Buprenorphine STADA 5 micrograms/h transdermal patch
Buprenorphine STADA 10 micrograms/h transdermal patch
Buprenorphine STADA 15 micrograms/h transdermal patch

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PUBLIC SUMMARY OF THE RISK MANAGEMENT PLAN

VI.2 Elements for a Public Summary

Buprenorphine STADA 5 micrograms/h transdermal patch

Buprenorphine STADA 10 micrograms/h transdermal patch

Buprenorphine STADA 20 micrograms/h transdermal patch

VI.2.1 Overview of disease epidemiology

Chronic pain which is not due to a tumour, such as low back pain or pain associated with osteoarthritis (OA) is a major health problem that is often inadequately treated. A large survey conducted in 15 European countries and Israel, involving 46,394 adults, found that 19% of adults are suffering from chronic pain of moderate or severe intensity.[1] The physical causes of pain are often categorised in two types, nociceptive (e.g. musculoskeletal pain) and neuropathic pain (felt as numbness and tingling in the feet or hands). Both components may be involved in chronic pain which is not due to a tumour. Treatment of chronic pain may include various painkillers (e.g. ibuprofen) or even an antidepressant (e.g. amitriptyline) if neuropathic pain is involved.

VI.2.2 Summary of treatment benefits

Buprenorphine STADA contain the active ingredient buprenorphine which belongs to a group of medicines called strong analgesics or 'painkillers'. They have been prescribed for you by your doctor to relieve moderate, long-lasting pain that requires the use of a strong painkiller.

Buprenorphine STADA should not be used to relieve acute pain.

Buprenorphine STADA act through the skin. After application, buprenorphine passes through the skin into the blood. Each patch lasts for seven days.

VI.2.3 Unknowns relating to treatment benefits

None.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability

[1] Breivik H, Collett B, Ventafridda V, et al. Survey of chronic pain in Europe: prevalence, impact on daily life, and treatment. Eur J Pain 2006;10:287-333

Breathing difficulties (Respiratory depression)	Buprenorphine may make some people breathe slowly or weakly. This side effect may be intensified if other medicines that may produce the same effects are taken at the same time.	Patients suffering from a disease that causes breathing difficulties must not use buprenorphine.
Drug dependence and withdrawal (Drug dependence and withdrawal)	Buprenorphine has a lower dependence liability than some other strong pain relievers, but after a long-term use, withdrawal symptoms (e.g. agitation, anxiousness, nervousness, sleeping disturbance, hyperkinesia, shiver, digestive system disorders) may occur	Short-term use can decrease the risk of dependence.
Abuse, misuse and inappropriate use (Abuse, misuse, and diversion)	Buprenorphine may cause addiction to drugs. Patients should tell the doctor if they feel that they need to increase the dose.	Patients who have been addicted to drugs should not use opioid patches.
Accidental exposure (Accidental exposure)	Sometimes patients forget when they have applied the patch and may apply several patches.	Patient should be advised to make notes of the date they have applied the patch.

Important potential risks

Risk	**What is known (Including reason why it is considered a potential risk)**
None	NA

Missing information

Risk	**What is known**
Use during pregnancy and lactation	There are no adequate data from the use of buprenorphine in pregnant women. Studies in animals have shown reproductive toxicity. The potential risk for humans is unknown. Towards the end of pregnancy high doses of buprenorphine may induce respiratory depression in the new-born infant even after a short period of administration. Chronic administration of buprenorphine during the last three months of pregnancy may cause a withdrawal syndrome in

	the new-born infant. Therefore administration of buprenorphine is contraindicated during pregnancy. Buprenorphine is excreted in human milk. Studies in rats have shown that buprenorphine can inhibit lactation. Buprenorphine should not be used during breast-feeding.
Use in paediatric patients < 18 years	There is no information on safety and efficacy of buprenorphine in children. Therefore, buprenorphine should not be used in children.

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

Not applicable