Health Canada
Santé Canada

DRUGS DIRECTORATE GUIDELINES

# DISPENSING METHADONE FOR THE TREATMENT OF OPIOID DEPENDENCE

Guidelines for Pharmacists

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# 1 INTRODUCTION

## 1.1 Background

Guidelines for the use of methadone in the treatment of opioid dependence were originally prepared in 1971 by a joint committee of the Canadian Medical Association and Health and Welfare Canada. In 1988, an Expert Advisory Committee was convened to review the guidelines. The committee's report was published in April 1990. Based on the comments received from interested groups and individuals, and discussions with medical and pharmacy licensing authorities, revised guidelines entitled The Use of Opioids in the Management of Opioid Dependence were prepared. These guidelines, intended for physicians, became effective January 1, 1993.

## 1.2 Guidelines for Pharmacists

The guidelines contained herein are intended to assist pharmacists involved in the dispensing of methadone for opioid dependence.

## 1.3 Additional Information

For specific information regarding the pharmacology, adverse drug reactions, contraindications, and drug interactions of methadone, please refer to specialized references that cover these areas.

## 2 BASIC PRINCIPLES FOR TREATMENT

### 2.1 Benefits

Pharmacotherapy may assist opioid abusers in re-establishing their lives along more constructive lines by promoting rehabilitation and reducing health risks and costs to the community.

The use of methadone in the treatment of opioid abuse and dependence may result in:

— a reduction in the use of illicit drugs, especially opioids;

— a reduction in mortality rates among opioid users;

— a reduction in the spread of infections associated with needle-sharing, such as AIDS; and

— improved psychosocial functioning and reduced criminal activity.

### 2.2 Other Opioid Treatments

The use of specific opioids other than methadone is permitted for detoxification under certain circumstances (see Section 3.2.2).

## 3 AUTHORIZATIONS

A physician who wishes to prescribe or administer methadone must obtain an authorization from the Minister of Health Canada. An authorization may be issued for a period varying from one day to one year, but is subject to cancellation.

Authorizations are revised and renewed annually.

### 3.1 Responsibility of the Pharmacist

It is the responsibility of the pharmacist to ensure that the practitioner is authorized to prescribe methadone prior to dispensing it to any patients.

### 3.2 Types of Authorizations

One of several types of authorizations may be issued to a physician:

— Methadone maintenance,

— Detoxification, or

— Analgesia.

For all authorizations, the physician may be restricted to prescribe methadone within an institution (affiliation authorization), or to specific patients (restricted authorization), or both.

In certain circumstances, the physician's authorization is not restricted to an institution or to specific patients.

An affiliation authorization is given when a physician practises within an institution and follows the protocol for the methadone program of that institution. The physician is only allowed to prescribe methadone to patients of that institution. The authorization is conditional on the physician's affiliation with the institution.

A physician may be restricted to treat a limited number of patients as determined by the medical licensing authority or the Bureau of Drug Surveillance. The names of the patients are then specified in the authorization and the dispensing pharmacy is advised of any patients added to the authorization.

#### 3.2.1 Methadone Maintenance

Methadone maintenance involves the daily oral administration of methadone, over a prolonged period, as an oral substitute for heroin or other morphine-like drugs.

In Canada, methadone is currently the only authorized opioid for long-term (more than 180 days) out-patient pharmacological treatment of opioid-dependent persons.

#### 3.2.2 Detoxification

Detoxification using methadone is the administration of gradually decreasing doses over a period not exceeding 180 days. This process permits weaning and avoids the onset of withdrawal symptoms such as mydriasis, piloerection, vomiting, restlessness, and rhinorrhea.

Other specific opioids may be used orally for detoxification for a period not exceeding 180 days:

— Codeine (for codeine dependence or where a short-acting opioid is required),

— Pentazocine (for pentazocine dependence), and

— Propoxyphene (for propoxyphene dependence).

Tincture of opium may be used in the treatment of an opioid-dependent neonate.

3.2.3 Analgesia

Methadone is also used for analgesic purposes in humans and in veterinary medicine.

