

المستقرّ، تشوُّش الرؤية، الشُّبَّات (انعدام النشاط ورَدّ الفعل)، الاكتئاب، مشاكل في النطق، نوبات مرصع مصدرها المخيخ، حالات ارتباك مع خذيان، الغيبوبة، وتشنُّج العضلات.

ليست لـ**بلمـميرز أقراص** أدوية مضادّة، لذا فإنّه في حال التسمّم، من المحتمل أن يقوموا – في غرفة الطوارئ في المستشفى – بإجراء غسيل معدة، أو قد يشجّعون على التقيؤ. تصفية الدم غير مفضّلة في مثل هذه الحالة.

في حالات التسمّم المهدّد للحياة من المحتمل أن يتمّ اتخاذ الخطوات التالية: استهلاك السوائل، تحميص البول، إعطاء أدوية مهدّنة، أدوية لمعالجة التشنُّج، أدوية مضادّة لاضطرابات النظم (ليدوكئين بإعطاء عن طريق الوريد)، فيزيوستيجمين بإعطاء عن طريق الوريد لمعالجة أعراض التسمّم العصبيّ. لدى الحاجة، سيُجرى لك الطبيب فحص كهربيّانية عمل قلب (إي.كي.جي.). إذا تناولت وجبة زائدة، أو إذا قام طفل – عن طريق الخطأ – ببلع شيء من الدواء، فتوجّه، فوراً، إلى الطبيب أو إلى غرفة الطوارئ في المستشفى، وأحضر علبه الدواء معك.

إذا **نسيبت تناول الدواء** في الوقت المحدّد، يُمنع تناول وجبة مضاعفة. خُدّ الوجبة التالية في الوقت العاديّ واستشّر الطبيب. تجنب المواظبة على العلاج حتنب توصية الطبيب. حتّى إذا طرأ تحمّن على حالتك الصحية، **يُمنع وقف العلاج بالدواء** أو تغيير الجرعة بدون استشارة الطبيب، لأنّ ذلك من الممكن أن يؤدي إلى تدهور حالتك. إذا كانت لديك أسئلة إضافية بالنسبة إلى استخدام الدواء، فاستشّر الطبيب أو الصيدليّ.

الأعراض الجانبية

كجميع الأدوية، قد يسيّب استعمال **بلمـميرز أقراص** أعراضًا جانبية لدى قسم من متناولي الدواء. لا تُصدّم عند قراءة قائمة الأعراض الجانبية. من المحتمل ألا تعاني من أيّ منها.

الأعراض الجانبية المتواترة

- اضطرابات النوم.
- انعدام الهدوء.
- احتباس البول لدى المرضى الذين يعانون من تضخّم غدّة البروستات.
- حالات من الهذيان البارانويدي، خصوصًا لدى المتعالجين الكبار الذين لديهم ميل للهذيان، وتيرة الأعراض الجانبية هذه من الممكن أن تزيد لدى المتعالجين الذين يتناولون – بالإضافة إلى **بلمـميرز أقراص** – أدوية أخرى لمعالجة الرُّعاش (بياركسون).
- ردود فعل في الجلد من قبيل الحكّة أو الطّفح، حيث تكون مصحوبة، أحيانًا، بوذمة في القسم السفليّ من الرجلين وفي الكاحلين.
- الغثيان.
- الدوخة.
- جفاف الفم.
- تغيّرات في ضبط مجرى الدم عند الوقوف أو النهوض.

أعراض جانبية نادرة

- تشوُّش الرؤية.

أعراض جانبية نادرة جدًا

- قلّة العدلات (عدد منخفض جدًا من خلايا الدم البيضاء)، قلّة الصفيحات (انخفاض عدد صفائح الدم).
- اضطرابات في وتيرة نبض القلب، من قبيل عدم انضباط دقات القلب البيطينيّ، الرجفان البيطينيّ، **torsade de pointes**، وتطويل المقطع QT. غالبية هذه الحالات ناتجة عن الجرعة الزائدة، الإعطاء المدمج مع أدوية أخرى، أو عوامل خطر لاضطرابات في وتيرة نبض القلب.
- فقدان البصر المؤقت.
- ازدياد الحساسية للضوء.
- نوبات الصرع (غالبًا لدى المتعالجين الذين تناولوا جرعة أعلى ممّا أوصى به الطبيب).
- تشنُّجات في العضلات واضطراب في الشعور بالأطراف.

