VI.2 Elements for a Public Summary

<Product name> 25 mg capsules, hard
<Product name> 50 mg capsules, hard
<Product name> 75 mg capsules, hard
<Product name> 100 mg capsules, hard
<Product name> 150 mg capsules, hard
<Product name> 200 mg capsules, hard
<Product name> 225 mg capsules, hard
<Product name> 300 mg capsules, hard

VI.2.1 Overview of disease epidemiology

Neuropathic pain
Neuropathic pain (neuralgia) is a pain that results from damage or a disease affecting signals from the nerves. The function of the nerve is affected in a way that it sends a pain message to the brain, even when no stimulus (reason for pain) is present. (1)
Pain sensations may be described as hot, burning, throbbing, stabbing, sharp, cramping, aching, tingling, numbness, or pins and needles. Peripheral and central neuropathic pain may be associated with mood changes, sleep disorders or tiredness, and impact on the quality of the patient's life. (2) Common reasons for neuropathic pain include spinal cord injury, stroke, diabetes, acquired immune deficiency syndrome and cancer. Neuropathic pain is estimated to affect between 1 and 8% of the population (7), with more estimates relying on prevalence of the underlying cause than actual neuropathic pain. Results from a survey performed in the UK indicated that patients with chronic nerve pain were more likely to be older, female, , unemployed (unable to work), smokers and with lower education than respondents without chronic pain. (3)

Epilepsy
Epilepsy is a common disorder of the brain that affects people of all ages. The proportion of the population with active epilepsy is estimated to be between 4 and 10 per 1000 people. In developed countries, between 40 and 70 new cases per 100 000 people are identified in the general population every year. Almost 80% of epilepsy cases are found in developing regions. The risk of premature death in patients with epilepsy is higher than it is for the unaffected population. (4)

Generalised Anxiety Disorder (GAD)
The symptoms of GAD are prolonged excessive and difficult to control anxiety and worry, which can cause restlessness, fatigue, concentration difficulties or memory impairment, irritability, muscle tension or sleep disorders. (2) GAD develops in about 1 in 50 people at some stage in their life, andtTwice as many women as men are affected. GAD usually develops in a person's 20s, but is frequently recognised in elderly (5).

VI.2.2 Summary of treatment benefits

<Product name> belongs to a group of medicines used to treat epilepsy, neuropathic pain and Generalised Anxiety Disorder (GAD) in adults.

Peripheral and central neuropathic pain: <Product name> is used to treat long lasting pain caused by damage to the nerves. A variety of diseases can cause peripheral neuropathic pain, such as diabetes or shingles. Pain sensations may be described as hot, burning, throbbing, shooting, stabbing, sharp, cramping, aching, tingling, numbness, pins and needles. Peripheral and central neuropathic pain may also be associated with mood changes, sleep disturbance, fatigue (tiredness), and can have an impact on physical and social functioning and overall quality of life.

Epilepsy: <Product name> is used to treat a certain form of epilepsy (partial seizures with or without secondary generalisation) in adults. Your doctor will prescribe <Product name> for you to help treat your epilepsy when your current treatment is not controlling your condition. You should take <Product name> in addition to your current treatment. <Product name> is not intended to be used alone, but should always be used in combination with other anti-epileptic treatment.

Generalised Anxiety Disorder: <Product name> is used to treat Generalised Anxiety Disorder (GAD). The symptoms of GAD are prolonged excessive anxiety and worry that are difficult to control. GAD can also cause restlessness or feeling keyed up or on edge, being easily fatigued (tired), having difficulty concentrating or mind going blank, feeling irritable, having muscle tension or sleep disturbance. This is different to the stresses and strains of everyday life.

VI.2.3 Unknowns relating to treatment benefits

Based on the currently available data, an important gap in knowledge was identified concerning pregabalin efficacy in the paediatric population (children and adolescents below 18 years).

