5 Things to Know about Prescriptions for Buprenorphine /Naloxone

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Community pharmacists are seeing increasing numbers of patients who are prescribed buprenorphine/naloxone sublingual tablets. Recently generic products considered as interchangeable with Suboxone®, have become available.

Many communities still do not have easy access to physicians who are exempted to prescribe methadone. The increased availability of buprenorphine/naloxone has improved access to opioid dependence treatment across Ontario. Additionally, buprenorphine/naloxone may provide an alternative for patients with concerns surrounding the stigma associated with methadone. Although increased access is important, there have been reports of errors during the dispensing process as a result of pharmacy teams not understanding the many unique elements in dispensing this drug.

Although physicians are required to be knowledgeable about treatment with buprenorphine, no exemption is required in order to prescribe buprenorphine/naloxone and pharmacists are not required to inform OCP that they are dispensing this medication.

Nevertheless, pharmacists need to be familiar with the use of this drug and to be aware of required processes, guidelines and standards of practice if they agree to provide pharmacy care and dispensing services with this unique opioid agonist. Buprenorphine / naloxone has many similarities with methadone. It is approved in Canada for the treatment of opioid use disorder. Although it may be safer in overdose and dissolved under the tongue (vs. swallowing methadone diluted in a vehicle that does not lend itself to injection — such as orange flavored Tang® or other suitable drink), much of the framework for prescribing and dispensing is very similar.

Some selected points pharmacists must know in order to provide buprenorphine treatment safely to their patients are:



INDICATION

Opioid dependence treatment is the most frequent, and the only approved, indication for buprenorphine/naloxone. It is being used in some settings for the treatment of opioid withdrawal (unapproved indication). There may also be some patients who are prescribed this medication "off-label" for combined chronic pain and opioid use disorder, as well as some who are receiving it for the sole treatment of chronic pain when other options have been ineffective. When it is used in the treatment of pain in those patients with a history of substance use, it is prescribed and dispensed in a framework similar to that used in the provision of methadone for opioid dependence.

Buprenorphine (without naloxone) is also available in a patch formulation, (BuTrans®), which is approved for the treatment of chronic pain (not approved for use in addiction).



PAY ATTENTION TO START AND STOP DATES

Start and stop dates for dispensing are usually (and preferably) used instead of the total numerical quantity of doses needed. Pharmacists are required to strictly adhere to these dates which form part of the prescription and authorize the dispensing of the quantity of buprenorphine/naloxone required for the treatment period indicated on the prescription.

As is the case for any narcotic prescription, where no total quantity is indicated, the quantity must be able to be clearly and exactly calculated. If the narcotic quantity cannot be accurately calculated or the prescriber's intent is unclear, it would be important to obtain clarification from the prescriber.

Increasingly, structured opioid therapy with other narcotics is being used in the context of chronic pain, and start and stop dates are being prescribed for medications like hydromorphone, morphine etc.



MISSED DOSES ARE NOT "OWING DOSES"

If a patient misses buprenorphine/naloxone doses on days during the interval indicated by the start and stop dates, these doses are not considered as "owing "to the patient. As for methadone, when an "observed dose" is missed, the next dose dispensed should be observed. Under no circumstances should doses be dispensed after the stop date on the prescription or for previous dates on which the client has not picked up doses. Pharmacists need to ensure that all pharmacy staff members involved in the dispensing of buprenorphine/naloxone are aware of this.



OBSERVED AND TAKE-HOME DOSES

Supervised dosing by the pharmacist is an important clinical component. This involves carefully, respectfully and discretely witnessing a patient placing the tablet(s) under the tongue and observing dissolution. This is best done in a private area, if possible. There are reports that some pharmacists are not adhering to this practice and patients are able to spit out doses and/ or divert easily. This has negative impact on treatment outcomes.

Carry doses are doses which may be taken home for later self-administration. They must be dispensed in a childproof container. A take home agreement can be completed with the patient.

There may be some special notes on the prescription requiring pharmacist attention, for example, notes about what to do if the pharmacy is closed on Sunday or a statutory holiday. Such notes should be considered to form part of the prescription, and if unclear, may warrant clarification with the prescriber directly.

In any case, the prescription should clearly indicate which doses, including which days of the week, are to be observed in the pharmacy and which doses may be taken home. Pharmacists need to adhere to these directions.



TRACKING MISSED DOSES AND COMMUNICATING WITH THE PRESCRIBER.

Information about missed doses is essential for the prescriber in making clinical decisions regarding buprenorphine therapy and for the pharmacist to medicate their patients safely. This information needs to be accurate and easily retrievable.

As with methadone, it is good practice to inform the prescriber of each missed dose. Prescribers should be contacted for direction after 3 missed doses of buprenorphine/naloxone, since this may indicate a considerable loss in patient stability. After more than 5 doses have been missed, the prescription should be cancelled since the dose will, in most cases, need to be decreased as per this table in the Buprenorphine/Naloxone Guidelines (1):

Buprenorphine Dose	Number of Consecutive Days Missed	New Starting Dose
> 8 mg	> 7 days	4 mg
> 8 mg	6-7 days	8 mg
6-8 mg	6 or more days	4 mg
2-4 mg	6 or more days	2-4 mg

REFERENCES

- Buprenorphine/Naloxone for Opioid dependence: Clinical Practice Guideline (CAMH)
 http://knowledgex.camh.net/primary_care/guidelines_materials/
 Documents/buprenorphine_naloxone_gdlns2012.pdf
- Buprenorphine for the Treatment of Opioid Dependence, Pharmacy Connection, Winter 2014. http://www.ocpinfo.com/library/practice-related/download/ Buprenorphine%20for%20the%20Treatment%20of%20 Opioid%20Dependence.pdf
- Opioid Agonist Maintenance Treatment. A Pharmacist's Guide to Methadone and Buprenorphine for Opioid Use Disorders. (CAMH, in press)