أعراض جانبية تواترها غير معروف

- وذمة في القرنية (تزوّل بعد التوقف عن تناول الدواء) – يجب أن تتوجّه إلى طبيب العيون فورَ ظهور أعراض مثل اضطرابات الرؤية وتشوُّشها، وذلك لأنّ وجود وذمة في القرنية.
- المادّة الصبغية الصفراء (E 110) يمكن أن تُثير ردود فعل تحسّسية.

إذا **تفانم أحد الأعراض الجانبية**، أو إذا عانيت **أعراضًا جانبية لم تُنكر في النشرة**، يجب أن تستشير الطبيب.

كيف يُخزّن الدواء؟

- تجنّب التسمّم! يجب حفظ هذا الدواء، وكلّ دواء آخر، في مكان مغلق، بعيدًا عن متناول أيدي الأولاد و/أو الأطفال، وهكذا تتجنّب التسمّم. لا تؤدّ إلى التقيؤ بدون أمر واضح من الطبيب.
- لا يجوز تناول الدواء في الظلام! تحقّق من الملمصق على الدواء ومن الجرعة الدوائية في **كلّ مرّة** تتناول فيها دواء. ضع النظارات الطبية إذا كنت بحاجة إليها.
- يُمنع تناول الدواء بعد انتهاء الصلاحية (**exp. date**) الظاهر على العبوة الخارجيّة. تاريخ انتهاء الصلاحية يُنسب إلى اليوم الأخير في الشهر.
- قم بخزن الدواء في درجة حرارة أقلّ من ٢٥°C.
- قم بالخزن بالعلبة الأصليّة.

معلومات إضافية

- بالإضافة إلى المادّة الفعّالة، **Amantadine Sulfate**، يحتوي الدواء، أيضًا:
- Lactose Monohydrate, Microcrystalline Cellulose, Potato Starch, Gelatin, Povidone, Talc, Colloidal Anhydrous Silica, Magnesium Stearate, Croscarmellose Sodium, Butylmethacrylat-(2-Dimethyl-Aminoethyl)-Methacrylate-Methyl-Methacrylate-Copolymer (1:2:1), Titanium Dioxide (E 171).
- كيف يبدو الدواء وماذا تحوي العبوة:
- أقراص مطلية مستديرة، برتقالية اللون، مع خط تصفيف من جانب واحد. مرزوم بيليستر ألومنيوم في رزم تحوي على ١٠، ٣٠، ١٠٠ قرص.
- قد لا يتمّ تسويق جميع أنواع الرزم.
- صاحب التسجيل وعتوانه: ميچافارم م.رض،.ص.ب. ٥١٩ هود هشارون ٤٥١٠٥١.
- اسم المنتج وعتوانه: Merz Pharma GmbH & Co.KgAا، Germany.
- تمّ فحص هذه النشرة والتصديق عليها من قِبَل وزارة الصحة في كانون الثاني ٢٠١٤.
- رقم تسجيل الدواء في سجلّ الأدوية الرسميّ في وزارة الصحة: ١٣٧٠٠٠٠٠٣٣-٤٣-٢٧١٠٠٠٠٠.
- لتيسيط قراءة هذه النشرة وتسهيّلها ورد النصّ بصيغة المدكّر، ومع هذا فالدواء معدّ لكلا الجنسين.

Side effects

As with any medicine, **PK-Merz tablets** may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

Very common side effects

- Sleep disorders
- Agitation
- Stoppage of urine in patients with an enlarged prostate gland
- Paranoid delusions, particularly in older patients with a tendency to delusions. This side effect could be more common in patients who are taking other medication apart from **PK-Merz tablets** to treat Parkinson's.
- Skin reactions such as irritation or rash, sometimes accompanied by swelling in the lower legs and ankles.
- Nausea
- Dizziness
- Mouth dryness
- Changes in blood flow regulation when standing or getting up.