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Increased body weight (Weight gain)	Some patients gain weight while treated with pregabalin.	Some patients with diabetes who gain weight while taking pregabalin may need an alteration in their diabetic medicines.
Swelling of the body, including extremities (Peripheral oedema and oedema-related events)	Some patients develop swelling of the body including extremities.	Patients should inform their doctor if they develop swelling of their body including extremities.
Dizziness, sleepiness, loss of consciousness, fainting and potential for accidental injury (Dizziness, somnolence, loss of consciousness, syncope and potential for accidental injury)	Pregabalin treatment has been associated with dizziness and sleepiness, which could increase the occurrence of accidental injury (fall) in the elderly population. There have also been reports of loss of consciousness, confusion and mental impairment.	Patients should be advised to exercise caution until they are familiar with the potential effects of the medicinal product. Patients should not drive, operate complex machinery or engage in other potentially hazardous activities until knowing whether this medicine affects the ability to perform these activities.
Events after pregabalin discontinuation (Discontinuation events)	After stopping long- and short- term pregabalin treatment, patients may experience certain side	Patients should not stop taking pregabalin unless their doctor tells them to do. If treatment is stopped it

	effects. These include trouble sleeping, headache, nausea, feeling anxious, diarrhoea, flulike symptoms, convulsions, nervousness, depression, pain, sweating and dizziness. It is not clear at this time whether these symptoms occur more commonly or severely if patients have been taking pregabalin for a longer period of time.	should be done gradually over a minimum of 1 week.
Interactions with other medications (Drug interactions (lorazepam, ethanol and CNS depressants))	Pregabalin and certain other medicines may influence each other. Pregabalin may potentiate the side effects seen with 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 (pain-killer), lorazepam (anti-anxiety) or alcohol.	Patients should tell their doctor or pharmacist if they are taking, have recently taken or might take any other medicines.
Euphoria	Some patients treated with pregabalin have experienced elevated mood.	Before taking pregabalin, patients should tell their doctor if they have a history of alcoholism or drug dependence. Patients should let their doctor know if they think they need more medicine than prescribed.
Hypersensitivity and allergic reactions	Patients may suffer from adverse reactions including skin redness, vesicles (blisters), swelling, itching skin (hives), eruption (rash), difficulty breathing (dyspnea) and whistling sound when breathing (wheezing) shortly after initiation of treatment with pregabalin.	Patients experiencing any of these reactions should contact their doctor immediately.
Heart failure (Congestive heart failure)	There have been reports of heart failure in some patients, mostly elderly with cardiovascular conditions, when taking pregabalin.	Before taking this medicine, patients should tell their doctor if they have a history of heart disease.

Vision-related events	Pregabalin may cause blurring, loss of vision or other changes in eyesight, many of which are temporary.	Patients should immediately tell their doctor if they experience any changes in vision.
Abuse, misuse and drug dependence	Cases of excessive or incorrect use, as well as drug dependence, have been reported.	Caution should be exercised in patients with a history of substance abuse. The patients should be monitored for tolerance, inappropriate dose escalation and drug-seeking behaviour.

Important potential risks

Risk	**What is known (Including reason why it is considered a potential risk)**
Suicidality	A small number of people being treated with antiepileptic drugs, including pregabalin, have had thoughts of harming or killing themselves. The mechanism is unknown, but a causal association with pregabalin has been suggested. If any time patients have these thoughts, they should immediately contact their doctor.
Haemangiosarcoma	Cancer of the blood vessels has been observed in mice. This has not been observed in rats, monkeys or humans. This might be specific to mice and there is no evidence of an associated risk to humans.
Off-label use in paediatric patients	Pregabalin is not approved in patients less than 18 years of age as data about the efficacy and safety in this subgroup of patients are lacking

Missing information

Risk	**What is known**
Pregnancy and lactation	No adequate information on the use of pregabalin in pregnant or lactating women is available. Pregabalin should not be taken during pregnancy, unless are told otherwise by their doctor. Pregabalin is not recommended while breastfeeding as it is not known if may be found in breast milk. Patients should ask their doctor or pharmacist for advice before taking any medicine while breast-feeding

VI.2.5 Summary of risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PL). The measures in these documents are known as routine risk minimisation measures.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

No post-authorisation studies have been imposed or are planned.

VI.2.7 Summary of changes to the Risk Management Plan over time