

VI.2 Elements for a Public Summary

Fentanyl CF 0,05 mg/ml, oplossing voor injectie

VI.2.1 Overview of disease epidemiology

Chronic pain is pain that is ongoing and recurring for lengthy periods of time. Globally, 1 out of 10 adults are diagnosed with chronic pain each year. The estimated prevalence of chronic pain in Europe ranges from 19% to 31% and in the US it is 33% to 64%. Chronic pain generally increases with age and has been diagnosed more commonly in women than in men. The negative impact of chronic pain includes depression, inability to work, disrupted social relationships, and suicidal thoughts. Five common conditions underlying chronic pain are cancer pain, neuropathic pain, osteoarthritis pain, rheumatoid arthritis pain, and chronic low back pain. Medical conditions associated with chronic pain include depression, anxiety, and sleep disturbance.

VI.2.2 Summary of treatment benefits

Fentanyl is a substance that reduces pain. Fentanyl is one of the strong, narcotic analgesics, also known as opioid analgesics. This drug provides pain relieve during surgery.

VI.2.3 Unknowns relating to treatment benefits

Not enough information is available on the use of fentanyl in children less than 2 years old.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Slow, weak breathing (Respiratory depression)	Slow, weak breathing is well-known for fentanyl; the risk increases with higher doses. Opioids, such as fentanyl, produce shallow or decreased breathing by direct action on the respiratory centres in the brain and reduce their responsiveness to increased carbon dioxide (normally the major trigger of breathing activity) as well as electrical stimulation.	Fentanyl is not indicated for patients suffering from severe breathing problems or severe lung conditions. Patients who breathe more slowly or weakly while using fentanyl should discontinue treatment.
Decrease in heart function (Cardiovascular depression)	Slow heart rate or complete loss of heart function may occur if too low dose of an anticholinergic medicine (e.g. atropine) was administered together with fentanyl.	Care should be taken to administer a sufficient dose of an anticholinergic medicine with fentanyl. Slow heart rate can be treated with atropine.
Abuse, misuse and dependence	Just as other opioids, fentanyl has the potential to cause dependence. Abuse or	Fentanyl is a prescription only medication and should only administered under the

	misuse of fentanyl may result in overdose and/or death.	supervision of a physician. Besides, patients who have ever abused or been dependent or shown withdrawal on alcohol, prescription medicines, or illegal drugs should be monitored for signs of misuse, abuse, or addiction.
Serotonin syndrome induced by interaction between fentanyl and serotonergic drugs	Serotonin syndrome can result from use of fentanyl with drugs that affect the nervous system. These medicines, e.g. those used to treat depression, may cause mental disorders like mental-status changes (e.g., agitation, hallucinations, coma), autonomic instability (e.g., tachycardia, labile blood pressure, hyperthermia), neuromuscular abnormalities (e.g., hyperreflexia, incoordination, rigidity), and/or gastrointestinal symptoms (e.g., nausea, vomiting, diarrhoea).	Patients taking fentanyl together with other serotonergic drugs (e.g. sertraline) should be closely monitored. If serotonin syndrome is suspected, rapid discontinuation of fentanyl should be considered.

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 in children under 2 years of age	Not enough information is available on the use of fentanyl in children less than 2 years old. Fentanyl should not be used in children less than 2 years old.
Use in patients with kidney or liver dysfunction	Not enough information is available. These organs have an effect on the way in which the system breaks down the medicine. Due to an impaired liver and/or kidney function the excretion of fentanyl may be delayed. Therefore, the risk of side effects is higher and your doctor may need to prescribe a lower dose of fentanyl.
Use in pregnant or	Not enough information is available on the use of fentanyl

breastfeeding woman	<p>during pregnancy and breastfeeding. The safety of fentanyl in pregnancy has not been established. Fentanyl studies in animals have shown reproductive harm. However, the potential risk for humans is unknown. Fentanyl should not be used during labor and delivery since fentanyl crosses the placenta and may cause respiratory depression in the foetus or in the infant.</p> <p>Fentanyl should not be used by breastfeeding women. Fentanyl is excreted into breast milk and may cause sedation and respiratory depression in the breast-fed infant.</p>
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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, as this is the initial Risk Management Plan for Fentanyl CF 0,05 mg/ml, oplossing voor injectie.