

Drug advisory: oxycodone hydrochloride (OxyContin)

Reason for advisory: Because a growing number of reports indicate that the long-acting opioid oxycodone hydrochloride (OxyContin) is being abused, the US Food and Drug Administration (FDA) has issued stronger warnings and precautions about when to prescribe it (see accompanying article on this page).

The drug: Oxycodone, an opioid analgesic approved for the treatment of moderate and severe pain, is approximately twice as potent as an equivalent dose of morphine when taken orally. It is usually taken every 12 hours because the intact tablet works on a controlled-release principle. The FDA says abusers are circumventing this by crushing the pills and either injecting or snorting the resulting powder. At least 100 deaths have been linked to the drug in the US.

On July 18, 2001, the FDA issued a warning to physicians that the drug should not be used as a prn medication or to treat mild or temporary pain or pain that develops in the immediate postopera-

tive period (www.fda.gov/medwatch/safety/2001/oxycotin.htm).

Overdose is characterized by respiratory depression, extreme somnolence and coma, muscle flaccidity, cold and clammy skin and, occasionally, bradycardia and hypotension; severe overdose may lead to apnea, circulatory collapse, cardiac arrest and death. For other adverse effects, consult the product monograph.

Physicians are reminded of the potential for abuse, misuse and diversion of oxycodone. In Canada oxycodone exists in regular oral, controlled-release oral and combination preparations sold under various trade names, including OxyContin, Supeudol, Endocet and Oxycoet.

What to do: Appropriate pain management is important. Oxycodone should be reserved for expected moderate or severe persistent pain. Physicians should be aware of the potential for abuse of this specific preparation and stress to patients that the drug is to be swallowed whole and not chewed or crushed. The

opioid antagonist naloxone HCl is a specific antidote for opioid-induced respiratory depression. However, in people physically dependent on opioids, opioid antagonists should be used with caution (see product monograph for details) because of the potential for serious acute withdrawal syndrome. — *Eric Woolton, CMAJ*

OxyContin-abuse problem appears limited to US

The US Food and Drug Administration warning about oxycodone (OxyContin) abuse that appears elsewhere on this page is the result of an abuse epidemic in several poor regions of the US, particularly the Appalachian states.

The opioid analgesic, which is approved for treating moderate and severe pain, operates on a controlled-release principle. The FDA says abusers are circumventing this by crushing the pills and either injecting or snorting the resulting powder. At least 100 deaths have been linked to the drug in the US.

The FDA-mandated changes mean that the drug's packaging will now contain a "black box warning," the strongest type available for an FDA-approved drug. (This means that the warning is placed within a black box in physician and patient labelling to make it more noticeable.) It is being done to ensure that physicians prescribe the drug only to patients in serious and continuous pain. In a letter sent to 800 000 US doctors in July, US manufacturer Purdue Pharma-

ceuticals said it should not be used to treat pain resulting from surgical procedures, or for mild or temporary pain.

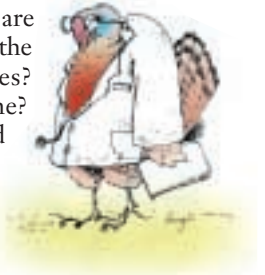
In Canada, several preparations containing oxycodone are available for prescription, including OxyContin, and many are diverted for street use. In a 1998 report, Dr. Brian Goldman said the relatively high street price of controlled-release opioids ("peelers" in street parlance) "should ring alarm bells" (*CMAJ* 1998;159[2]:149-50).

Goldman, an expert in the diversion of prescription drugs, warned: "Now that controlled-release oxycodone has been licensed in Canada, we can expect that it and other controlled-release opioid analgesics will also find their way onto the black market." (In July, the College of Physicians and Surgeons of Ontario announced that it had suspended the licence of Dr. Galdino Pontarini of Mississauga for 9 months; he was convicted of trafficking in oxycodone in 1999.)

In an interview, Goldman said he has heard of no OxyContin-related

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overdoses in Toronto, where he practises part time as an emergency physician. "But any opioid can be abused. The flavour of the week [for drug diversion] in the US used to be Vicodin [hydrocodone/acetaminophen], and now it's OxyContin. Here it's still the usual suspects: Percocet, Percodan and Tylenol 3s."

Dr. Janet Griffiths of Health Canada's Bureau of Licensed Product Assessment said the department is currently reviewing the product monograph for OxyContin and will likely be introducing changes, which will be publicized. She said Health Canada conducted adverse drug report searches in May and July and found no reports involving the drug. — *Patrick Sullivan, CMAJ*