FENTANYL OROMUCOSAL FORMULATIONS FOR BREAKTHROUGH CANCER PAIN

HIGH RISK MEDICINES

NSW TAG NSW Therapeutic Advisory Group Inc.

This Advisory applies to ***rapid-acting buccal and sublingual formulations of fentanyl*** and is intended for use by health care professionals. (Intranasal fentanyl products are not discussed).

Deaths have occurred with the inappropriate dosing of these potent products in opioid-naïve patients

Appropriate selection of patient

USE **ONLY FOR BREAKTHROUGH CANCER PAIN (BTCP)** IN ADULTS WHO ARE:

- Opioid tolerant (i.e. **stabilised** for > 7 days on oral morphine daily doses ≥ 60 mg*); AND
- When other immediate release opioid formulations e.g. morphine and oxycodone are inadequate or unsuitable (e.g. dysphagia, intractable nausea/vomiting; poor absorption); AND
- Under the care of specialist palliative care clinician(s)

**Approximate daily dose equivalences:*

60 mg oral morphine = 30 mg oral oxycodone = 12 mg oral hydromorphone = 25 microgram/hour transdermal fentanyl

ALSO CONSIDER PATIENT-SPECIFIC RISK FACTORS: (for more details see full Product Information)

- Older age or frailty: greater susceptibility to adverse effects, especially in presence of co-morbidities/ polypharmacy or during acute illness e.g. infection or dehydration.
- Potential misuse, abuse, addiction and overdose: patient/family history or psychiatric history.
- Potential drug interactions: other sedative medicines, serotonergic medicines, CYP3A4 inhibitors and inducers.

Safe dosing & administration

- Document and communicate clearly the specific product and dosing information.
  - The various oromucosal fentanyl formulations are rapid-acting, however they **ARE NOT INTERCHANGEABLE. (Do NOT convert fentanyl products on a microgram: microgram basis,** including between oromucosal fentanyl products).
  - Numerous strengths of the various oromucosal fentanyl products are available.
  - Recommended maximum doses or frequencies should be stated and not exceeded.
  - Keep a record of supplied quantity and frequency of use.
- Frequently review adequacy of regular background opioid medication. If the dose of the regular opioid medication changes, re-titrate dose of oromucosal fentanyl product.
  - Dosing to treat and re-treat episodes of BTCP differ between the products.
- Tolerance to the analgesic effects but not adverse effects can develop quickly. Consider hyperalgesia, tolerance and progression of underlying disease if inadequate pain control.
- Monitor sedation and cardiorespiratory status of patient closely.

PATIENT/CARER COUNSELLING IS ESSENTIAL

- Discuss place in treatment plan, what to expect and specific instructions on use, possible side effects, what to do if side effects occur and provide a CMI and/or written information.

Appropriate storage, handling, recording & disposal

- Patients/carers should be educated about safe and appropriate storage and disposal.
- *KEEP OUT OF REACH OF CHILDREN* at all times as accidental exposure can be fatal.
- Never give a fentanyl product to another person for use.
- Record each formulation on its own separate page in the Schedule 8 register.
- In hospital, disposal in an appropriate, approved container and destruction of accountable medicines by healthcare workers requires witnessing, see NSW PD2017_026 and PD2013_043.

Key safety messages

- **Fentanyl must NOT be used in opioid-naïve patients: appropriate patient selection essential.**
- **Abstral®, Fentora® & Actiq® are NOT interchangeable.**
- **Provide explicit dosing instructions for management of breakthrough pain episodes and specify the maximum total dose in 24 hours.**
- **Always ask about breakthrough pain relief and confirm medicine, brand, strength, dosing instructions, circumstances and frequency of use.**
- **Ensure patients/carers are alert to signs of opioid overdose: sedation, respiratory depression, confusion.**
- **Extra precautions are required for safe use, storage and disposal of fentanyl products.**

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