Rare side effects

- Blurred vision

Very rare side effects

- Leukopenia (very low number of white blood cells), thrombocytopenia (drop in the number of blood platelets).
- Disturbances in the heart rate such as ventricular tachycardia, ventricular fibrillation, torsade de pointes, and prolongation of the QT interval. Most of these symptoms are the result of an overdose, or taking the medicine in conjunction with other medication, or other risk factors for heart rhythm disturbances.
- Temporary loss of vision.
- Increased sensitivity to light.
- Epileptic attacks (mostly in patients who have taken a higher dose than recommended by the physician).
- Muscle spasms and disturbances of sensation in the limbs.

Side effects of unknown frequency

- Swelling of the cornea (reversible after stopping treatment) – contact an ophthalmologist immediately if you experience symptoms such as blurred vision, in order to rule out swollen cornea.
- The yellow coloring (E 110) could cause allergic reactions.

If any side effect gets worse, or if you suffer from a side effect not mentioned in the leaflet, you should consult your physician.

How to store the medicine?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.
- Do not take medicines in the dark! Check the label and the dose **each time** you take a medicine. Wear glasses if you need them.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Store at a temperature below 25 C.
- Store in the original package.

Additional information

- In addition to the active ingredient, Amantadine Sulfate, the medicine also contains: Lactose Monohydrate, Microcrystalline Cellulose, Potato Starch, Gelatin, Povidone, Talc, Colloidal Anhydrous Silica, Magnesium Stearate, Croscarmellose Sodium, Butylmethacrylat-(2-Dimethyl-Aminoethyl)-Methacrylate-Methyl-Methacrylate-Copolymer (1:2:1), Yellow-Orange Lacquer (E 110), Titanium Dioxide (E 171).
- What does the medicine look like and what are the contents of the package? Round, orange film-coated tablets, with a scoring line on one side. Packed in aluminum blister packs in packages containing 10, 30 and 100 tablets.
- Not all packs may be marketed.
- Registration holder: MegaPharm Ltd., P.O.B. 519, Hod Hasharon 4510501
- Manufacturer: Merz Pharma GmbH & Co. KgAا، Germany
- This leaflet was checked and approved by the Ministry of Health in January 2014
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 137-43-27100-00

Using the medicine and food

The tablets can be swallowed with or without food.

Using the medicine and alcohol consumption

Do not drink alcoholic beverages while using **PK-Merz tablets**, as it reduces tolerance for alcohol.

Pregnancy and breastfeeding

If you are pregnant, planning to get pregnant or are breast-feeding, you should consult a physician before taking **PK-Merz tablets**.

This medicine should only be taken during pregnancy if the physician determines that it is essential.

There is insufficient research on the use of this medicine during pregnancy.

Use of this treatment in the first trimester of pregnancy must be under medical observation.

If you are planning pregnancy or think you may be pregnant, inform your physician immediately so that he can decide whether to continue the treatment, stop it or replace it with another medicine.

The active ingredient Amantadine is transferred through breast milk.If you are breastfeeding, and the physician decides that you can take this medicine, your baby must be regularly checked for symptoms such as skin rash, lack of urine, vomiting.The physician might advise you to stop breastfeeding.

Driving and using machines

Use of this medicine could affect alertness and vision. Therefore you should not drive or operate dangerous machinery or engage in any activity requiring alertness without consulting your physician.

Important information about some of the medicine's ingredients

This medicine contains Lactose. If you have been told that you suffer from intolerance to some or all sugars, consult your physician before taking **PK-Merz tablets**.

How should you use the medicine?

Always use according to your physician's instructions. You should check with the physician or the pharmacist if you are unsure. The dosage and treatment will be determined only by the physician.

PK-Merz tablets should be swallowed with a little liquid, preferably in the morning and early afternoon. Do not take the last dose for the day after 4 p.m. Duration of treatment will be determined by your physician, taking account of your condition and how you respond to the treatment. Do not stop treatment without consulting the physician.

Adults: particularly those suffering from restlessness, confusion or delusions, should start with a lower dose.

If **PK-Merz tablets** are taken in conjunction with other medication for Parkinson's, the physician will adjust the dose accordingly.

If you have previously been treated with PK-Merz infusion, your physician might start treatment with **PK-Merz tablets** at a higher dosage.

