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| Oxycodone tamper-resistant tablets |
| Information for prescribers |
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# Background

Pharmaceutical drug abuse has become a serious problem in Australia, with overdose deaths now exceeding the number of road deaths in Victoria.[[1]](#endnote-1)

Opioid analgesics are among the most commonly misused drugs and contribute to an increasing number of overdose deaths and other serious harm.[[2]](#endnote-2) Despite the limited evidence about the efficacy and safety of opioids for treating chronic non-malignant pain, the supply of opioid analgesics in Australia has increased, with new opioids, new formulations and increased prescribing. For instance, between 1997 and 2012, oxycodone and fentanyl supply increased 22-fold and 46-fold respectively.[[3]](#endnote-3)

People seeking opioids for non-medical use usually prefer high-dose formulations of modified-release opioids such as MS Contin, Kapanol and OxyContin. These drugs may be misused by mouth, injection or snorting after the tablets are crushed and dissolved.[[4]](#endnote-4)

There is an active street market for these opioid analgesics, with MS Contin 100mg and OxyContin 80mg being trafficked for $40–100 a tablet across Australia.[[5]](#endnote-5)

# Misuse of oral medications

One-third of people who inject drugs report obtaining them from illicit sources, including from patients to whom they had been prescribed.[[6]](#endnote-6) These type of misuse is often facilitated by crushing tablets in order to:

* override the modified-release properties designed to release the active drug over 12 hours;
* snort the powder or inject a solution; and
* enable rapid onset of the intoxicating effect sought by many drug misusers

Reformulated oxycodone modified-release tablets (OxyContin) are designed to deter tampering by resisting crushing and, when liquid is added to a crushed tablet, they form a thick gel that is difficult to inject or snort.[[7]](#endnote-7)

While a determined user seeking to inject or snort the oxycodone from this product may persist in tampering with reformulated OxyContin, it is still recommended over other oxycodone modified-release products (e.g. Oxycodone Sandoz) that are not tamper-resistant.

With mounting evidence of serious harm arising from diversion and misuse of opioid analgesics, and little evidence to support the safety and efficacy in the treatment of chronic non-malignant pain,[[8]](#endnote-8) prescribers should review the need for these drugs in every patient.

# What prescribers need to know

## Clarification of terminology

**Tamper-resistant does not mean abuse-resistant.** Some patients can abuse tamper-resistant tablets because they take them orally, or those previously injecting may transition to oral misuse.

* There is evidence that a high proportion of those misusing it simply swallow whole tablets,[[9]](#endnote-9) and many former users who injected simply transition to taking it by mouth.

**Tamper-resistant does not mean tamper-proof.** People determined to misuse oxycodone can overcome the tamper-resistant properties of this product by different means. Nevertheless it is a difficult process and may deter most people intent on misuse.

Avoiding brand substitution

Some bioequivalent oxycodone preparations are not presented in tamper-resistant formulations. These preparations may be more subject to misuse, abuse and trafficking because the tablets can be more readily crushed to facilitate injection or intranasal use.

Prescribers, who wish to ensure that an oxycodone prescription does not enable a patient to obtain a preparation that is not tamper-resistant, are advised to specify a tamper-resistant formulation (e.g. OxyContin®) and mark the ‘do not substitute’ box on the prescription to ensure the pharmacist cannot lawfully supply a different brand without the prescriber’s knowledge (e.g. Oxycodone Sandoz does not possess tamper-resistant properties).

## Changing to other opioids may increase the risk of overdose

**Requests to change to another opioid analgesic may be a red flag.** A request by a patient, who was managed on OxyContin® before the introduction of the tamper-resistant formulation, may indicate that the patient was tampering and misusing this product, or trafficking the medication.

**Transferring to another opioid may increase the risk of overdose.** There are particular risks associated with transferring patients to certain opioids – methadone, fentanyl patches and hydromorphone.

