
VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Epilepsy

Epilepsy is the commonest neurological condition affecting people of all ages, race and social class. Approximately 50 million people currently live with epilepsy worldwide. The estimated proportion of the general population with active epilepsy (i.e. continuing seizures or with the need for treatment) at a given time is between 4 and 10 per 1000 people. However, some studies in low- and middle-income countries suggest that the proportion is much higher, between 7 and 14 per 1000 people.

Globally, an estimated 2.4 million people are diagnosed with epilepsy each year. In high-income countries, annual new cases are between 30 and 50 per 100 000 people in the general population. In low- and middle-income countries, this figure can be up to two times higher.

Neuropathic pain

General population studies have found that 7–8% of adults currently have chronic pain with neuropathic characteristics. A study in Germany revealed 37% of people attending primary care clinics with chronic low back pain had predominantly neuropathic pain.

In the United Kingdom, 26% of people with diabetes were found to have peripheral neuropathic pain. Worldwide, this figure translates to some 47 million individuals, which will increase as the prevalence of diabetes grows (from 2.8% in 2000 to an estimated 4.4% in 2030). Of the 33 million people infected with HIV across the world, around 35% have neuropathic pain, which does not respond well to standard treatments. A Norwegian study found that 40% of people have persistent pain after surgery, of which a quarter of cases have neuropathic characteristics. Neuropathic postsurgical pain is more likely to be severe and persistent than non- neuropathic postsurgical pain.

Approximately 20% of people with cancer have cancer-related neuropathic pain, as a result of either the disease or its treatment.

VI.2.2 Summary of treatment benefits

Epilepsy

Gabapentin is indicated as adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults and children aged 6 years and above.

Gabapentin is indicated as monotherapy in the treatment of partial seizures with and without secondary generalization in adults and adolescents aged 12 years and above.

Treatment of peripheral neuropathic pain

Gabapentin is indicated for the treatment of peripheral neuropathic pain such as painful diabetic neuropathy and post-herpetic neuralgia in adults.

VI.2.3 Unknowns relating to treatment benefits

No specific studies have been performed with Gabapentin 100, 300 and 400mg capsules on women of child bearing potential, pregnant and lactating females. There are no adequate data from the use of Gabapentin in elderly patients.

VI.2.4 Summary of safety concerns

Table 11: Important Identified Risk(s)

Risk(s)	What is known	Preventability
Intention to kill oneself and behavior for self-harm (Suicidal ideation and behavior)	It is known that patients being treated with antiepileptics such as Gabapentin have had thoughts of harming or killing themselves.	Patients (and caregivers of patients) should be advised to seek medical advice should signs of suicidal ideation or behaviour emerge.
Light headedness and sleepiness (Dizziness and somnolence)	Use of this medication may produce dizziness, drowsiness and tiredness.	Patients should not drive, operate complex machinery or take part in other potentially hazardous activities.
Serious or life-threatening skin reaction affecting blood cells (Drug rash with eosinophilia and systemic symptoms (DRESS))	Use of this medication may result in severe skin reactions that require immediate attention, swelling of the lips and face, skin rash and redness, and/or hair loss (these may be symptoms of a serious allergic reaction).	If such signs or symptoms are present, the patient should be evaluated immediately. Gabapentin should be discontinued if an alternative etiology for the signs or symptoms cannot be established.
Loss of effectiveness when given along with other medicinal products (Interaction with other medicinal products and other forms of interaction)	It is known that combination of Gabapentin with opioids may cause symptoms like sleepiness and/or decrease in breathing. If taken together with antacids containing aluminium and magnesium are taken at the same time, absorption of Gabapentin from the stomach may be reduced.	It is recommended that Gabapentin is taken at the earliest two hours after taking an antacid or opioid medicinal product.
Allergic reactions (Hypersensitivity)	Severe, life-threatening, hypersensitivity reactions have been reported in patients taking antiepileptic drugs including gabapentin.	It is important to note that early manifestations of hypersensitivity, such as fever or lymphadenopathy, may be present even though rash is not evident. Gabapentin should be discontinued if an alternative etiology for the signs or symptoms cannot be established.
Decreased ability of the body to digest lactose, a type of sugar (Lactose Intolerance)	Symptoms of lactose indigestion such as abdominal pain, bloating, diarrhea, gas, nausea may occur in patients with lactose intolerance, such as those with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption	Patients with a known intolerance to some sugars should contact their doctor before taking gabapentin. Gabapentin should be discontinued should symptoms of lactose intolerance appear and an alternative etiology cannot be established.

Table 12: Important Potential Risk(s)

Risk(s)	What is known
Swollen pancreas (Acute pancreatitis)	There is a possibility of inflammation in the pancreas during the use of this medicinal product. Discontinuation of gabapentin should be considered in this case.
Uncontrolled jerking movement resulting in fits (Seizure)	As with other antiepileptic medicinal products, some patients may experience an increase in seizure frequency or the onset of new types of seizures with Gabapentin.
Repeated excessive use of drug that can cause self-harm and adaptation of body to this repeated use (Abuse and dependence)	Drug-seeking behavior and intolerance has been reported in some patients using Gabapentin.

Table 13: Missing Information

Risk(s)	What is known
Use during pregnancy and breast-feeding (Use during pregnancy and lactation)	Data are not available for use of Gabapentin during pregnancy and its effect on unborn child.
Use in patients older than 65 years of age (Use in Elderly > 65)	No clinical studies in patients 65 years or older have been conducted with Gabapentin.

VI.2.5 Summary of risk minimisation measures by safety concern

All medicines have an SmPC which provides physicians, pharmacists and other HCPs 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. 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 study is planned for this product.

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

This section is not applicable as this is version 1.0 of RMP.