

## Controlled Drugs Update

### Transdermal Fentanyl Patches for Non-Cancer Pain: Do Not Use in Opioid-Naive Patients

MHRA [drug safety update](#) 23 September 2020

Following a review of the risks associated with use of opioid medicines for non-cancer pain, the Commission on Human Medicines (CHM) has recommended that fentanyl transdermal patches are **contraindicated in opioid-naïve patients** in the UK.

Fentanyl is a potent opioid.

As an indication of potency, 72-hour Fentanyl patches are approximately equivalent to the following 24-hour doses of oral morphine [BNF](#) in relation to palliative care:

Other sources quote differing equivalence. Figures should be used as a guide only and never for direct clinical care – comprehensive data are lacking and there is significant inter-individual variation.

Fentanyl Patch	Morphine oral 24 hour dose
12 microgram/hr	30mg
25 microgram/hr	60mg
50 microgram/hr	120mg
75 microgram/hr	180mg
100 microgram/hr	240mg

Cambridgeshire and Peterborough CCG has a long standing [restricted place in therapy for transdermal opioids which is detailed on netFormulary](#). **Non-opioids and oral opioids should always be used before transdermal opioids.**

Patients **must** be counselled on the correct use of fentanyl patches:

- [Fentanyl skin patches: How to use and dispose of them safely](#) (MHRA PIL: October 2018).
- make patients and caregivers aware of the **signs and symptoms of fentanyl overdose** and advise them to seek medical attention immediately (by dialling 999 and requesting an ambulance) if overdose is suspected.
- beware of **fever** causing overdose (SARS-CoV-2)
- remind patients that **long-term use of opioids** in non-cancer pain (longer than 3 months) carries an **increased risk of dependence and addiction**, even at therapeutic doses.
- before starting treatment with opioids, agree with the patient a **treatment strategy** and **plan for end of treatment**.

### Stock Shortage: Pethidine 50mg Tablets

Due to a problem at the active pharmaceutical ingredient manufacturing site, [pethidine tablets are out of stock with no resupply date](#).

The Faculty of Pain Medicine of the Royal college of Anaesthetists note:

*Pethidine is particularly unsuitable for patients with persistent pain. Its high lipid solubility and rapid onset/offset may predispose patients to problem drug use. Its active metabolite norpethidine can lead to serious central nervous system side effects. It does not produce less smooth muscle spasm than equivalent doses of other opioids and so has no advantage for patients with visceral colic or pain.*

#### ACTION:

- Do not initiate pethidine prescriptions for new patients.
- Existing patients should be **reviewed for ongoing need with advice sought where necessary from pain clinics or CGL services**.
- Specials are not routinely recommended and should only be considered a last resort due to stability of the market, ease of supply and variable costs to the NHS.

### Report to the Yellow Card Scheme

Please report medication errors resulting in harm, including overdose and accidental exposure to a medicine, or any other suspected side effects on a [Yellow Card](#).

If a patient **experiences any side effect related to dependence or is recognised by the prescriber to be dependent**, report this to the MHRA through the [Yellow Card scheme](#) with the term 'dependence'. Use of this specific term will assist the MHRA to monitor further the rates reported in the UK and therefore to further protect public health.

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## Opioids: Risk of Dependence and Addiction

MHRA [Drug Safety Update](#) 23 September 2020

Following a review of the risks of dependence and addiction associated with prolonged use of opioids for non-cancer pain the Commission on Human Medicines (CHM) has recommended **before prescribing opioids**, discuss with the patient the risks and features of **tolerance, dependence, and addiction**, and agree together a **treatment strategy** and **plan for end of treatment**.

- Opioids provide relief from serious short-term pain; however long-term use in non-cancer pain (longer than 3 months) carries an increased risk of **dependence** and **addiction** even at therapeutic doses.
- Doses above **120mg oral morphine equivalent** are not recommended for chronic pain, prescribe lowest dose for the shortest time.
- Provide patient leaflet [OPIOID MEDICINES AND THE RISK OF ADDICTION](#).

The CHM also recommended packaging be to labelled with **can cause addiction** and **contains opioid** and patient information be updated with information about tolerance, dependence and addiction.

When prescribing consider and **discuss with the patient**:

- agree a treatment **strategy** and **plan for end** of treatment **before** starting treatment. What does treatment success look like? Patients should not expect complete pain relief.
- explain the risks of **tolerance** and **potentially fatal unintentional overdose**, and counsel patients and caregivers on **signs and symptoms** of opioid overdose to be aware of.
- provide regular **monitoring** and **support** especially to individuals at increased risk, such as those with current or past history of substance use disorder (including alcohol misuse) or mental health disorder.
- **taper dosage slowly** to reduce the risk of withdrawal effects associated with sudden cessation of opioids; tapering from a high dose may take weeks or months.
- consider **hyperalgesia** if a patient on long-term opioid therapy presents with increased sensitivity to pain.
- check latest advice for opioids during pregnancy and breastfeeding.