Certain opioids carry a substantially increased risk of overdose and should be avoided if transferring a patient suspected of misusing oxycodone to another opioid. Conversion rates between opioids should be interpreted conservatively.

Fentanyl patches can be misused by a number of different means. Further information is available in a document, *‘Fentanyl patch misuse: serious injury, overdose and death’*, which can be accessed via the following link: <https://www.health.vic.gov.au/publications/fentanyl-patch-misuse-serious-injury-overdose-and-death>

Methadone has a complex pharmacokinetic profile, with a long and variable half-life. In most cases methadone cannot be lawfully prescribed in Victoria unless the prescriber first obtains a permit; prescribing should usually be confined to prescribers experienced in its use, or after consultation with a pain specialist.

Hydromorphone is a highly potent opioid analgesic, and caution is required in converting to this opioid

## Careful patient selection

Evidence does not support the long-term efficacy and safety of opioid analgesics for chronic non-cancer pain.[[10]](#endnote-10) Prescribers should avoid sole reliance on opioids for chronic pain, assess risk of misuse, examine for evidence of self-injection, and use urine drug screening if appropriate.

## Universal precautions for all patients

It is difficult to identify all problematic opioid users, prescription drug seekers and prescription shoppers, so guidelines recommend universal precautionsfor **all** patients, regardless of whether they fit stereotypical perceptions of drug-seeking patients or not.

## Treatment of opioid dependence

If an individual is identified as an opioid misuser, they may be referred for treatment for opioid dependence to an addiction medicine physician or alcohol or drug clinic. Referral information is available from DirectLine, a 24-hour telephone counselling and referral service.

Alternatively, if a practitioner wishes to manage a patient’s treatment or offer medication-assisted treatment of opioid dependence, in Victoria, prescribers may treat up to ten patients with buprenorphine/naloxone (Suboxone®) film or long-acting injectable buprenorphine (Buvidal® and Sublocade®), without comprehensive training.

As is the case with prescribing a Schedule 8 drug to any drug-dependent person, a permit is required before prescribing Suboxone® Buvidal® and Sublocade® for each patient. More information is available on the MPR website (<http://www.health.vic.gov.au/dpcs>), in the section relating to ‘*Pharmacotherapy’*.

## Seek advice from a specialist service

The Drug and Alcohol Clinical Advisory Service provides clinical advice to health practitioners who have concerns about the clinical management of patients and clients with alcohol and other drug problems.

**Report adverse drug events (ADEs) involving reformulated oxycodone** **to the Therapeutic Goods Administration (TGA) to help identify opportunities to prevent further harm.** For more information visit: [www.tga.gov.au/hp/problem-medicine-reporting-reactions.htm](http://www.tga.gov.au/hp/problem-medicine-reporting-reactions.htm)

# Supporting evidence

A large proportion of Victorian oxycodone-related drug overdose deaths in 2012 involved injecting the drug prepared by crushing and dissolving OxyContin tablets.[[11]](#endnote-11) This was prior to OxyContin reformulation as a tamper-resistant product.

The following evidence also shows that high-dose modified-release oxycodone products without tamper-resistant qualities are subject to tampering and misuse:

