
PUBLIC SUMMARY OF RISK MANAGEMENT PLAN

GABAPENTIN ORION 600 MG AND 800 MG, FILM-COATED TABLETS

ORION CORPORATION

DATE: 22-03-2017, VERSION 1.2

VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Epilepsy

Epilepsy is a chronic disorder of the brain that affects people in every country of the world. Epilepsy is said to occur when an individual has two or more unprovoked seizures. Seizures are brief episodes of involuntary shaking which may involve a part of the body (partial) or the entire body (generalized) and sometimes accompanied by loss of consciousness and control of bowel or bladder function. The episodes are a result of excessive electrical discharges in a group of brain cells. Different parts of the brain can be the site of such discharges. Seizures can vary from the briefest lapses of attention or muscle jerks, to severe and prolonged convulsions. Seizures can also vary in frequency, from less than one per year to several per day. Epilepsy appears sometime during life in 1% of the general population.

Peripheral neuropathic pain

Peripheral neuropathy, a result of nerve damage, often causes weakness, numbness and pain, usually in hands and feet, but it may also occur in other areas of the body. People generally describe the pain of peripheral neuropathy as tingling or burning, while they may compare the loss of sensation to the feeling of wearing a thin stocking or glove. Peripheral neuropathy can result from problems such as traumatic injuries, infections, metabolic problems and exposure to toxins. One of the most common causes is diabetes.

VI.2.2 Summary of treatment benefits

Epilepsy

Gabapentin is used in epilepsy as adjunctive therapy for partial seizures with or without secondary generalisation in patients refractory to standard antiepileptics. In clinical studies in such patients seizure frequency was reduced when gabapentin was added to the treatment. Long-term efficacy of gabapentin has been encouraging and its lack of potential for interactions with other antiepileptics is considered to make it particularly suitable for adjunctive treatment.

Peripheral neuropathic pain

Among patients with neuropathic pain caused by traumatic or postsurgical peripheral nerve injury, the overall patient status, pain relief, and sleep interference due to pain were significantly improved during gabapentin treatment in a clinical study. Pain associated with multiple neuropathic syndromes including trigeminal neuralgia, and direct nerve injury has also been relieved. Gabapentin has also been effective in case reports of neuropathic cancer pain.

VI.2.3 Unknowns relating to treatment benefits

There is little data available on the use of gabapentin in pregnant or lactating women and the effects of gabapentin on foetal development or breast-fed infants are unknown. Likewise little information is available on the long term effects on learning, in growth, endocrine function, puberty and childbearing potential in children.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Abuse and dependence	Cases of abuse and dependence have been reported for gabapentin from the post-marketing experience.	If a patient has a history of abuse or dependence, his/her physician should be informed.
Concomitant use with opioids	Opioids may increase the effect of gabapentin. In addition, combination of gabapentin with opioids may cause symptoms like sleepiness and/or decrease in breathing.	If a patient is taking any medicines containing opioids (such as morphine), his/her physician should be informed.
Drug Rash with Eosinophilia and Systemic Symptoms (DRESS)	Gabapentin may cause a serious or life-threatening hypersensitivity reaction called Drug Rash with Eosinophilia and Systemic Symptoms (DRESS) that may affect skin or other parts of body such as liver or blood cells.	<p>A physician should be contacted right away if patient has any of the following symptoms:</p> <ul style="list-style-type: none"> - skin rash - hives - fever - swollen glands that do not go away - swelling of lip and tongue - yellowing of skin or of the whites of the eyes - unusual bruising or bleeding - severe fatigue or weakness - unexpected muscle pain - frequent infections <p>These symptoms may be the first signs of a serious reaction. A physician should examine patient to decide if he/she should continue taking gabapentin.</p>

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Suicidality	A small number of people treated with anti-epileptics, including gabapentin, have had thoughts of harming or killing themselves. If a patient at any time has these thoughts, physician should be immediately contacted.
Inflammation of pancreas (Pancreatitis)	Under treatment with gabapentin cases of acute pancreatitis have been reported. A physician should be contacted right away if patient has persistent stomach pain, feeling sick and being sick as these may be symptoms of acute pancreatitis (an inflamed pancreas).

Missing information

Risk	What is known
Long term effects on learning, in growth, endocrine function, puberty and childbearing potential in children	Long term effects on learning, in growth, endocrine function, puberty and childbearing potential in children have not been adequately studied. The benefits of prolonged therapy must therefore be weighed against the potential risks of such therapy.
Use during pregnancy and lactation	<p>Gabapentin should not be taken during pregnancy, unless told otherwise by treating physician. Women of childbearing potential must use effective contraception. There have been no studies specifically looking at the use of gabapentin in pregnant women, but an increased risk of harm to the foetus has been reported particularly when the mother has used more than one seizure medication at the same time. Therefore, only one seizure medication during pregnancy should be taken, unless otherwise decided by the treating physician.</p> <p>If a patient is pregnant or breast-feeding, thinks that she might be pregnant or is planning to have a baby, she should ask her physician or pharmacist for advice before taking this medicine. She should not suddenly discontinue taking gabapentin as this may lead to breakthrough seizures, which could have serious consequences for her and the baby.</p>

VI.2.5 Summary of risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SmPC) 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. The Summary of Product Characteristics and the Package leaflet for Gabapentin Orion can be found in the national authority's web page.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan (if applicable)

Not applicable.

VI.2.7 Summary of changes to the risk management plan over time

Not applicable.