NICE expect to publish [Chronic pain: assessment and management](#) in January 2021. The draft included recommendation **do not offer** [as treatment] **opioids**.

Further information can be found at [Opioids Aware - Faculty of Pain Medicine at the Royal College of Anaesthetists](#) including [patient information](#) and a [checklist for prescribers](#).

**Note: not all opioids are scheduled under Misuse Drugs Regulations.**

## Serotonin Syndrome and Opioid Analgesics

Concomitant administration of **opioids with other serotonergic agents**, such as **MAO inhibitors, SSRIs, SNRIs or tricyclic antidepressants** may result in serotonin syndrome, a potentially life-threatening condition.

Many patients with chronic pain and polypharmacy are prescribed opioids and antidepressants:

- Please **identify and review** patients prescribed opioids with serotonergic products.

**Fentanyl** and **buprenorphine** (all formulations) summary of product characteristics ([SPC](#)) have been updated with information about serotonin syndrome and serotonergic agents.

Tramadol (classified locally hospital only) was [scheduled](#) in part due to overdose causing serotonin syndrome.

Tapentadol (classified locally as grey) was subject to [MHRA drug safety update January 2019](#) relating to serotonin syndrome.

Information about serotonin syndrome for patients is available via [www.nhs.uk](http://www.nhs.uk)

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## HMP Peterborough

Please be advised that the healthcare team at HMP Peterborough have started providing residents released on medication, with FP10s/FP10MDAs as part of their release planning. Within Sodexo HMP and YOI sites, FP10/FP10MDA prescription forms can be used to access urgent medicines that cannot be supplied via the usual dispensing pharmacy or they can be issued to patients who are released **unplanned** from the prison so they can get their medicines dispensed by a community pharmacy.

## Coroner Letters

Courts and Tribunals Judiciary publish [Prevention of Future Deaths](#) letters according to [The Coroners \(Investigations\) Regulations 2013](#) Regulation 28.

### Tramadol Overdose (published July 2020)

A patient died as a result of tramadol toxicity.

The Coroner raised the following matters of concern to Sir Simon Stevens:

- That repeat medication is not being adequately monitored, leading to many patients building-up dangerous quantities of prescribed medication.
- That the inadequate supervision of prescribed (repeat) medication is so widespread that the consequent waste of resources has an adverse impact on the overall provision of healthcare.

### Morphine (published February 2020)

A member of care home staff died from morphine toxicity. The Coroner raised the following matters of concern to CQC:

- Controlled drug check processes had been such that it was not easily identified that drugs were not accounted for.
- No clear process for handling/recording the use of controlled drugs.

### ACTION POINTS:

- Review repeat prescribing procedure for controlled drugs. If CDs are issued as repeats, how many issues are authorised before patient has a medication review (in person or by telephone/video call)?
- Review tramadol prescribing. Tramadol is not recommended for prescribing in Primary Care in Cambridgeshire and Peterborough due to safety concerns.
- Review monitoring processes for CDs kept on the premises. [See NICE NG46](#).

## Risk of 10 Time Overdose with Alfentanil Preparations

Alfentanil is an injectable opioid analgesic used in patients with poor renal function, or when a patient is unable to tolerate first or second line analgesia. **It should only be used under specialist advice or in a hospital setting.**

Alfentanil has a rapid onset, and a short duration of action so is less useful for breakthrough pain. Often other opioids are used as required for breakthrough.

The NHSE and NHSI CD Accountable Officers (CDAOs) have advised of two recent administration errors where a 10 times overdose of alfentanil was administered to patients. These resulted in severe harm and/or death reported as the outcomes. On further review there were 38 patient related errors reported to the CDAOs between June 2018 and June 2020 involving alfentanil. Advice was [first published by CQC in 2017](#).

Alfentanil is roughly **15 times** as potent as subcutaneous (s/c) morphine, so 1mg s/c alfentanil is equivalent to 15mg s/c morphine. A typical starting dose if patients are opioid naive is 0.5mg in 24 hours. Dose conversion should be used as a guide only and never for direct clinical care. **Dosing advice should be obtained from Specialist Services.**

Please be aware, alfentanil is available in three different sized ampoules, so it is important to check carefully which one you are prescribing, dispensing, and also upon administration:

- 500microgram/ml -2ml ampoule (1mg/2ml)
- 500microgram/ml -10ml amp (5mg/10ml)
- **5mg/ml -1ml ampoule (high strength)**

A message has been added to OptimiseRx to request a double check of prescribed formulation when the high strength product is selected.

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