2. Elements for a public summary

[<invented name>] 35 micrograms/h transdermal patch
[<invented name>] 52.5 micrograms/h transdermal patch
[<invented name>] 70 micrograms/h transdermal patch

2.1 Overview of disease epidemiology

Chronic non-malignant pain, 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 found that 19% of adults are suffering from chronic pain of moderate or severe intensity. The physical causes of pain are often categorised in two types, nociceptive (e.g. musculoskeletal, visceral, visceral, somatic pain) and neuropathic pain (e.g. neuropathic pain). Both components may be involved in chronic non-malignant pain.[3]

2.2 Summary of treatment benefits

Current (gold) standards of treatment of chronic pain are NSAIDs, COX-2 inhibitors as starting drugs for mild pain and opioid analgesic drugs for moderate or severe pain.[4;5]
As an opioid, buprenorphine is a first-line analgesic for moderate or severe pain. Buprenorphine transdermal patch provides continuous delivery of the drug, thereby reducing fluctuations of plasma concentrations and potentially reducing the incidence of adverse events.[2:5]

2.3 Unknowns relating to treatment benefits

NA

2.4 Summary of Safety Concerns

Important identified risks

Risk	**What is known**	**Preventability**
Patients who have difficulty in breathing	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.
Patients who are at risk of becoming dependent	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 false use	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 use	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**
NA	NA

NA

Missing information

Risk	**What is known**
Pregnant and breast-feeding women	There are no adequate data from the use of burpenorphine 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 infantneonate even after a short period of administration. Chronic long-term administration of buprenorphine during the last three months of pregnancy may cause a withdrawal syndrome in the new-born infantneonate. Therefore, buprenorphine should not be used during pregnancy. Buprenorphine is excreted in human milk. Studies in rats have shown that buprenorphine can to inhibit milk production. Therefore, 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.

2.5 Summary of additional 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.

2.6 Planned post-authorisation development plan

NA

2.7 Summary of changes to the risk management plan over time

NA