* Australian sales of OxyContin 80 mg tablets (the highest strength and most commonly sought for diversion) decreased by 28 per cent in the five months following introduction of reformulated OxyContin on 1 April 2014.[[12]](#endnote-12)
* Similar reductions in prescriptions for OxyContin occurred in the United States when tamper-resistant OxyContin was introduced: OxyContin 80mg, 40–60mg and 10–39mg supply decreased by 31 per cent, 15 per cent and seven per cent respectively.[[13]](#endnote-13) This dose-related reduction in supply suggests misuse by tampering was prevalent because higher dose formulations are preferred by those seeking to misuse them by tampering. This data also suggests that a substantial proportion of total supply was diverted for tampering and misuse prior to reformulation.
* A study by the National Drug and Alcohol Research Centre (NDARC) recruited more than 600 people who reported tampering with OxyContin prior to the introduction of the tamper-resistant formulation.[[14]](#endnote-14) When asked about their methods of obtaining prescription opioids for misuse, 81 per cent reported obtaining them from a dealer, 72 per cent bought them from a patient to whom they had been prescribed and only 12 per cent obtained them directly from multiple prescribers. This suggests that obtaining prescription opioids for misuse is largely supported by methods that rely on diverting from licit to illicit use of drugs prescribed to others.
* People who inject drugs reported that, in 2013 (prior to the tamper-resistant formulation being introduced), the mean street price for OxyContin 80mg was $40 a tablet.[[15]](#endnote-15)
* It has been reported that dealers trafficking in prescription opioids recruit a number of elderly patients to on-sell some of their prescription opioids to the dealer for a small fee, a phenomenon described as ‘fossil farming’.[[16]](#endnote-16)
* Pharmacists have reported that many patients actively sought remaining supplies of the previous tamper-prone OxyContin formulation from numerous pharmacies after 1 April 2014.[[17]](#endnote-17)
* Medical practitioners report that some long-term users of OxyContin sought to be transferred to alternative opioid medications after 1 April 2014.[[18]](#endnote-18)
* The Department of Health & Human Services noted a dramatic decrease in the number of forged prescription reports for OxyContin after 1 April 2014.[[19]](#endnote-19)
* The Department of Health & Human Services has identified that a large number of patients transferred from the previous non-tamper-resistant formulation of OxyContin to MS Contin or Kapanolfollowing the introduction of tamper-resistant OxyContin in April 2014.[[20]](#endnote-20)
* In a recent study of American patients presenting for treatment for opioid dependence in 150 clinics in 48 states, questioning of a subset identified 88 patients who persisted despite the tamper-proofing: 23 per cent because they had been misusing OxyContin by mouth all along; 43 per cent transitioned from injecting to taking it orally; and 34 per cent continued by finding a way to overcome the tamper-resistance.[[21]](#endnote-21)

# For further information

## Department of Health (DH)

### Medicines and Poisons Regulation

50 Lonsdale Street

Melbourne, 3000

Fax: 1300 360 830

Email: dpcs@health.vic.gov.au

Web: www.health.vic.gov.au/dpcs

* For information and details, relating to current, recent and pending Schedule 8 permits, please refer to the patient’s profile on the SafeScript database.
* For queries relating to the Act or regulations, please:
	+ refer to the ‘Documents to print or download’ that are available on the MPR website (see below); or
	+ if you are unable to address your query by referring to those documents, forward your query via e-mail to dpcs@health.vic.gov.au

## Documents to print or download from the MPR website

The [Medicines and poisons webpage](http://www.health.vic.gov.au/dpcs) <http://www.health.vic.gov.au/dpcs> on the Health.Vic website in the section for ‘Documents to print or download’, contains summaries of legislative requirements that have been prepared in relation to issues that relate to multiple categories of health practitioner as well as to individual categories of health practitioner.

## Other possible sources of information

### Australian Health Practitioner Regulation Agency (Ahpra)

Web: [www.ahpra.gov.au](http://www.ahpra.gov.au)

### Drug and Alcohol Clinical Advisory Service (1800 812 804)

Registered health practitioners (only) may phone the **DACAS** at any time to seek **clinical advice** from specialists or other practitioners, who have been specially trained to provide advice in relation to pain, addiction and mental health issues, and for assistance with developing safe treatment plans, gradual dose tapering and alternative treatment options.

