# Good Practice Guidelines: Use of fentanyl transdermal patches

## Safe use of fentanyl patches

Transdermal fentanyl patches are safe and effective for relieving pain when used according to the instructions. **However, the patches may cause serious harm to patients and others if the instructions are not followed carefully.** Medication errors have been recorded due to old patches not being removed at the time of application of a new patch or due to cutting or taping of patches in an attempt to reduce the dose. Accidental exposure to transdermal fentanyl can occur if a patch is swallowed or transferred to another individual. Despite advice being issued by the Medicines and Healthcare Products Regulatory Agency (MHRA) in 2014[1], the MHRA continue to receive reports of preventable, accidental transfer of fentanyl patches leading to accidental exposure, overdose and product adhesion issues resulting in harm to individuals including fatalities. Further advice was issued by the MHRA about how to use and dispose of fentanyl patches safely in October 2018[2] including a patient/care giver information leaflet[3]. In summary:

### Don't

- exceed the prescribed dose / number of patches
- cut the patches for any reason or use the patch if the seal is broken, altered, cut or damaged.
- take the fentanyl patch out of its wrapper until you are ready to apply to the skin site
- apply a fentanyl patch straight after a hot bath or shower while the skin temperature is still raised as heat can cause a dangerous amount of fentanyl to be released from the patch.
- expose skin site to external heat sources eg heat pads, electric blanket or hot baths/showers.
- use soap, oils, lotions, alcohol or other agents which might irritate the skin site

### Do

- monitor patient for signs of toxicity eg respiratory depression (difficulty in breathing or shallow breathing), tiredness, excessive drowsiness, confusion and small "pin-prick" pupils. Monitoring should continue even after the fentanyl patch is discontinued.
- remove patch immediately if patient experiences serious adverse events and monitor for 24 hours seek medical advice immediately if toxicity is suspected.
- seek urgent medical attention for anyone accidentally exposed to a fentanyl patch.
- remove the old patch first, before applying a new one and avoid touching the adhesive side.
- ensure the patch is stuck on securely, especially around the edges by pressing for 30 seconds
- always wash hands after handling fentanyl patches.
- dispose of the old patch by folding in half as soon as it is removed so that the sticky side sticks firmly to itself and put back in the original sachet
- store patches safely, securely and out of the sight and reach of children and vulnerable adults
- report any cases of accidental exposure where harm has occurred via the Yellow Card Scheme[4]

## Aim

These Good Practice Guidelines aim to support safer use of transdermal fentanyl patches and are intended for use by healthcare professionals and carers involved in the care of patients in nursing and residential homes and those patients receiving domiciliary care within their own homes.

## Indications

Fentanyl is a strong pain killer which is often used in the management of severe pain. It is one of a group of drugs called opioids and is similar to morphine. Fentanyl is available as a self-adhesive patch that is changed every 72 hours (3 days). The patch allows a continuous delivery of fentanyl through the skin and ultimately into the patient's bloodstream over the 72 hour period. Fentanyl patches may be suitable in people who have:

- intolerable side effects with oral morphine e.g. vomiting, hallucinations
- difficulty in swallowing oral medication
- poor compliance with oral medication
- breakthrough pain which is not responding to Oramorph or increased doses of twice daily morphine or other strong opioid
- renal (kidney) impairment.

Fentanyl patches are **not** suitable for patients who have acute pain or where a rapid titration of opioid medication is needed. There is a delay after a patch is applied before pain relief is achieved and similarly there is a delay after removal before the pain killing effect stops working. They are also not usually suitable for patients who are not already prescribed strong opioids eg morphine ie opioid naïve patients (see "initiating therapy" section)

## Side effects

The side effects of fentanyl are similar to other strong opioids, although fentanyl is less constipating and causes less nausea and vomiting than morphine. Side effects of fentanyl include nausea, vomiting, dizziness, drowsiness (including day time drowsiness) confusion and hallucinations, constipation and sweating. Patients should be monitored for side-effects particularly during the first 72 hours after initiating treatment or after an increase in dose. Side-effects experienced when opioids are commenced or increased often reduce over the subsequent 48 - 72 hours. About 10% patients experience opioid withdrawal when changing from morphine to fentanyl. Symptoms are "flu-like" and may last for a few days Toxicity is more likely to occur in the elderly and those with liver / kidney disease. Signs of toxicity include:

- respiratory depression
- excessive drowsiness/reduced level of consciousness / confusion
- twitching
- small "pin-prick" pupils

**Medical advice should be sought immediately if any of these symptoms are experienced.**

## Formulation

There are two different patch formulations currently available although the release of fentanyl from these two types of patches is similar, it is recommended the patient remains on the same type of patch.