3.3 Compliance

Authorized physicians must comply with the guidelines set out in the Drugs Directorate Guidelines entitled The Use of Opioids in the Management of Opioid Dependence. Compliance with the guidelines is a condition of authorization to prescribe methadone; failure to comply with the conditions stipulated in the authorization may lead to revocation or non-renewal of the authorization.

## 4 AVAILABILITY

Methadone is available in Canada as a white, odourless, crystalline powder. As with other narcotic or controlled drugs, it is available through various licensed dealers. Should a pharmacist require more information concerning the names of companies that manufacture methadone, the Bureau of Drug Surveillance or Regional Offices, Health Protection Branch, may be contacted (see Appendix A).

## 5 DOSAGE

For both methadone maintenance and detoxification programs, dosages are individualized and determined by the treating physician. The majority of patients can be treated at a dose lower than 80 mg/day. For patients requiring doses of more than 100 mg/day, physicians must consult with their medical licensing authority and inform, in writing, the Bureau of Drug Surveillance.

## 6 DISPENSING

### 6.1 Formulation

Methadone must be dispensed in 100 mL of a vehicle that does not easily lend itself to injection (e.g., “Tang” prepared according to the directions on the package and used full-strength).

A patient who claims an intolerance to “Tang” should be referred to his or her physician, who may choose an alternate vehicle.

### 6.2 Administration

In the treatment of opioid dependence, the dispensing and administering of methadone to patients must be done on a daily basis, except for weekends and statutory holidays, and for patients who have been granted carry privileges.

For those patients receiving their dose of methadone on a daily basis, the medication must be consumed under the direct supervision of a health professional. The health professional must ensure that the methadone has been swallowed (e.g., by making the patient talk after drinking).

### 6.3 Carry Privileges

In view of the risks associated with the diversion of methadone, carry privileges may be provided only upon the written order of the physician. Carry privileges are granted usually as a “reward” for compliance with therapy. The following specific conditions apply:

a) In all instances (except for pregnant women—see paragraph d), below), carry privileges must be limited to a maximum period of four days or a maximum total dosage of 400 mg, whichever is less.

b) No carry privileges, except for weekends and statutory holidays, will be granted to patients receiving more than 100 mg of methadone per day.
c) Carry privileges are not permitted for patients receiving methadone for detoxification purposes, except for weekends and statutory holidays.
d) For opioid-dependent pregnant patients, it is recommended that no carry privileges be provided, except in emergencies or situations where there is no easy access to a distribution centre and public health services cannot provide a daily supply. In such instances, the carry privileges will be limited to a maximum period of four days, or a maximum total dosage of 320 mg, whichever is less.

### 6.4 Labelling and Dispensing

For patients that have been granted carry privileges, the medication should be labelled according to federal/provincial requirements. A warning must be included to the effect that the amount of drug contained could cause serious harm or toxicity if taken by someone other than for whom it was prescribed.

It is recommended that doses of methadone be dispensed in individual bottles with safety caps.

### 6.5 Refills

As for any other narcotic medication, refills and replacement for lost supplies or stolen medication are not permitted.

### 6.6 Travelling Arrangements

Patients that will be travelling should consult their physician to make other arrangements for treatment while away from their residence. Only licensed dealers with appropriate permits may import or export narcotic and controlled drugs across international borders.

# 7 STORAGE AND STABILITY

## 7.1 Storage

Methadone powder should be kept in an airtight container and protected from light. Like all narcotics, methadone must be kept in a secure place at all times.

## 7.2 Stability

The stability of methadone has been demonstrated under the conditions shown in Table 7-1. The results were similar for concentrations of 0.2 mg/mL, 0.8 mg/mL, and 1.5 mg/mL.

TABLE 7-1
Stability of Methadone According to
the Diluent Used and Conditions of Storage

| Diluent | Period of Stability | |
|---|---|---|
| | Room Temperature (20-25_C) | Refrigerated (5_C) |
| Grape-flavoured Kool-Aid* | 17 days | 55 days |
| Orange-flavoured Tang* | 11 days | 49 days |
| Allen's Apple Juice | 9 days | 47 days |
| Grape-flavoured Crystal Light* | 8 days | 34 days |
| Grape-flavoured Crystal Light with 0.1% sodium benzoate | 29 days | |

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* Prepared according to manufacturer's instructions

## 8 VERIFICATION OF PRESCRIPTIONS AND REPORTING REQUIREMENTS

Methadone is a reportable narcotic and is subject to the same federal regulations as other narcotic medications.