### Direct Line (1800 888 236)

* 24-hour confidential **drug and alcohol counselling** serviceforpatients
* 24-hour advisory service about available **treatment facilities** for patients, family or health practitioners
1. Finding: 225412. Kirk Ardern, viewed 30 March 2015, <http://www.coronerscourt.vic.gov.au/home/coroners+written+findings/findings+-+225412+kirk+ardern>. [↑](#endnote-ref-1)
2. Rintoul A, Dobbin MDH, Drummer OH, Ozanne-Smith J 2011, ‘Increasing deaths involving oxycodone, Victoria, Australia, 2000–09’, Injury Prevention;17**:**254–259 [↑](#endnote-ref-2)
3. Dobbin M 2014, ‘Pharmaceutical drug misuse in Australia’, *Australian Prescriber*;37:79–81. [↑](#endnote-ref-3)
4. Stafford J, Burns L 2014, Australian drug trends 2013. Findings from the Illicit Drug Reporting System (IDRS). *Australian Drug Trend Series No. 109.* Sydney, National Drug and Alcohol Research Centre, UNSW Australia. [↑](#endnote-ref-4)
5. Stafford & Burns 2014, op. cit. [↑](#endnote-ref-5)
6. National Drug and Alcohol Research Centre (NDARC). Evaluating the potential impact of a reformulated version of oxycodone upon tampering, non-adherence, and diversion of opioids: the National Opioid Medications Abuse Deterrence (NOMAD) study protocol. Degenhardt L, Laance B, Bruno R, Lintzeris N, Ali R, Farrell M. NDARC, Sydney 2014. [↑](#endnote-ref-6)
7. Coplan PM, Kale H, Sandstrom L, Landau C, Chilcoat HD 2013, ‘Changes in oxycodone and heroin exposures in the National Poison Data System after introduction of extended release oxycodone with abuse-deterrent characteristics’, *Pharmacoepidemiol Drug Safety*;22(12) :1274–1282. [↑](#endnote-ref-7)
8. Hunter Integrated Pain Service 2014, Reconsidering opioid therapy, viewed 10 April 2015, <http://www.hnehealth.nsw.gov.au/\_\_data/assets/pdf\_file/0007/76039/Reconsidering\_opioid\_therapy\_May\_2014.pdf>. [↑](#endnote-ref-8)
9. Cicero TJ, Ellis MS 2014, ‘Abuse-deterrent formulations and the prescription opioid abuse epidemic in the United States: lessons learned from OxyContin’, *JAMA Psychiatry*. doi:10.1001/jamapsychiatry.2014.3043 [↑](#endnote-ref-9)
10. Hunter Integrated Pain Service 2014, op. cit. [↑](#endnote-ref-10)
11. Rintoul et al. 2011, op. cit. [↑](#endnote-ref-11)
12. MundiPharma. Some good news: the old (easily crushed) form of Oxycontin has been removed from the Australian market. Thank you for the role you played. Letter to Australian prescribers, 28 August 2014. [↑](#endnote-ref-12)
13. Coplan et al. 2013, op. cit. [↑](#endnote-ref-13)
14. NDARC 2014, op. cit. [↑](#endnote-ref-14)
15. Cogger S, Dietze P, Lloyd B 2014, Victorian drug trends 2013. Findings from the Illicit Drug Reporting System (IDRS). *Australian Drug Trends Series No. 112.* Sydney, National Drug and Alcohol Research Centre, UNSW, Australia. [↑](#endnote-ref-15)
16. Oxford Australia 2012, *The future of Australian English*, Australian National University, Canberra, viewed 17 December 2014,

<http://andc.anu.edu.au/sites/default/files/WOTM%20fossil%20farming%20Dec%202012.pdf>. [↑](#endnote-ref-16)
17. Victorian DHHS prescription monitoring activities 2015 [↑](#endnote-ref-17)
18. Victorian DHHS prescription monitoring activities 2015 [↑](#endnote-ref-18)
19. Victorian DHHS prescription monitoring activities 2015 [↑](#endnote-ref-19)
20. Victorian DHHS prescription monitoring activities 2015 [↑](#endnote-ref-20)
21. Cicero & Ellis 2015, op. cit.

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 [↑](#endnote-ref-21)