

METHADOSE[®] INFORMATION FOR ONTARIO PHARMACISTS

Centre for Addiction and Mental Health (CAMH), Toronto

In Ontario, methadone for treatment of opioid dependence will be prepared using Methadose[®] Oral Concentrate as the stock solution, and stock solutions will no longer be compounded by pharmacies.

Information in the Methadose[®] product monograph is not always consistent with the College of Physicians and Surgeons of Ontario (CPSO) Methadone Maintenance Treatment Program: Standards and Clinical Guidelines (February, 2011) and the Ontario College of Pharmacists' Methadone Maintenance Treatment (MMT) and Dispensing Policy in Ontario.

This article will briefly review the topics that can be misunderstood or misinterpreted with the new products:

***METHADOSE Sugar-Free Oral Concentrate (10 mg/mL): DIN 02394618**
Dye-free, sugar-free and unflavoured liquid concentrate

METHADOSE Oral Concentrate (10 mg/mL): DIN 02394596
Red, cherry-flavoured liquid concentrate

**METHADOSE[®] Sugar-Free Oral Concentrate (DIN: 02394618) is the recommended product for pharmacies to use as stock solution to prepare methadone maintenance treatment (MMT) doses.*

DOSING GUIDELINES

Dosing of methadone must adhere to the 4th edition of the CPSO's *Methadone Maintenance Treatment Program: Standards and Clinical Guidelines* (February, 2011).

See chart on opposite page.

ACCURACY WHEN MEASURING DOSES

- Special care must be taken in measuring this concentrated formulation (10 mg/mL). Measured

doses should be double-checked and double-signed against the original prescription, whenever possible. There have been instances in Ontario in which major life-threatening errors in measurement have been made (e.g. a dose of 190 mg for someone prescribed 19 mg).

- As per OCP policy, Methadose[®] doses must be accurately measured using devices able to deliver 0.1 mL increments. Even small measurement errors may be clinically significant with methadone's narrow therapeutic range. Graduated cylinders and certain syringes may not be appropriate for this purpose.
- Most pharmacies have previously compounded a different concentration of stock solution (e.g. 5 mg/mL). **Extra caution with measuring is required during this transition period.**
- If using a dispensing pump system, check with the manufacturer for any re-calibration needed for the new products. There may be issues using the cherry flavour product in some systems.

DILUTION WITH FRUIT DRINK STILL REQUIRED WITH METHADOSE[®]

- Dilution with a vehicle that deters injection or diversion (e.g. orange drink) to 100 mL is still required as per the OCP Methadone Policy **for all observed and carry doses.**
- At this time, both forms of Methadose[®] Oral Concentrate require dilution as above. Water is not considered a vehicle that deters injection. *For this reason it is recommended to use the unflavoured product diluted with fruit drink.*

CLEAR LABELLING OF THE BOTTLE

The prescription label requirements for methadone doses have not changed. Moving from a compounded product to a commercial product however, requires that the commercial product be clearly identified. Please note, that when the concentration and volume of Methadose[®] appears on the label for the bottle containing diluted product, this can be misinterpreted. *There have been errors related to labelling where partial*

Dosing discrepancies between Methadose® monograph and CPSO guidelines:

	CPSO GUIDELINES	METHADOSE® MONOGRAPH
Initial dosing	<p>Initial dose of 10–30mg on the first day</p> <p>Maximum total daily dose of 30mg on the first day.</p> <p>Increases should occur only every 3–5 days; decisions within these parameters are based on the clinical situation (see page 40 of Guidelines).</p>	<p>Initial dose of 20–30 mg.</p> <p>An additional 5–10mg may be given on the first day for a total daily dose of 35–40mg on the first day.</p>
Missed doses	<p>Dosage adjustment is required if:</p> <p>2 consecutive doses are missed during early stabilization or</p> <p>3 consecutive doses are missed in the maintenance phase</p>	<p>Loss of tolerance should be considered if opioids are not taken for 5 days.</p>

volumes of the diluted product were thought to contain the daily dose. Therefore, labelling must be considered carefully. The label should make the following very clear:

1. The drug product (name, manufacturer) and amount in the bottle.
2. The total dose in milligrams of methadone contained in the bottle.
3. A notation that the drug product has been diluted.
3. A notation: "Drink entire contents of bottle."
4. The date for ingestion for carries.

Examples of acceptable labels:

Pharmacy Address	Rx# Date
Jane Doe	
Drink entire contents of bottle (METHADONE 80 mg in orange drink) on Friday, June 27, 2014.	
80mg Methadone (MAL) DIN02394618	
Dr. Smith	


Pharmacy Address	Rx# Date
Jane Doe	
Drink entire contents of bottle (METHADONE 80 mg in orange drink) on Friday, June 27, 2014.	
(8) mL Methadone HCl 10mg/mL (MAL) DIN02394618	
Dr. Smith	

The following auxiliary labelling should also be included:

- "Keep Refrigerated" for carries
- Methadone may cause serious harm to someone other than the intended patient. **MAY BE FATAL TO CHILD OR ADULT.**

Additional information required as per OCP Policy (2014) must be included as well: <http://www.ocpinfo.com/regulations-standards/policies-guidelines/methadone2>

COMMUNICATION WITH PATIENTS

Inform your patients of the change in product and reassure them that they should not notice any difference in the effectiveness of their MMT doses, although there might be a change in taste. Patient information provided by the manufacturer may not be consistent with the guidelines, so distribution of the Ontario Public Programs' "Changes to Methadone Maintenance Frequently Asked Questions" should be considered. 

1. College of Physicians and Surgeons of Ontario (CPSO) Methadone Maintenance Treatment Program Standards and Clinical Guidelines (2011): <http://www.cpso.on.ca/uploadedFiles/members/MMT-Guidelines.pdf>
2. Revised OCP Methadone Maintenance Treatment (MMT) and Dispensing Policy: <http://www.ocpinfo.com/regulations-standards/policies-guidelines/methadone2/>
3. Ontario Public Programs, Ministry of Health and Long-Term Care: Changes to Methadone Maintenance Treatment: Frequently Asked Questions for Patients: http://www.health.gov.on.ca/en/pro/programs/drugs/opdp_eo/notices/cmmt_faqs_patients_20140620.pdf