- **Matrix patch** - the fentanyl is distributed evenly throughout a matrix which controls the release of fentanyl e.g. Fencino®, Durogesic D Trans®
- **Reservoir patch** - the fentanyl is contained within a reservoir and the release of fentanyl is controlled by a rate-limiting membrane e.g.Fentalis®.

## Application

- Ensure all old patches are removed prior to application of a new patch. Ensure the package is retained for use when disposing of the used patch.
- Fentanyl patches should be applied to clean, dry, non-inflamed, non-irradiated, hairless skin on the upper arm or trunk. If needed, the skin site can be washed with water only prior to application (soap products may alter absorption). Ensure that the skin is dried thoroughly. Body hair may be clipped but do not shave.
- The patch should be pressed in place firmly with the palm of the hand for 30 seconds. Some patients may need a semipermeable dressing to ensure adherence.
- Patch sites should be rotated. Ideally the underlying skin should be allowed to rest for 3-6 days before applying another patch to the same area.
- A new patch should not be applied immediately after a bath or a shower or immediately after using creams, talc or soap on the skin.
- Heat increases the rate of transdermal drug absorption and can cause toxicity. Residents can bathe or shower (with care) whilst wearing a patch but the water should not be too hot. Avoid soaking in hot baths, saunas and sunbathing.
- Heat e.g. electric blankets, hot water bottles should NEVER be applied over the top of the patch as it may enhance the absorption of fentanyl.
- If the patient has a persistent temperature of 39°c - 40°c the patch dose may need reviewing by the prescriber. Concentrations of fentanyl in the blood may increase if the skin temperature increases to 40°c. The patient should be monitored for signs of toxicity and advice from the patient's GP should be sought.
- Site irritation, usually from the adhesive, may necessitate a change of brand and so should be discussed with the patient's GP.

## Initiating therapy

- There are five strengths of patches available which deliver 12, 25, 50, 75 and 100micrograms fentanyl per hour. Patches should NOT be cut to achieve a different dose than the ones available.
- Patients should already be taking strong opioid analgesics (eg morphine or oxycodone) prior to conversion to fentanyl patches.
- When converting a patient to fentanyl patches, the conversion should always be clearly documented in their care plan and on the MAR chart. This is to ensure both preparations are not continued as often two products will be required for a very short period of time whilst the fentanyl patch becomes effective. The modified release (M/R) version of opioid must stop before the patch starts however any 'when required' (prn) doses of immediate release opioid are still safe and need to continue. Further information and advice on the above should always be sought from the patient's GP or pharmacist.
- If prior treatment with oral opioids is not considered possible and fentanyl patches are considered to be the only appropriate treatment option for "opioid-naïve patients", only the lowest starting dose (i.e. 12 mcg/h) should be considered. In such circumstances, the patient must be closely monitored. The potential for serious or life-threatening respiratory depression exists even if the lowest dose of fentanyl is used in initiating therapy in opioid-naïve patients
- Some analgesic effect will be achieved within 12-24 hours after the first patch is applied although maximum effect will not be reached until the 2nd patch is applied. Previous analgesic therapy should be phased out gradually from the time of the first patch application until effective pain control is obtained. Ask the resident's GP for specific instructions regarding this.
- The initial dose of fentanyl prescribed should be based on the resident's previous 24 hour opioid analgesic requirement. For example, 90mg of oral morphine taken over 24 hours is approximately equivalent to one fentanyl 25 micrograms/ hour patch.
- Residents must have "when required" (PRN) normal release strong analgesia available for breakthrough pain once a fentanyl patch is prescribed (normally one sixth of the equivalent 24 - hour total oral morphine dose) Normal release morphine (tablets or liquid) is commonly used. When to use PRN normal release strong analgesia available for breakthrough pain should be clearly documented in the resident's care plan and dosages, when given, clearly documented on the resident's MAR chart.

