**HYDROMORPHONE IS A HIGH RISK MEDICINE**
USE WITH CAUTION AND ENSURE THE DIRECTIONS WITHIN THIS PROTOCOL ARE FOLLOWED CAREFULLY

Please note: This protocol sets out minimum requirements for all SESLHD facilities. Please refer to local Clinical Business Rules for specific requirements at your facility.

<table>
<thead>
<tr>
<th>Areas where applicable</th>
<th>SESLHD Hospitals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Areas where not applicable</td>
<td>This protocol does not apply to the use of HYDROMORPHONE via PCA or continuous infusion.</td>
</tr>
<tr>
<td>Authorised Prescribers</td>
<td>All Medical Officers and Nurse Practitioners</td>
</tr>
<tr>
<td>Indication for Use</td>
<td>Moderate to severe, acute or chronic pain.</td>
</tr>
</tbody>
</table>

**Place in Therapy**

- **Acute pain:** HYDROMORPHONE is not an appropriate first line analgesic for acute pain for most patients. Use in acute pain must always be on the advice of a registrar or above. Where possible, advice should be sought from the Pain team or other relevant specialist prior to initiation of HYDROMORPHONE.

- **Chronic pain:** Initiation of HYDROMORPHONE for chronic pain management should be on the advice of a registrar or above, and should ideally be done in consultation with the Pain or Palliative Care team.

**Important Safety Considerations**

- HYDROMORPHONE is 5 to 7 times more potent than morphine. The dosing schedules of hydromorphone and morphine are frequently confused.

- HYDROMORPHONE has a narrow therapeutic index and response can vary considerably from patient to patient. HYDROMORPHONE should be dosed cautiously and titrated gradually according to response.

- HYDROMORPHONE is available in a variety of oral and injectable formulations. Errors can arise from prescribing or administering the incorrect formulation.

- HYDROMORPHONE has different dosing schedules for different routes. Oral and injectable routes of administration are non-equivalent, and recommended ratios for route conversion may differ according to a patient’s degree of opioid-tolerance.
### Contraindications

- Known hypersensitivity to HYDROMorphone
- Respiratory depression with hypoxia or elevated carbon dioxide levels in the blood in the absence of resuscitative equipment
- Status asthmaticus
- Paralytic ileus
- Concurrent Monoamine Oxidase Inhibitors (MAOIs) or within 14 days of therapy
- Pregnancy

### Precautions

- **Elderly and debilitated patients**
  Start with lower doses, titrate dose carefully and monitor for adverse effects.

- **Renal Impairment**
  Start with lower doses, titrate dose carefully and monitor for adverse effects. Accumulation of the metabolite hydromorphone-3-glucuronide also occurs in renal impairment and may cause psychotic symptoms.

- **Hepatic Impairment**
  Reduce dose in moderate hepatic impairment. Not recommended in severe impairment

- **Respiratory Disease**
  Use with extreme caution in patients with respiratory depression, severe obstructive airways disease, at risk of upper airways obstruction (e.g. sleep apnoea), asthma or decreased respiratory reserve.

- **Gastrointestinal Disease**
  Use with caution; consider parenteral route of administration if oral absorption is a concern.

- **Other Precautions**
  Comatose patients; Uncorrected endocrine abnormalities; hypothyroidism; adrenocortical insufficiency; acute alcoholism; myasthenia gravis; CNS depression; epilepsy or a recognised risk for seizure; raised intracranial pressure; hypotension or shock; phaeochromocytoma

  **In all of the above circumstances, advice from the Pain or Palliative Care team or other relevant specialist should be sought.**

### Important Drug Interactions

- CNS depressants
- Monoamine Oxidase Inhibitors (MAOIs) or within 14 days of therapy
**Dosage**

HYDROMorphone is approximately 5 to 7 times more potent than morphine. Care should be exercised in calculating and documenting the dosage.

Doses should be started low and titrated gradually according to analgesic response, respiratory rate and sedation score.

Initial dose reduction is required in the following:

- the elderly
- opioid naïve patients
- patients with renal impairment
- patient with risk factors (see ‘Precautions’)
- patients receiving other medications that can potentiate the effects of HYDROMorphone.

Refer to facility Clinical Business Rules for specific dosing recommendations in various patient groups.

**Duration of therapy**

**Acute pain:**

The intended duration of therapy should be documented at initiation of therapy and included in a pain management plan provided to the patient/carer at discharge. This plan should also be communicated to ongoing care providers.

