Matrifen (fentanyl) Prescribing Information

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 Takeda UK Ltd. Tel 01628 537900.

Matrifen (fentanyl) PRESCRIBING INFORMATION Refer to Summary of Product Characteristics (SmPC) before prescribing. Presentation: Fentanyl: available as 12, 25, 50, 75, 100 mcg/hr transdermal patches. **Indication:** *Adults (aged ≥16 years):* severe chronic pain adequately managed only with opioid analgesics. *Children (aged 2-16 years):* long term management of severe chronic pain in children receiving opioid therapy from 2 years of age. **Dosage and administration:** Should be applied to non-irritated and non-irradiated skin on a flat surface of the torso or upper arm that is preferably hairless. Hair at the application site should be clipped (not shaved) prior to application. Water should be used to cleanse the skin prior to application (i.e. not soaps, oils, lotions, alcohol). Skin should be completely dry before application of patch. A short shower can be taken with patch in-situ. Once a patch has been removed, avoid using the same application site for at least 7 days. *Adults (aged ≥16yrs):* initial dose should not exceed 25mcg/hr when the opioid response pattern for the pain condition is not fully known. See SmPC for guidance on: dosage level; titration steps; changing from another opioid (withdrawal symptoms when switching from long-term morphine can occur despite adequate analgesic effect with matrifen). *Dose titration and maintenance:* maximum analgesic effect to be evaluated after 24hrs; replace patch every 72 hrs, or between 48-72hrs if necessary; titrate dose individually until analgesic efficacy is attained; additional or alternative methods of analgesia or alternative administration of opioids should be considered when the Matrifen dose exceeds 300 mcg/hr. Additional short-acting analgesia may be required for breakthrough pain. Discontinuation should be gradual in order to prevent withdrawal symptoms. *Special populations:* elderly, cachectic, or febrile patients and patients with renal or hepatic impairment: observe carefully and reduce dose if necessary. *Children (aged 2-16 yrs):* Application is recommended to the upper back, i.e. out of the reach of the child. Matrifen should be administered only to opioid-tolerant children who are already receiving ≥30 mg oral morphine equivalent per day. See SmPC for recommendations on: initial doses; conversion schedule; switching to Matrifen; titration steps. *Children (aged <2yrs):* Not to be administered. **Contraindications:** known hypersensitivity to fentanyl or excipients of the patch; acute or postoperative pain; severe respiratory depression; severe CNS impairment. **Warnings & Precautions:** keep out of the reach of children before and after use; high quantities of fentanyl remain in the patch after use. Do not cut the patches or use damaged patches. Do not expose the application site to direct sources of external heat. Monitor patients for further 24hrs if they experience serious adverse events. Observe patients for signs of respiratory depression, especially with concomitant CNS depressants. Caution in patients with: existing respiratory depression, chronic pulmonary disease; increased intracranial pressure, impaired consciousness, coma, brain tumours, hypotonia, myasthenia gravis, bradyarrhythmias, hypovolaemia. Drug dependence may occur. Dose reduction might be needed in the elderly, patients with fever, hepatic and/or renal impairment: observe for toxicity. May impair the ability to drive and use machines. Do not use in opioid-naive children. **Overdose:** most serious manifestation: respiratory depression. Recommended management: establish and maintain patent airway; administer oxygen; ventilator support may be required; remove patch; physically/ verbally stimulate patient; administer e.g. naloxone – repeat doses or continuous infusion might be needed; maintain body temperature and fluid intake; parenteral fluids should be considered if persistent hypotension occurs. **Interactions:** Concomitant use of MAO inhibitors, buprenorphine, nalbuphine, and pentazocine not recommended. Increased plasma Matrifen concentration may be seen with concomitant use of CYP3A4 inhibitors e.g. ritonavir, ketoconazole, itraconazole, troleandomycin, clarithromycin, nelfinavir, nefazodone, verapamil, diltiazem, and amiodarone – not recommended unless closely monitored, dose adjustments of Matrifen may be needed. Concomitant use with CNS depressants, including opioids, sedatives, hypnotics, general anaesthetics, phenothiazines, tranquilizers, skeletal muscle relaxants, sedating antihistamines and alcohol may produce additive depressant effects – special care and observation required. **Fertility, Pregnancy & Lactation:** Not to be used in pregnancy unless clearly necessary. Not recommended during childbirth. Discontinue use at least 72 hours before breast-feeding. **Undesirable Effects: Refer to the SmPC for details on full side effect profile and interactions**. *Very common (≥1/10):* somnolence, dizziness, headache, nausea, vomiting, and constipation. *Common (≥1/100 to <1/10):* hypersensitivity, anorexia, insomnia, confusional state, depression, anxiety, hallucination, dyspepsia, tremor, paraesthesia, vertigo, palpitations, tachycardia, hypertension, dyspnoea, diarrhoea, dry mouth, abdominal pain, upper abdominal pain; *Other Serious Undesirable Effects: uncommon (≥1/1,000 to <1/100):* convulsion, amnesia, bradycardia, cyanosis, hypotension, respiratory depression, respiratory distress, ileus; *rare (≥1/10,000 to <1/1,000):* apnoea, hypoventilation; *not known*, anaphylactic shock, anaphylactic reaction, anaphylactoid reaction, bradypnoea. *Children:* similar side effect profile to adults; very common adverse events – fever, vomiting, nausea. **Basic NHS price:** 5 patches available in 5 strengths - 12 mcg/hr: £7.52, 25 mcg/hr: £10.76, 50 mcg/hr: £20.12, 75 mcg/hr: £28.06, 100 mcg/hr: £34.59 **Legal Classification:** POM. **Marketing Authorisation:** 16189/0014- 18. Further information is available from Takeda UK Ltd, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, HP10 0HH United Kingdom. Tel +44 1628 537900. Fax +44 1628 526617. **PI Approval Code:** UK/MAT/1402/0001. **Date of revision:** March 2014