## Maintenance therapy

- The patches are worn continuously and changed every 72 hours.
- More than one patch can be used at a time for doses greater than 100micrograms per hour but the patches should be changed at the same time to avoid confusion. The resident's GP will advise if this is required and it should be clearly documented in the resident's care plan

## Dosage adjustments

- Dosage adjustments should only be undertaken in line with the resident's prescription and clearly documented in the resident's care plan.
- If necessary, dose adjustment of fentanyl patches, should be made in steps of 12-25 micrograms/ hour. After an increase in dose, it may take up to 6 days for the patient to reach equilibrium on the new dose level. Therefore after a dose increase, patients should usually wear the higher dose patch through two 72-hour applications before any further increase in dose
- Particular caution is needed with the elderly and residents with renal (kidney) failure.
- If after 48-72 hours, two or more rescue doses per day of morphine have been required (e.g. Oramorph) then the resident's GP may increase the patch strength.
- If hallucinations or confusion occurs then the dose may need reducing.
- If the pain is not controlled then alternative analgesia may need to be considered. In either of the above circumstances this should be discussed with the resident's GP.

## Discontinuation

A reservoir of fentanyl accumulates in the body and significant levels persist for at least 24 hours after removal of a fentanyl patch. Therefore on discontinuation of fentanyl patches the resident should still be carefully monitored for toxicity. When discontinuing fentanyl patches and converting to another strong opioid the conversion should always be clearly documented in the resident's care plan and on the MAR chart to ensure both products are not continued.

## Disposal

(1) **Used patches** - still contain a small quantity of fentanyl. After removal, the patch should be folded with the adhesive sides inwards so that the adhesive side of the patch adheres to itself and placed back in the original sachet. They can then be disposed of in clinical or household waste ensuring that they are kept out of the reach of children or vulnerable adults. If there is cause for concern, used patches can be returned to the community pharmacy.

(2) **Unused patches** - disposal should be in-line with the care home's policy. Good practice would be:

- ***Care homes with nursing*** – the unwanted fentanyl patch should be denatured as with any other schedule 2, 3 and 4 (part 1) CD prior to disposal by a waste disposal company.
- ***Care homes without nursing*** – unwanted fentanyl patches should be stored in the CD cupboard (separated from CDs in current use) and returned promptly to the supplying community pharmacy for destruction.
- ***Patients with domiciliary care*** – unused patches should be stored safely away from children and vulnerable adults and returned to the community pharmacy as soon as possible.

**Ensure that hands are washed thoroughly after handling the patches**

## Storage

Fentanyl is a Schedule 2 controlled drug (CD) and so within care homes its use must be entered into a controlled drug (CD) register and any stock must be stored in an approved CD cabinet. Fentanyl patches, including ones which have already been used should always be kept away from children and vulnerable adults.

## Recording

It is good practice to:

- indicate on the patient's care plan the indication for treatment and intended outcomes
- if another analgesic is to be commenced it should be clearly documented as to whether the fentanyl patch should be continued or stopped.
- have a personalised patch application template (see appendix 1)
- record the patch location on the body map and the MAR sheet to avoid a new patch being placed in the same area.
- clearly annotate the MAR sheets to highlight when the next patch change is required and cross out the days when a patch change is not required.
- check and sign that the patch is in place each day clearly document both the care plan and the MAR sheet when a patch falls off.

## Report harm from accidental exposure to fentanyl to the Yellow card Scheme

Please report medication errors resulting in harm, including accidental exposure to a medicine, or suspected side effects on a Yellow Card[4].

