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Summary of the risk management plan (RMP) for Pregabalin Mylan (pregabalin)

This is a summary of the risk management plan (RMP) for Pregabalin Mylan, which details the measures to be taken in order to ensure that Pregabalin Mylan is used as safely as possible. For more information on RMP summaries, see here.

This RMP summary should be read in conjunction with the EPAR summary and the product information for Pregabalin Mylan, which can be found on Pregabalin Mylan's EPAR page.

Overview of disease epidemiology

Pregabalin Mylan is a medicine used to treat adults with epilepsy or generalised anxiety disorder.

Epilepsy

Epilepsy is a long-term condition affecting the brain and is characterised by recurring seizures (or fits). It is one of the most serious disorders of the brain, affecting around 50 million people globally and every year about 50 new cases are diagnosed per 100,000 people in the population. For most patients there is no identifiable cause, though the condition can be caused by injury or damage to the brain as happens, for example, following strokes or in patients with brain tumours.

Generalised anxiety disorder

Generalised anxiety disorder is long-term anxiety or nervousness about everyday matters. The cause of generalised anxiety disorder is not clear although it is believed to be related to both genetic factors and life experiences.

Generalised anxiety disorder is one of the most prevalent mental disorders seen in primary care, accounting for up to 10% of such disorders. The number of people affected by this condition varies between different counties and cultures, with around 2% of the adult population affected in Europe. Regardless of geography, however, women are more likely to be affected than men. There also appear to be more cases of generalised anxiety disorder among older people up until the age of 60, when the number of cases begins to decline. A study conducted in Norway found the combined estimate of the number of new cases of panic and generalised anxiety disorder to be 1.10 per 100,000 people per year.

Summary of treatment benefits

Pregabalin Mylan contains the active substance pregabalin and is available as capsules (containing 25, 50, 75, 100, 150, 200, 225 and 300 mg of pregabalin). Pregabalin Mylan is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Lyrica.

Because Pregabalin Mylan is a generic medicine, its benefits and risks are taken as being the same as the reference medicine's. Studies in people have been limited to tests to determine that it is

bioequivalent to the reference medicine, Lyrica. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

Unknowns relating to treatment benefits

The safety and efficacy of pregabalin in children and adolescents below the age of 18 years have not been established. No data are available. There are also no adequate data on the use of pregabalin in pregnant women. Pregabalin Mylan should not be used during pregnancy unless clearly necessary (if the benefit to the mother clearly outweighs the potential risk to the fetus).

Summary of safety concerns

Important identified risks

Risk	**What is known**	**Preventability**
Weight gain	Some patients may experience weight gain whilst taking pregabalin.	Some patients with diabetes who gain weight while taking pregabalin may need an alteration in their diabetes medicines.
Swelling (oedema), including in the extremities	Swelling of the body including in the extremities may affect more than 1 person in 100, and joint swelling may affect more than 1 person in 1,000.	Patients should inform their doctor if they develop swelling.
Dizziness, sleepiness (somnolence), loss of consciousness, fainting (syncope), and potential for accidental injury	Pregabalin has been associated with dizziness and somnolence, which could increase the occurrence of accidental injury (e.g. falls) in older patients. There have also been post-marketing reports of loss of consciousness, confusion and mental impairment. Dizziness, sleepiness and decreased concentration may be increased if pregabalin is taken with certain other medicines. Dizziness and sleepiness may influence the ability to drive or use machines. Overdose may cause sleepiness.	Patients should be advised to exercise caution until they are familiar with the potential effects of the medicine. Patients are advised not to drive, operate complex machinery or engage in other potentially hazardous activities until it is known whether this medicinal product affects their ability to perform these activities.
Events after pregabalin discontinuation (withdrawal symptoms)	After stopping treatment with pregabalin, side effects such as trouble sleeping, headache, nausea, feeling anxious, diarrhoea, flulike symptoms, convulsions, nervousness,	Patients should not stop taking pregabalin unless their doctor tells them to. If treatment is to be stopped, this should be done gradually over a minimum of 1

