

VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Buprenorphine is used to relieve moderate, long-lasting pain that requires the use of a strong painkiller.

Chronic pain is defined as disabling condition that has lasted longer than three to six months. Common chronic pain complaints include arthritis pain, and neurogenic pain (pain resulting from damage to the peripheral nerves or to the central nervous system itself). Chronic pain conditions affect older adults and are more common in women. A recent market research report indicates that more than 1.5 billion people worldwide suffer from chronic pain and that approximately 3- 4.5% of the global population suffers from neuropathic pain, with incidence rate increasing in complementary to age.

VI.2.2 Summary of treatment benefits

Based on the available data from clinical studies and clinical experience of several years, buprenorphine represents an effective drug in management of moderate, long-lasting, which can only be adequately managed with opioid analgesics.

If administered as indicated in the Summary of Product Characteristics and taking into account the contra-indications, the warnings and precautions, buprenorphine can be considered effective in the approved indications.

VI.2.3 Unknowns relating to treatment benefits

Not applicable.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Respiratory depression (Severely depressed breathing)	People who have taken buprenorphine overdose may feel very sleepy and sick. They may also have breathing difficulties or lose consciousness and may need emergency treatment in hospital. Serious side effects that may be associated with buprenorphine are similar to those seen with other strong painkillers and include difficulty in breathing.	Don't use buprenorphine if you have breathing problems. Buprenorphine must be used with caution if you are also taking benzodiazepines (medicines used to treat anxiety or to help you sleep). This combination may cause serious breathing problems which could be fatal in case of overdose. Tell your doctor if you are taking this combination. Remove the patch and tell your doctor immediately if you get any difficulties in breathing.
Drug dependence and withdrawal	There is a risk that you may become addicted or reliant on buprenorphine patch. Some people may have side effects when they have used strong painkillers for a long time and stop using them. The risk of having effects after stopping buprenorphine patch is very low.	Don't use buprenorphine patch if you are addicted to drugs. Talk to your doctor before using buprenorphine patch if you have ever been addicted to drugs. Tell your doctor if you feel agitated, anxious, nervous or shaky, if you are overactive, have difficulty sleeping or digestive problems.
Abuse, misuse and diversion	As soon as you discover that you have used more patches than you should, remove all patches and call your doctor or hospital straight away. People who have taken an overdose may feel very sleepy and sick. They may also have breathing difficulties or lose consciousness and may need emergency treatment in hospital.	Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. You should not apply more than two patches at the same time, regardless of the patch strength. If you feel that the effect of the buprenorphine patch is too weak or too strong, talk to your doctor or pharmacist.
Accidental exposure	There is a risk of serious side effects from accidental exposure to buprenorphine patch.	Keep this medicine out of the sight and reach of children. One transdermal patch is sealed in one child-resistant sachet. Patient should be advised to make notes of the date they have applied the patch.

Risk	What is known	Preventability
		Additional patches should not be applied to make up for the forgotten application.

Missing information

Risk	What is known
Pregnancy and lactation	Buprenorphine should not be used if you are pregnant, if you could become pregnant during treatment or if you are breastfeeding.
Use in paediatric patients < 18 years	Buprenorphine patch should not be given to children and adolescents below 18 years.

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.

No additional risk minimisation measures are proposed.

VI.2.6 Planned post authorisation development plan

Not applicable.

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

Not applicable.