
PUBLIC SUMMARY OF RISK MANAGEMENT PLAN

BUPROPION ORION 150 MG MODIFIED-RELEASE TABLETS BUPROPION ORION 300 MG MODIFIED-RELEASE TABLETS

ORION CORPORATION

DATE: 23-3-2015, VERSION 1.2

VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Depression

Depression is medical illness that is caused by a disorder of the brain. There are a variety of causes, including genetic, environmental, psychological, and biochemical factors. Depression causes a persistent feeling of sadness and loss of interest and can cause physical symptoms, too. It can lead to a variety of emotional and physical problems and affect normal day-to-day activities. Depression is chronic illness that usually requires long-term treatment. Most people feel better with medication, psychological counseling or other treatment.

VI.2.2 Summary of treatment benefits

Bupropion is one of a group of medicines called antidepressants. It's thought to interact with chemicals in the brain called noradrenaline and dopamine. Disturbances in the noradrenalin-dopamine-serotonin-system are considered an important factor in the development of depression. It's thought that bupropion eases depression by affecting chemical messengers (neurotransmitters) used to communicate between brain cells. Most antidepressants work by changing the levels of one or more of these naturally occurring brain chemicals. Changing the balance of these brain chemicals seems to help brain cells send and receive chemical messages, which in turn boosts mood. The safety and efficacy of bupropion for the treatment of major depressive episodes has been established in various studies.

VI.2.3 Unknowns relating to treatment benefits

Bupropion Orion is not indicated for use in children or adolescents aged less than 18 years since the safety and efficacy of Bupropion Orion in patients under 18 years of age have not been established.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Fits (seizures)	Bupropion has been shown to cause fits (seizures) in about 1 in a 1000 people. The chance of this happening is higher if you take too much of bupropion, if you take certain medicines concomitantly, or if you are at higher than usual risk of fits.	Your doctor needs to know before you take bupropion: <ul style="list-style-type: none">• if you have a condition that causes fits (seizures), such as epilepsy, or if you have a history of fits• if you regularly drink a lot of alcohol• if you have diabetes for

Risk	What is known	Preventability
		<p>which you use insulin or tablets</p> <ul style="list-style-type: none"> • if you have had a serious head injury or a history of head trauma • if you are taking, have recently taken or might take any other medicines, herbs or vitamins, including products you bought yourself.

Risk	What is known	Preventability
Allergic reactions	Some people may get allergic reactions (also severe) to bupropion.	Do not take Bupropion Orion if you are allergic to bupropion or any of the other ingredients of this medicine. If you have any signs of an allergic reaction contact a doctor at once. Don't take any more tablets.

Risk	What is known	Preventability
High blood pressure	Some people taking bupropion have developed high blood pressure which needs treatment. If you already have high blood pressure, it can become worse. This is more likely if you are also using nicotine patches to help you stop smoking.	You will have your blood pressure checked before you take Bupropion Orion and while you are taking it, especially if you already have high blood pressure. If you are also using nicotine patches, your blood pressure needs to be checked every week. If your blood pressure increases, you may need to stop taking Bupropion Orion.

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Interactions	Some medicines don't mix with bupropion. Some of them may increase the chance of fits or seizures. Other medicines may increase the risk of other side effects. Therefore it is important to tell your doctor if you are taking, have recently taken or might take any other medicines, herbs or vitamins, including products you bought yourself.
Thoughts of suicide and worsening of depression	If you are depressed you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer. If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.
Heart rhythm and electrical conduction disorder	Some people may experience increased heart rate and palpitations while using bupropion. Tell your doctor before taking Bupropion Orion if you have a heart disease.

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 Bupropion 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.