### References


[1] https://www.gov.uk/drug-safety-update/transdermal-fentanyl-patches-reminder-of-potential-for-life-threatening-harm-from-accidental-exposure-particularly-in-children

[2] https://www.gov.uk/drug-safety-update/transdermal-fentanyl-patches-life-threatening-and-fatal-opioid-toxicity-from-accidental-exposure-particularly-in-children

[3] https://assets.publishing.service.gov.uk/media/5bbdfd58ed915d732b992548/Fent-patient-sheet-FINAL.pdf

[4] https://yellowcard.mhra.gov.uk/

**Appendix 1**

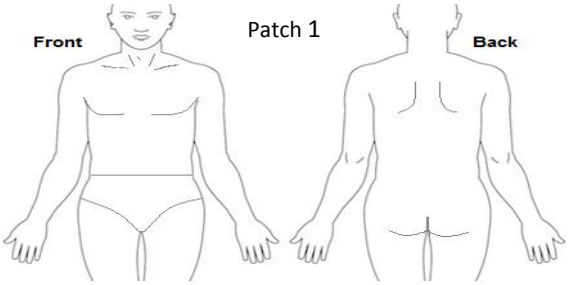
# Good Practice Guidance for Care Homes

## Transdermal Patch Application Record Chart

**When using this chart, write 'see Transdermal Patch Application Record Chart' on main MAR.**
**DO NOT DOUBLE RECORD**

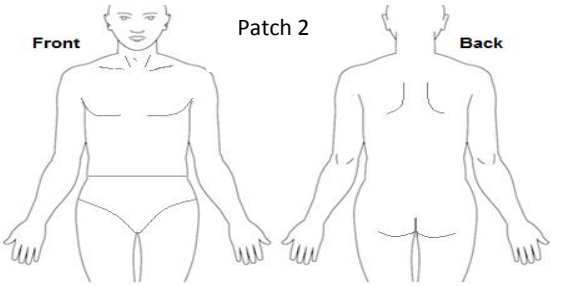
| | | | |
|---|---|---|---|
| **Patient Name:** | | **Date of Birth:** | |
| **Room No:** | | **Preparation:** | |
| **Indication:** | | **Frequency of application:** | |
| **Chart produced by/date:** | | **Chart checked by/date:** | |

**Special Instruction**: Record with a "X" where the patch is placed, It must be placed on to a cool, clean, dry non hairy area part of the body where a either a visiting child or in some cases the resident cannot reach.




**Always remove old patch before applying a new patch.**
**(Fold old patch in half (sticky sides together) and dispose of appropriately)**

| Patch: | Date: | Signed: | | Date: | Signed: |
|---|---|---|---|---|---|
| **Applied:** | | | **Daily check of patch in place on:** | | |
| **Daily check of patch in place on:** | | | | | |
| | | | | | |
| | | | **Removed:** | | |

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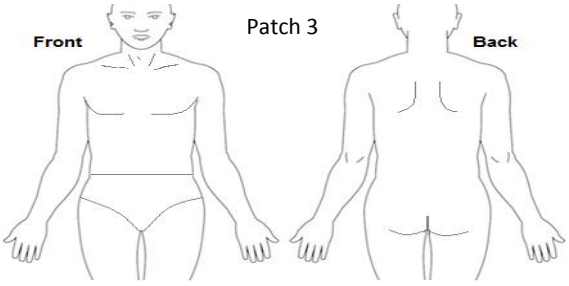
| Patch: | Date: | Signed: | | Date: | Signed: |
|---|---|---|---|---|---|
| **Applied:** | | | **Daily check of patch in place on:** | | |
| **Daily check of patch in place on:** | | | | | |
| | | | | | |
| | | | **Removed:** | | |

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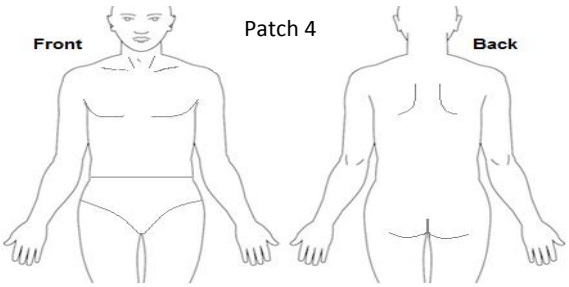
| Patch: | Date: | Signed: | | Date: | Signed: |
|---|---|---|---|---|---|
| **Applied:** | | | **Daily check of patch in place on:** | | |
| **Daily check of patch in place on:** | | | | | |
| | | | | | |
| | | | **Removed:** | | |

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| Patch: | Date: | Signed: | | Date: | Signed: |
|---|---|---|---|---|---|
| **Applied:** | | | **Daily check of patch in place on:** | | |
| **Daily check of patch in place on:** | | | | | |
| | | | | | |
| | | | **Removed:** | | |