Fencino® transdermal patches (fentanyl) - abbreviated prescribing information

Refer to the Summary of Product Characteristics for full product information.

Presentation: Transdermal patches releasing 12.5/25/50/75/100 micrograms of fentanyl per hour.

Indication:
Adults: Chronic pain which can only be treated adequately and effectively with opioid-analgesics.
Children: Long term management of severe chronic pain in children receiving opioid therapy from 2 years of age.

Dosage and Administration: Refer to SmPC for details and recommendations.
Adults: For patients who have not received strongly active opioids so far, therapy should commence with the lowest concentration of the active substance. For patients previously treated with other intensively active opioids, the appropriate dose of fentanyl treatment is based upon analgesic requirement and the dose of analgesic which has been administered so far. Dose adjustments may be necessary with long-term therapy in line with analgesic requirement of the patient.
Children: Children aged 16 and above will follow the adult dosage. Children aged 2 to 16 years who are already opioid-tolerant and receiving at least 30 mg oral morphine equivalents per day should be prescribed Fencino® 12 micrograms/hour. Fentanyl 25 µg/h should not be used for treatment of children under 12 years of age unless the doctor has explicitly prescribed the transdermal patch. The fentanyl 50, 75 and 100 µg/h transdermal patches provide too high a dose for children, and thus should not be prescribed for children under the age of 12.
Administration: The patch should be applied to a hairless part of the skin of the upper body and changed after 72 hours. The new patch should be applied to a new area of skin. For young children, the upper back is the preferred location to apply the patch to minimise the potential of the child removing the patch.

Contra-indications: Hypersensitivity to fentanyl, peanut, soya or to any of the excipients of the transdermal patch, acute or post-operative pain, severe impairment of the central nervous system, severe respiratory depression.

Precautions and Warnings: Patients who have experienced serious adverse events should be monitored for at least 24 hours after removal of the patch.

Use with caution in patients with existing respiratory depression, chronic pulmonary disease, bradyarrhythmias, myasthenia gravis, impaired liver or kidney function, chronic constipation, in patients who are particularly susceptible to CO_2-retention, elderly patients and patients suffering from drug or alcohol dependence. Fencino® should not be administered to opioid-naïve paediatric patients. Fencino® should not be used during pregnancy unless clearly necessary or during breast-feeding. Tolerance, physical dependence and psychological dependence can develop on repeated use of Fencino®.

The application site should not be exposed to sources of heat.

Accidental exposure: Inadvertent transfer of a fentanyl-containing patch to the skin of another person (especially a child) may induce opioid overdose. Patients should be advised that inadvertently transferred patches must be removed from the non-patch wearer immediately. To prevent accidental ingestion by children, the application site for Fencino® must be chosen carefully and patch adhesion monitored closely.

Driving: Fencino® may impair the ability to drive or use machines at the onset of treatment, upon increase of dose or when used in combination with other medicinal products. This class of medicines (opioid) is in the list of drugs included in the UK regulations under 5a of the Road Traffic Act 1988. Patients should be told the drug-driving legislation information before using fentanyl patches.

Withdrawal: Symptoms such as nausea, vomiting, diarrhoea, panic attacks or shivering may be experienced when therapy is changed from another strongly active opioid to fentanyl, following abrupt termination of therapy or sudden reduction in dose. If the treatment is terminated, the dose must be reduced gradually to prevent withdrawal symptoms.

Interactions: Central depressant medicines (e.g. opioids, sedatives, hypnotics, general anaesthetics, muscle relaxants, phenothiazines, tranquilizers, sedating antihistamines or alcohol) may enhance the sedating effects of fentanyl when simultaneously administered, in this case the dose of one or both should be reduced.

Cytochrome P450 3A4 (CYP3A4) inhibitors (e.g. ritonavir, ketoconazole, itraconazole, fluconazole, voriconazole, troleandomycin, clarithromycin, nelfinavir, nefazodone, verapamil, diltiazem and amiodarone) may enhance the therapeutic and undesirable effects of fentanyl. Similar interactions with fentanyl can be anticipated with co-administration of monoamine oxidase inhibitors (MAOIs).

CYP3A4 inducers (e.g. rifampicin, carbamazepine, phenobarbital, phenytoin) may reduce the therapeutic effects of fentanyl and dose adjustment of fentanyl may be required.

The concomitant use of fentanyl with other serotonergic drugs, such as a Selective Serotonin Re-uptake Inhibitor (SSRI), or a Serotonin Norepinephrine Re-uptake Inhibitor (SNRI) or a MAOI may increase the risk of serotonin syndrome.

Buprenorphine, nalbuphine and pentazocine may trigger withdrawal symptoms when co-administered in opioid dependent patients.

Side effects: Refer to SmPC for full list. The most serious undesirable effect of fentanyl is respiratory depression. Very commonly reported side effects are: somnolence, dizziness, headache, nausea, vomiting and constipation.

Less commonly reported are: hypersensitivity, anorexia, insomnia, depression, anxiety, confusional state, hallucination, disorientation, tremor, paraesthesia, convulsions, amnesia, speech disorder, depressed level of consciousness, loss of consciousness, conjunctivitis, blurred vision, vertigo, palpitations, tachycardia, bradycardia, hypertension, hypotension, dyspnoea, respiratory depression, diarrhoea, dry mouth, abdominal pain, dyspepsia, ileus, hyperhidrosis, pruritus, rash, erythema, eczema, dermatitis, muscle spasms, urinary retention, erectile dysfunction, fatigue, peripheral oedema, asthenia, malaise, feeling cold, application site reaction, withdrawal syndrome.

Rarely reported: myosis, arrhythmia, vasodilation, apnoea, hypoventilation, subileus. Also reported: painful flatulence, oliguria cystalgia, anaphylactic shock, anaphylactic reaction, bradypnoea.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard
Adverse events should also be reported to Medical Services Information - enquiries@medinformation.co.uk

Price: 12mcg - £8.46, 25mcg - £12.10, 50mcg - £22,62, 75mcg - £31.54, 100mcg - £38.88

Legal category: POM. Controlled Drug.

Further Information: For full prescribing information see Summary of Product Characteristics.

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