Risk	What is known	Preventability
	depression, pain, sweating, and dizziness may be experienced. These symptoms may occur more commonly or severely following long-term use.	week.
Interactions with other medicines	Pregabalin may potentiate (increase) the side effects of other medicines, including respiratory failure and coma. The degree of dizziness, sleepiness and decreased concentration may be increased if Pregabalin is taken together with medicinal products containing oxycodone (used as a pain-killer), lorazepam (used for treating anxiety) or alcohol.	Patients should tell their doctor or pharmacist if they are taking, have recently taken or might take any other medicines.
Euphoria (elevated mood)	Patients may experience elevated mood whilst taking pregabalin which may affect more than 1 person in 100.	Caution should be exercised in patients with a history of substance abuse.
Hypersensitivity reactions, including allergic reactions	Patients may experience hypersensitivity reactions, including allergic reactions with symptoms such difficulty breathing, as swelling of the face, lips, tongue, and throat, as well as diffuse skin rash whilst taking pregabalin.	Patients should not to take the product if they are allergic to pregabalin or any of the other ingredients. Patients are advised to stop taking pregabalin and immediately seek medical advice if they experience swollen face or tongue, or if their skin turns red and starts to blister or peel. Treatment with Pregabalin Mylan should be discontinued immediately if symptoms of swelling occur.
Congestive heart failure	Patients may experience congestive heart failure whilst taking pregabalin and this is more common in elderly patients with pre-existing cardiovascular conditions.	Patients are advised to tell their doctor if they have a history of heart disease before taking the product. Discontinuation of pregabalin may resolve this side effect. Pregabalin Mylan should be used with caution in patients with heart problems.
Vision-related events	Patients may experience blurred vision, double vision, changes in vision including tunnel vision,	Patients should immediately tell their doctor if they experience any changes in vision.

Risk	What is known	Preventability
	flashes of light, swinging vision, altered perception of depth, visual brightness and vision loss whilst taking pregabalin. Many of these changes are temporary.	Discontinuation of Pregabalin Mylan may result in resolution or improvement of these visual symptoms.
Abuse, misuse and dependence	Cases of misuse, abuse and dependence have been reported.	Before taking the product, patients should tell their doctor if they have a history of alcoholism or drug dependence or abuse. Patient should be monitored for symptoms of pregabalin misuse, abuse or dependence. Patients should tell their doctor if they think they need more medicine than prescribed.

Important potential risks

Risk	What is known
Cancer of the blood vessels (haemangiosarcoma)	Cancer of the blood vessels has been observed in mice at higher exposures, but there is no evidence of an associated risk to humans.
Thoughts of self-harming or suicide	A small number of patients being treated with anti-epileptics, such as Pregabalin Mylan have had thoughts of harming or killing themselves. Patients should be monitored for sign of suicidal behaviour and appropriate treatment should be considered. Patients should immediately contact their doctor if at any time they have such thoughts.
Off-label (unauthorised) use in children	The safety and efficacy in children and adolescents (under 18 years of age) has not been established and therefore, Pregabalin Mylan should not be used in this age group.

Missing information

Risk	What is known
Use during pregnancy and breastfeeding	Pregabalin Mylan should not be taken by patients during pregnancy, unless they are told otherwise by their doctor. Effective contraception must be used by women of child-bearing potential. As pregabalin passes into breast milk, a decision must be made whether to discontinue treatment with pregabalin or to discontinue breastfeeding, taking into account the importance of the treatment to the mother. Patients who are pregnant or breastfeeding, think they may be pregnant or are planning to have a baby, should ask

Risk	What is known
	their doctor or pharmacist for advice before taking this medicine.

Summary of risk minimisation measures by safety concern

All medicines have a summary of product characteristics (SmPC) which provides physicians, pharmacists and other healthcare professionals with details on how to use the medicine, and also describes the risks and recommendations for minimising them. Information for patients is available in lay language in the package leaflet. The measures listed in these documents are known as 'routine risk minimisation measures'.

The SmPC and the package leaflet are part of the medicine's product information. The product information for Pregabalin Mylan can be found on Pregabalin Mylan's EPAR page.

This medicine has no additional risk minimisation measures.

Planned post-authorisation development plan

No studies are planned.

Summary of changes to the risk management plan over time

Not applicable.

This summary was last updated in 05-2015.