Patients with renal insufficiency:

The physician will adjust your dose of **PK-Merz tablets** according to your GFR value (the measured value of the rate at which your kidneys filter blood liquids).

The tablet can be split in two.

Do not exceed the dose recommended by your physician.

If you have accidentally taken a higher dose you should contact your physician or a hospital emergency room as you may experience symptoms of serious poisoning, such as: vomiting, nausea, hypersensitivity, trembling, unsteady gait, blurred vision, lethargy (inactivity, lack of response), depression, speech problems, epileptic fits originating in the small brain, confusion and delusions, coma, muscle spasms.

There is no antidote to **PK-Merz tablets** so in the event of poisoning the hospital might pump the stomach or encourage vomiting. Blood filtration is not recommended in this case.

In cases of life threatening poisoning, the following actions might be taken: drinking fluids, urine oxygenation, taking sedatives and medication to treat spasms, antiarrhythmic drugs (intravenous lidocaine), intravenous physostigmine to treat symptoms of nervous poisoning.

If necessary, the physician will perform an ECG test.

If you have taken an overdose, or if a child has accidentally swallowed the medicine, go immediately to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine at the scheduled time, do not take a double dose. Take the next dose at the usual time and consult your physician. Continue the treatment as recommended by the physician.

Even if there is an improvement in your health, **do not stop treatment** with this medicine or change the dosage without consulting your physician as this could cause your condition to deteriorate.

If you have any other questions regarding the use of the medicine, consult the physician or the pharmacist.

If you experience strong heart palpitations, dizziness or fainting, stop taking **PK-Merz tablets** immediately and consult your physician. Once the physician has checked your heart rate and determined there are no arrhythmias, it is possible to resume treatment with **PK-Merz tablets** (in accordance with contraindications and interactions with other medicines).

Do not stop taking **PK-Merz tablets** suddenly; this could cause deterioration in your mobility and in the worst case, you could lose all mobility.

Patients who take **PK-Merz tablets** together with medicines to treat mental or emotional disorders, could develop a life-threatening condition (malignant neuroleptic syndrome) if the treatment with **PK-Merz tablets** is stopped suddenly. This condition is characterized by a sudden rise in body temperature, muscle rigidity and disorders of the autonomous nervous systems.

Symptoms such as low blood pressure, increased saliva, sweating, increased body temperature, sensation of heat, oedema and depression are often observed in Parkinson's patients. They should be treated with attention to side effects and possible interactions with **PK-Merz tablets**.

Consult your physician if you experience problems urinating.

If you experience eyesight problems, such as blurred vision, you must consult an ophthalmologist to check if there is a swelling of the cornea. In that case, the physician will stop treatment with **PK-Merz tablets**. Swelling of the cornea is generally reversible and in most cases will disappear after a month.

Tell your physician or the pharmacist if you are taking or have recently taken other medicines, including non-prescription medicines and food supplements. In particular inform the physician or the pharmacist if you are taking:

- Medicines that are known to prolong the QT interval in ECG tests, such as:
 - Anti-arrhythmic medicines to treat cardiac rhythm problems: Class IA - quinidine, disopyramide, procainamide; Class III – amiodarone and sotalol, budipine.**do not use with PK-Merz tablets!**
- Anti-psychotic medicines to treat delusions, such as: thioridazine, chlorpromazine, haloperidol and pimozide
- Tricycline or tetracycline medicines to treat depression, such as amitriptyline
- Antihistamine medicines to treat hay fever, such as astemizole terfenadine
- Antibiotics of the macrolide group to treat microbial and fungal infections, such as: erythromycin and clarithromycin
- Medicines to treat microbial infections such as sparfloxacin (one of the medicines that inhibits the gyrase enzyme)
- Medicines to treat fungal infections such as azole antifungals
- Other medicines, such as: (halofantrine, cotrimoxazole, pentamidine, cisapride or bepridil).

This list does not cover all possible interactions. Your physician will study the physician's leaflet in order to ensure there are no other interactions that could occur with other medicines that you are taking together with **PK-Merz tablets**.

