

PK-MERZ TABLET

Amantadine Sulphate (100mg)

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What PK-Merz Tablet is used for

PK-Merz film-coated tablet is used to reduce the symptoms of Parkinson's disease such as stiffness, trembling and loss of voluntary movement.

How PK-Merz Tablet works

PK-Merz Tablet contains amantadine sulphate which relieves the Parkinson symptoms by increasing the levels of certain chemicals which transmit impulses in the nervous system, including the brain.

Before you take PK-Merz Tablet

- When you must not take it

Do not take PK-Merz Tablet if you:

- are allergic to amantadine, coloring agent or any of the other ingredients of PK-Merz Tablet (listed in Product Description),
- have heart problems, or any problems related to heart rhythm, or family history of heart disease,
- are taking budipine or any other medicine, which cause irregular heart rhythm,
- have severe kidney impairment,
- have low levels of potassium or magnesium in the blood.

- Before you start to take it

Please tell your doctor if you have any of the following conditions:

- enlarged prostate gland
- increased pressure in the eye, e.g. glaucoma
- kidney problem
- agitation, confusion and serious mental disorders
- prone to seizures
- have a heart pacemaker

- experience problems when passing urine
- taking any medication for flu (influenza A viral infection)
- at risk of losing electrolyte such as potassium or magnesium (for example vomiting/diarrhea or are using diuretics)

Not to be used in children.

Pregnancy & Lactation:

Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or breast-feeding before using this medicine.

PK-Merz Tablet must only be taken during pregnancy if the benefit is more than the risk to the fetus. If you take this medication during the first trimester, an ultrasound is recommended to check on the baby's health.

Amantadine is secreted into the breastmilk, and due to the risk of side effects in the baby, you should only take this medicine if the benefit is more than the risk. Monitor your baby for any skin rash, trouble urinating, or vomiting. Stop breastfeeding if any of these occur, and get medical attention immediately.

- Taking other medicines

Tell your doctor if you are taking:

Medications known to cause heart rhythm problems such as:

- quinidine, disopyramide, procainamide, amiodarone, sotalol (used for heart rhythm problems)
- thioridazine, chlorpromazine, haloperidol, pimozide (used for mental health conditions)
- amitriptyline (used for depression)
- astemizole, terfenadine (used for allergies)
- erythromycin, clarithromycin, sparfloxacin, co-trimoxazole (used for bacterial infections)
- pentamidine (used for fungal infections)
- halofantrine (used for malaria)
- cisapride (used for digestive issues)
- bepridil (used for heart conditions)

Other medications, that include:

- levodopa, bromocriptine, trihexyphenidyl, budipine (antiparkinson medications)
- trihexyphenidyl, benzatropine, scopolamine, biperiden, orphenadrine (used to reduce muscle spasms or treat parkinson's symptoms)
- medications that stimulates the central nervous system
- memantine (used for dementia)
- triamterene/hydrochlorothiazide combination (diuretics)

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

How to take PK-Merz Tablet

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- How much to take

Adults:

The required dose and length of treatment depend on the type and severity of the symptoms and will be determined by your doctor.

Starting dose:

Begin with 1 tablet once daily for the first 4–7 days. Increase by 1 tablet weekly until reaching the required dose determined by your doctor.

Elderly patients:

Your doctor will start with a lower dose, especially if there's a history of confusion or agitation.

Individual with kidney problems:

Your doctor will adjust the dose according to your kidney function.

Children:

Not to be used in children.

- When to take it

To be taken as directed by your doctor or pharmacist. Take tablets with water, preferably in the morning and afternoon. Avoid taking them after 4

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p.m. to reduce the risk of sleep disturbances.

- How long to take it

Take PK-Merz Tablet for the duration that the doctor recommends. Only your doctor can decide when to stop treatment. Sudden discontinuation can worsen symptoms severely.

- If you forget to take it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you take too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause nausea, vomiting, restlessness or feeling over-excitedness, shaking (tremors), loss of coordination or trouble with balance, blurred vision, extreme drowsiness or lethargy, mood changes including depression, speech difficulties, seizures, confusion or hallucinations (seeing or hearing things that are not there), and irregular heartbeat (a rare but serious symptom).

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all doctors, dentists and pharmacists treating you that you are taking PK-Merz Tablet.

Tell your doctor immediately if you become pregnant while taking this medication.

Take PK-Merz Tablet only with a doctor's prescription.

Seek medical advice if any signs of suicidal ideation or behaviour emerge.

- Things you must not do

Do not stop taking the medicine or reduce the dose without telling your doctor first.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give PK-Merz Tablet to anyone else, even if they have the same symptoms or condition as you.

Do not take alcohol while taking PK-Merz Tablet.

- Things to be careful of

If you develop symptoms, such as palpitations, dizziness, or fainting, stop the medication and contact your doctor immediately or go to the Emergency Department of your nearest hospital.

Your doctor might conduct an ECG periodically to monitor your heart while you are taking this medicine.

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets affect your vision, cause shaking, difficulty to control movements, dizziness, or lethargy, do not drive or use machines and contact your doctor immediately.

Side Effects

Like all medicines, PK-Merz Tablet can cause side effects, although not everybody gets them.

Common side effects

- dizziness
- sleep issues (trouble sleeping)
- feeling restless or agitated (especially in older adults)
- nausea and dry mouth
- skin changes like marbling (a lacy red or blue pattern) on the skin, sometimes with swelling in the legs or ankles
- urinary issues (especially trouble urinating in men with prostate problems)
- low blood pressure when standing, causing lightheadedness
- mental changes (confusion, hallucinations, paranoia, especially in those on other Parkinson's medications)

Uncommon side effects

- blurred vision

Rare side effects

- corneal issues (eye problems like cloudiness or reduced vision)

Very rare side effects

- blood disorders (low white blood cell or platelet counts, which can increase infection or bleeding risk)
- heart problems or irregular heartbeat
- seizures (usually with high doses)
- vision loss (temporary or increased light sensitivity)

Unknown frequency

- impulse control issues (unusual behaviors like compulsive shopping, gambling, overeating, or increased sexual urges)
- allergic reactions (especially from certain coloring agents in the tablets)

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of PK-Merz Tablet

- Storage

Keep out of the sight and reach of children.

Do not store above 25°C.

Do not take PK-Merz Tablet after the expiry date which is stated on the blister pack and box.

- Disposal

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These

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measures will help to protect the environment.

Product Description

- What it looks like

Biconvex film-coated tablet with score line on one side.

- Ingredients

– Active ingredient

Amantadine Sulphate 100mg

– Inactive ingredients

Colloidal anhydrous silica, yellow orange lacquer (E 110), titanium dioxide (E 171), gelatin, lactose monohydrate, potato starch, butylmethacrylat-(2-dimethyl-aminoethyl)-methacrylat-methyl-methacrylat-copolymer (1:2:1), talc, croscarmellose sodium, microcrystalline cellulose, povidone, magnesium stearate.

- MAL Number

MAL19860850ARZ

Manufacturer

Merz Pharma GmbH & Co. KGaA
Ludwigstraße 22,
64354 Reinheim, Germany.

Product Registration Holder

Summit Company (Malaysia) Sdn.
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