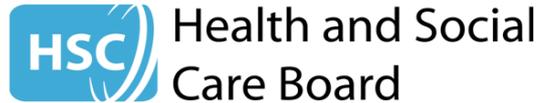


Medicines Safety Advice



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To:

Community Pharmacists
GP practices

6 February 2015

Dear Colleague

Re: TRANSDERMAL FENTANYL PATCHES*

Introduction

Fentanyl is a potent opioid analgesic and the patch formulation is licensed for the management of malignant and non-malignant pain.

A number of adverse incidents have been reported in Northern Ireland involving the use of transdermal fentanyl products (patches)¹ and these have had significant consequences for patients including death.

The incidents have had various contributory factors:

1. Accidental exposure
2. Inappropriate use and misuse
3. Incomplete cross tolerance
4. Exposure to heat sources

1. Accidental exposure

Accidental exposure to fentanyl patches, e.g. where a patch is inadvertently transferred or applied to another individual, can cause life threatening harm. Accidental exposure has occurred in a number of cases in children. On removal of an opioid patch, a reservoir of the drug remains under the skin with levels falling by 50% approximately every 18 to 24 hours. Therefore patient monitoring for a period of up to 24 hours after removal of a patch after accidental exposure is important.

To reduce the risk of accidental exposure it is important that patients and carers are given the following advice:

- Choose the patch application site carefully (see instructions in the patient information leaflet)
- Check the adhesion of the patch once applied, especially the edges

*Examples include Durogesic DTrans®, Mezolar®, Matrifen®, Fencino®, Fentalis®, Opiodur®, Osmanil®, Tilofyl®, Victanyl®

- Fold the used patch as soon as it is removed so that the adhesive side of the patch sticks firmly to itself and dispose of the folded patch safely
- If a patch is transferred to another person, remove it immediately and seek medical advice
- If a patch is swallowed or chewed, seek medical help immediately.

2. Inappropriate use and misuse

Fentanyl patches are designed to release the drug over 72 hours and patches should be replaced every 3 days. Abuse can occur in many ways including excessive transdermal application and inappropriate drug extraction, for example by chewing the patches. GPs and community pharmacists should have systems in place to identify and deal with potential compliance or abuse issues e.g. regular reviews of patients receiving the patches.

Key Prescribing Points:

The following information should be borne in mind when prescribing fentanyl:

- It is important that prescribers are aware of the potency of fentanyl:
25 microgram per hour fentanyl patch is equivalent to 60-89 milligrams of oral morphine over 24 hours²
- Fentanyl should only be used in patients who have previously tolerated other opioids, as there is a significant risk of respiratory depression in opioid naïve patients
- Fentanyl patches are NOT appropriate when rapid titration of opioids is required e.g. acute pain
- On first applying a patch or increasing the dose to be delivered via a patch, systemic therapeutic levels are not reached for at least 12 hours so additional analgesia may be required
- Patch strengths should not be increased more regularly than every 48 hours.

3. Incomplete Cross Tolerance

Adverse incidents have occurred when transferring from other strong opioids to a transdermal patch i.e. incomplete cross tolerance. Incomplete cross tolerance is where there is tolerance to a currently administered opioid that does not extend completely to other opioids, if the patient's medication is switched. It may mean that a lower dose of the new opioid is required.

It is recommended that a **25-50% reduction** of the calculated dose of the **new** opioid should occur to allow for this. The new drug dose should then be titrated according to patient response. For further information, refer to the Northern Ireland guidelines on converting doses of opioid analgesics for adult use, November 2014.

<http://www.medicinesgovernance.hscni.net/joint-publications/medicines-safety-documents/opioids/>

*Examples include Durogesic DTrans®, Mezolar®, Matrifen®, Fencino®, Fentalis®, Opiodur®, Osmanil®, Tilofyl®, Victanyl®

4. Exposure to heat sources

Fatal incidents have occurred where patients have died of fentanyl toxicity due to exposure to heat sources while wearing a fentanyl patch². Heat sources include hot water bottles, heat or tanning lamps, electric blankets, prolonged hot baths, heating pads and hot spa baths.

It is important that carers and patients are aware of the signs of fentanyl overdose which include troubled or shallow breathing; tiredness; extreme sleepiness or sedation; inability to think, walk or talk normally; and feeling faint, dizzy or confused. Patients or caregivers should be advised to seek medical attention immediately if overdose is suspected. Patches should be removed immediately and the patient monitored for up to 24 hours after the patch removal.

Conclusion

Advice to Patients for safe use

Healthcare professionals involved in the prescribing and dispensing of fentanyl patches must inform patients and carers about directions for safe use:

- Follow the instructions in the patient information leaflet for the correct administration of the patch, checking the adhesion once the patch has been applied
- Follow the prescribed dose and correct frequency of administration
- Ensure old patches are removed before applying a new one
- Do not cut patches
- Avoid touching the adhesive side and wash hands after application
- Follow instructions for safe storage and disposal
- Seek medical advice immediately if a patch is accidentally transferred to another person or if a patch is swallowed or chewed
- Be aware of the signs and symptoms of fentanyl overdose.

Steps should also be taken to ensure that there are systems in place to facilitate review of patients receiving fentanyl, particularly where there has been a change in dose or preparation.

Advice to Prescribers in respect of management chronic pain

HSCB has provided information in respect of the management of chronic pain which may be applicable:

- The patient should be made aware of what is a realistic expectation of pain relief that is achievable with medication i.e. only 1 in 6-8 patients achieve 30% reduction in pain.

*Examples include Durogesic DTrans®, Mezolar®, Matrifen®, Fencino®, Fentalis®, Opiodur®, Osmanil®, Tilofyl®, Victanyl®

- The patient should agree specific goals which will be considered as evidence of treatment effectiveness e.g. decreased sleep disturbance or increase in functionality. These targets should be met if treatment is to continue.
- If pain relief is not achieved or pre-agreed goals are not met, the dose should not be increased and the opioid stopped in an agreed stepwise reduction.
- The patient should be assessed for depression, addictive traits and alcohol abuse prior to treatment and specialist input sought where appropriate.

Further information on prescribing in chronic pain is available at http://primarycare.hscni.net/Pharmacy_and_Meds%20Management_Pain.htm

If you have any queries regarding this letter, please contact your local Medicines Governance Adviser or Medicines Management Adviser.

Yours sincerely



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References:

1. Drug Safety Update Volume 7, issue 12 , July 2014
<http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON432900>
2. Medicines Safety Matters Vol 2 Issue 1 March
<http://www.medicinesgovernance.hscni.net/primary-care/newsletters/medicines-safety-matters-prescribers-community-pharmacists/>