- It is possible to take **PK-Merz tablets** with other medication to treat Parkinson's (there are no specific studies on this subject), such as levodopa, bromocriptine, trihexyphenidyl, or medicines to treat Alzheimer's, such as memantine. It may be necessary to adjust the doses of the medicines.
- Treatment with the following medicines together with **PK-Merz tablets** could cause the following interactions:
 - Anticholinergic drugs: reinforcing the side effects of anticholinergic drugs (such as confusion or delusions) when used with other medicines such as: trihexyphenidyl, benztropine, scopolamine, biperiden, orphenadrine
 - Medications that stimulate the sympathetic nervous system will increase the effect of Amantadine on the central nervous system
 - Levodopa (used to treat Parkinson's) increases the therapeutic effect shared with **PK-Merz tablets**
 - Memantine (used to treat Alzheimer's) increases the therapeutic effect and the side effects of **PK-Merz tablets**
 - Diuretic medicines such as hydrochlorothiazide could reduce secretion of the active substance Amantadine and cause a toxic level in the blood leading to mobility problems, spasms and confusion. Therefore, medicines of this type should not be given in conjunction with **PK-Merz tablets**.

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) 1986

This medicine is to be supplied by physician's prescription only

PK-Merz tablets

Film-coated tablets

Active ingredient: Amantadine Sulfate 100mg

For the complete list of ingredients see “Additional information”.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains summary information about this medicine. If you have any further questions, refer to the physician or the pharmacist. This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar.

What is this medicine intended for?

Parkinsonian syndromes: Treatment of symptoms of Parkinson's disease such as rigor, tremor, hypokinesia and akinesia.

Therapeutic group: Anti Parkinson's drugs.

Before using this medicine

Do not use this medicine if: <ul style="list-style-type: none">You are sensitive (allergic) to the active ingredient Amantadine Sulfate, Amantadine compounds, Lactose, Yellow Orange Lacquer (E 110) or to any of the other ingredients of this medicine; please see “Additional information” You suffer from cardiac insufficiency (which is not compensated) You suffer from various cardiac problems (cardiomyopathies, myocarditis) You suffer from problems in the nervous transmission of the heart muscle (blockage between nerves leading to cardiac chambers) You suffer from low heart rate (less than 55 beats a minute) You suffer from abnormal ECG results (prolongation of the QT interval, U waves) You have a close relative suffering from congenital heart disease (QT syndrome) You have previously suffered from severe heart rhythm problems (ventricular rhythm disturbances, torsade de pointes) You suffer from low level of potassium or magnesium in the blood <p>PK-Merz tablets must not administrate together with budipine or other medicines that could prolong the QT interval.</p>

Special warnings regarding the use of this medicine

Before using PK-Merz tablets, tell your physician if:

- You suffer from enlargement of the prostate gland
- You suffer from intraocular pressure such as glaucoma
- You suffer from renal insufficiency
- You suffer from agitation and confusion
- You suffer from delusions or mental disturbances
- You are being treated with medicines containing the active substance memantine.

Children

There is insufficient information regarding the use of **PK-Merz tablets** by children.

Adults

The physician may need to adjust the dose for adult patients, particularly those suffering from agitation, confusion or delusions.

Important additional information

Your physician will perform ECG tests on you:

- Before treatment, and after one to three weeks of treatment.
- Before increasing the dose and two weeks later.
- Routinely at least once a year.

In the event of strong heart palpitations, dizziness or fainting, stop taking **PK-Merz tablets** immediately and contact your physician or go to a hospital emergency room.

For patients with a heart pacemaker whose QT interval cannot be determined, the treating physician will use his judgment to decide whether treatment with **PK-Merz tablets** is possible.

For patients suffering from impaired kidney function, there may be an increase in the level of the active ingredient, which could cause symptoms identical to those caused by an overdose. Therefore the treating physician must adjust the dose of **PK-Merz tablets**.

For patients suffering from organic brain disease or spasms and taking **PK-Merz tablets**, extra caution should be exercised as their condition may deteriorate.

Patients who have a tendency to suffer from seizures or have previously suffered from seizures, as well as patients with cardiac and blood vessel disorders, must be regularly checked by their physician while being treated with **PK-Merz tablets**.