Prescriptions for methadone must be written, dated, and signed by a physician who has received an authorization from the Minister of Health Canada.

### 8.1 Verification

A pharmacist who wishes to verify that a physician has been authorized to prescribe methadone may contact the Bureau of Drug Surveillance in Ottawa at (613) 954-6777, or the closest Regional Office (see Appendix A).

A list of physicians entitled to prescribe methadone is also updated and distributed annually to pharmacies. This list is confidential and is for professional use only. For physicians not appearing on this list, the pharmacist will be advised of the authorization for treatment of a given patient.

### 8.2 Reporting Requirements

Hospital pharmacies that dispense methadone to in-patients are required to keep records but are not required to submit reports. Community pharmacies that dispense methadone, and hospitals that dispense methadone to out-patients, must keep records and submit reports along with the regular narcotic and controlled drug sales reports. Dispensing physicians must keep records and submit reports on a monthly basis.

As stipulated by the Narcotic Control Regulations, methadone must be recorded each time it is dispensed to a patient. Methadone must be reported as the number of milligrams dispensed, as indicated in Table 8-1.

TABLE 8-1
Format for Methadone Dispensing Report

| |
|---|
| Date |
| Prescription Number |
| Written/Verbal |
| Description |
| Purchaser |
| Practitioner |
| d/m/y |
| 123456 |
| w |

80 mg
Methadone
Solution

Full name
Address

Full name
Address

## 9 REFERENCES

1. Ball, J. C. and A. Ross, “The Effectiveness of Methadone Maintenance Treatment,” New York, USA: Springer-Verlag 1991.

2. Compendium of Pharmaceuticals and Specialities, 29th ed., C. Krogh, ed., Canada: Canadian Pharmaceutical Association, 1994:B117.

3. Drugs Directorate Guidelines: The Use of Opioids in the Management of Opioid Dependence. Health and Welfare Canada, 1992.

4. Ruel, J.-M. and P. Hickey, “Diversion of Methadone: What are the Risks?” BC Medical J. 35 (1993): 420-21.

5. Ruel, J.-M. and P. Hickey, “Survey of Methadone Patients in Canada,” Can. J. Public Health 81 (1990): 272-274.

6. Lauriault, G., M. J. Lebelle, B. A. Lodge, et al., “Stability of Methadone in Four Vehicles for Oral Administration,” Am. J. Hosp. Pharm. 48 (1991): 1252-1256.

7. Narcotic Control Regulations.

APPENDIX A

Bureau of Drug Surveillance
Health Protection Branch
Health Canada
Ottawa, Ontario
K1A 1B9

Telephone: (613) 954-6777
Fax: (613) 952-7738

Regional Offices
Health Protection Branch

1. Atlantic Region

Chief
Inspection Division
Health Protection Branch
P.O. Box 1060
1992 Baffin Street
Dartmouth, Nova Scotia
B2Y 3Z7

Telephone: (902) 426-5775
Fax: (902) 426-4035

2. Quebec Region

Supervisor
Dangerous Drugs Unit
Health Protection Branch
1001 St. Laurent Street W.
Longueuil, Quebec
J4K 1C7

Telephone: (514) 928-4110
Fax: (514) 928-4437

3. Ontario Region

Supervisor
Drug Control Unit
Health Protection Branch
2301 Midland Avenue
Scarborough, Ontario
M1P 4R7

Telephone: (416) 973-5673
Fax: (416) 973-7137

4. Central Region (Manitoba and Saskatchewan)

Supervisor
Drug Control Unit
Health Protection Branch

510 Lagimodière Blvd.
Winnipeg, Manitoba
R2J 3Y1

Telephone: (204) 983-5453
Fax: (204) 983-5547

5. Western Region (Alberta, British Columbia, Northwest Territories and Yukon)

Chief
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3155 Willingdon Green
Burnaby, British Columbia
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