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Safety Notice 016/18

Abnormalities with Suboxone 2/0.5 mg film

20 November 2018

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Directors of Alcohol and Drug Health Services
- Clinical Directors of Alcohol and Drug Services
- Director Regulation & Compliance Unit

Action required by:

- Chief Executives
- Directors of Clinical Governance
- Directors of Pharmacy
- Directors of Alcohol and Drug Health Services

We recommend you also inform:

- Directors of Nursing and Midwifery
- Opioid Treatment Program Nurse Unit Managers
- Patients receiving unsupervised dosing of Suboxone

Expert Reference Group

Content reviewed by:

- Office of the Chief Health Officer
- Alcohol and Other Drugs Branch
- Pharmaceutical Services
- Addiction Medicine Representative
- Director Patient Safety

Clinical Excellence Commission

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Review date

November 2019

Background

Suboxone® is the only registered combined buprenorphine/naloxone product available in Australia for the treatment of opioid dependence. The product is delivered as one film within a single sachet and is available in two doses (2 mg buprenorphine/ 0.5 mg naloxone and 8 mg buprenorphine/ 2 mg naloxone).

The Therapeutic Goods Administration (TGA) has received several reports in recent months [Product Defect Alert RC-2018-RN-01418-1] of product abnormalities. A range of defects have been identified including instances where there is more than one film within a single sachet of Suboxone® Film 2 mg buprenorphine. The film(s) present in the sachet may be undersized, full sized or oversized (see Figure 1 and 2 on next page). The film may also be folded over or layered on top of another film.

All batches supplied to the Australian market are potentially affected. To date, this issue has not been reported for the Suboxone® Film 8 mg buprenorphine, however as a precaution this should be considered a possibility. No adverse clinical events have been reported in relation to this issue. From the number of cases reported the incidence of this occurring is currently assessed as low.

Should a patient take an oversized or additional film, exposure to buprenorphine will be higher than the usual dose and euphoria or sedation may occur. Should a patient take an undersized film, exposure to buprenorphine will be lower than the usual dose and symptoms of withdrawal may occur. Those on a lower dose of buprenorphine and/or with lower levels of opioid tolerance are more likely to be adversely affected.

Actions

1. Inspect the sachet contents prior to administration in a directly supervised dose administration setting. As a precaution, inspection of the 8 mg film prior to administration is also recommended;
2. Once open, check that the film(s) dimensions are as expected (see page 2).
3. If the film is a different size or shape, if any excess film is detected in the sachet or if the film is abnormal, the entire sachet and contents should be quarantined in the ward/clinic safe and pharmacy should be notified. A new sachet should then be used;
4. Patients being dispensed 'take-away' doses should be advised of potential defects by staff prescribing or dispensing the medication and the need to inspect the contents of the sachet before taking;
5. If patients detect excess films or abnormalities in the film, patients should return the entire sachet to the dose administration point and seek an alternative sachet, if this is practical to their individual situation;
6. Any patients reporting increased levels of euphoria or sedation, symptoms of withdrawal or other related concerns should be immediately referred to their prescribing doctor for clinical review to discuss their treatment or be assessed by an appropriate health practitioner.

Suggested actions by Local Health Districts/Networks

1. Disseminate this Safety Notice to all staff involved in the care of patients prescribed Suboxone® Film.
2. Report any incidents of abnormal or excess films in the sachet in the Incident Information Management System (IIMS), and to the TGA (<https://www.tga.gov.au/medicine-or-vaccine-defect-report>).
3. Inform hospital pharmacy staff of any abnormalities in Suboxone films. Pharmacy to send images of defective stock to CEC-MedicationSafety@health.nsw.gov.au prior to destruction.
4. Instruct medical, nursing and pharmacy staff to advise patients receiving unsupervised Suboxone® Film administration ('take-away doses'), to inspect the contents of each sachet and notify their health care provider or pharmacist of any abnormalities or concerns.



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Figures 1 and 2 are examples of potential abnormalities.



Figure 1. Full sheet of Suboxone® Film 2/0.5 mg (left) with an additional abnormal film (right) within a single sachet



Figure 2. Two abnormal sheets of Suboxone® Film 2/0.5 mg within a single sachet

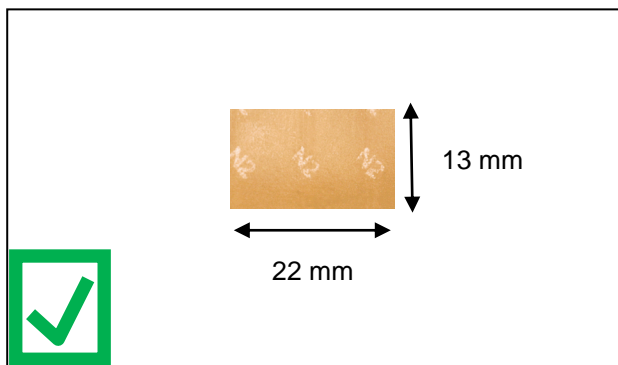


Figure 3. Expected presentation – single sheet of Suboxone® Film 2/0.5 mg and dimensions