily dose should preferably be taken in late afternoon to avoid sleep disturbances.

SIDE EFFECTS:

Sleep disturbances, restlessness and agitation. Visual hallucinations may be triggered, particularly in predisposed elderly patients. Occasional dryness of the mouth, constipation, dysuria, central nervous disturbances in older arteriosclerosis patients. Rare reports of cardiac arrhythmias such as ventricular tachycardia, ventricular fibrillation, QT prolongation etc (most of the cases occurred after over dosage).

CONTRAINDICATIONS:

PK-Merz Tablets must not be used in patients with:
Hypersensitivity to Amantadine.
Prostate hypertrophy.
Narrow angle glaucoma.
Myasthenia Gravis.
Epilepsy.

CAUTIONS:

Use in Pregnancy and Lactation:

Amantadine was found to be embryo toxic and teratogenic. During pregnancy Amantadine should only be used after careful assessment of the risks and benefits. Amantadine passes into breast-milk. If use during breast feeding is necessary, the infant should be monitored for possible side-effects of the drug (skin rash, urinary retention, vomiting) breast feeding should be discontinued where necessary.

INTERACTIONS:

Anticholinergics can potentiate the action.

STORAGE:

Store at room temperature 15 to 30°C away from light and moisture.

PRESENTATION:

Pack of 20 Tablets.

زمرہ بندی اور دوا سے ہونے والے پارکن سونیم میں ایک گولی دو مرتبہ روزانہ
نی کے مری کی گولیاں پارکن سونیم کی دوسری دواؤں کے ساتھ بھی ملائی جاسکتی ہے اگر ملا کر دے رہے
ہوں تو خوراک کا لگ سے تجویز کرنا پڑتا ہے۔
احتیاط:

عالم اور دودھ پلانے والی خواتین میں استعمال کیے کے لیے بھی نقصان دہ ہے اس لیے
حمل میں بہت احتیاط کے ساتھ جانچ کے بعد نادرہ نقصان کو مدنظر رکھتے ہوئے دینی چاہیے۔
Amantadine ماں کے دودھ میں پائی جاتی ہے اس لیے اگر دودھ پلانے والی ماں کو دوا دینی ضروری
ہے تو بچے پر پیدا ہونے والے مضامرات کو مدنظر رکھنا چاہیے مثلاً جلدی سوزش، الٹیاں، پیشاب کا کارنا،
ضرورت کے تحت دودھ پلانا ترک کر دینا چاہیے۔
اسٹورج:

15 سے 30 ڈگری سنٹی گریڈ درجہ حرارت پر روشنی اور نمی سے بچا کر رکھیے۔

خوراک اور طریقہ استعمال:

- پانچ ٹائمنس سی کے علاج میں تین دواؤں کے ساتھ استعمال کے لیے
ایک گولی دن میں دو مرتبہ انٹرفرون اور رابنا ورن کے ساتھ چھ مہینے تک استعمال کریں
- انٹرفرون کی ناکامی کی صورت میں اکیلے استعمال کرنے کیلئے
ایک گولی دن میں دو دفعہ چھ مہینے تک
- پانچ ٹائمنس سی جس میں رابنا ورن منع ہے
ایک گولی دن میں دو دفعہ چھ مہینے تک
- پارکن سونیم کیلئے
4 ہفتوں تک 1 گولی دن میں دو مرتبہ روزانہ استعمال کریں۔
4 ہفتوں کے بعد ایک گولی دن میں تین دفعہ استعمال کریں
شدید پارکن سونیم میں 5 گولیاں روزانہ دی جاسکتی ہے۔

brookes

Manufactured by:

Brookes Pharma Private Limited
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Karachi 74900 Pakistan

Under Licence from:
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