**Chronic pain:**

The duration of therapy may be indefinite (according to response), but an updated pain management plan should be clearly communicated to ongoing care providers at discharge.
All medication orders must be legible and clear indicating the full name of the prescribing doctor. All orders for HYDROmorphine must include:

i. Drug, including both generic and trade name
ii. Dose, route and frequency
iii. Maximum daily dose for PRN orders
iv. Indication

Each individual order should be for one route only, there should never be more than one route on each individual HYDROmorphine order.

Both the generic and trade names must be included in the order to distinguish between the modified-release and immediate-release formulations. If a modified-release (MR) formulation is intended, this must be indicated by ticking the MR box on the medication chart or selecting a MR formulation in an electronic system.

**Patients admitted on HYDROmorphine**
The formulation, dose, route and frequency taken by the patient must be confirmed with the patient and a second source and documented in the medical record before prescribing.

**Newly initiating HYDROmorphine**
When newly initiating HYDROmorphine, the following must be clearly documented in the medical record in addition to prescribing on the medication chart:

i. Drug, including both generic and trade name
ii. Dose, route and frequency
iii. Maximum daily dose for PRN orders
iv. Indication
v. Name and designation of medical officer who has provided advice (if relevant) – essential if prescribed by a JMO, see ‘Place in Therapy’ above.

**Modifying a HYDROmorphine order**
When modifying an order for HYDROmorphine (e.g. increasing the dose, changing the route), the following must be clearly documented in the medical record, in addition to prescribing on the medication chart:

i. Current formulation, dose, route, frequency and maximum dose for PRN orders
ii. New formulation, dose, route and frequency and maximum dose for PRN orders
iii. Indication
iv. Reason for change

**Recharting a HYDROmorphine order**
Care should be taken when recharting an order for HYDROmorphine (at the same, dose, route and frequency), to ensure all details are transferred correctly. Where possible, the new medication chart should be checked by another medical officer or a pharmacist prior to use.

**Converting to HYDROmorphine from another opioid**
Locally-approved dose conversion tools, appropriate for use in both opioid-naive and opioid-tolerant patients, must be available to medical officers to guide safe and appropriate conversion between different opioids.
opioids. Dose conversions must be clearly documented in the medical record, including:

i. Current drug, dose, route and frequency
ii. HYDROmorphine dose, route and frequency
iii. Intended HYDROmorphine formulation (including trade name)
iv. The mathematical calculation of the new dose
v. Name of person who has authorised prescribing of HYDROmorphine

Referral mechanisms to either a Pharmacist or the Pain or Palliative Care Service (or other relevant specialist) should be available to support prescribers at all times.
Administration Instructions

Nursing Staff should not administer HYDROmorphine if the prescribing requirements above are not met. Any concerns must be escalated immediately to the prescribing doctor. If this fails to resolve the issue, concerns should be escalated to the Nurse Unit Manager or After Hours Nurse Manager.

Always check carefully and confirm the correct dosage, route, frequency and formulation before each administration, with reference to the medical patient's medical record.

A second person check is mandatory as per NSW Health Policy Directive PD2013_043 Medication Management in NSW Public Health Facilities.

Monitoring Requirements

The following observations must be routinely recorded for all patients receiving HYDROmorphine:
- Sedation
- Respiratory rate
- Pain score

The frequency of monitoring will be determined by the individual circumstances and should be clearly documented by the prescribing medical officer in the medical notes.

The frequency of monitoring should be increased for patients newly prescribed HYDROmorphine, or when the HYDROmorphine dose has been increased. Patients on long-term stable therapy and palliative care patients may require less frequent monitoring.

Refer to local Clinical Business Rules for specific recommendations on monitoring in various patient groups.

Management of possible complications

<table>
<thead>
<tr>
<th>Complication</th>
<th>Management</th>
</tr>
</thead>
</table>
| Sedation score 2 | - Ensure oxygen therapy is in progress and monitor oxygen saturation  
- Activate PACE Tier 1 call |
| Respiratory rate 6 to 10 breaths per minute | - Ensure oxygen therapy is in progress and monitor oxygen saturation  
- Activate PACE Tier 1 call |
| Sedation score 2 and respiratory rate less than or equal 5 breaths per minute | - Initiate code blue / PACE Tier 2 call  
- Commence ventilatory assistance if required |
| Sedation score 3 | - Initiate code blue  
- Commence ventilatory assistance if required |
In the event of unexpected complications when using modified release preparations, further advice should be sought from Pain or Palliative Care teams or other approved specialist as specified within facility Clinical Business Rules. The long half-life of the drug may necessitate an infusion of naloxone.

In the event of a severe, acute complication other than those listed above (e.g. anaphylaxis), code blue should be initiated.

In patients who have an end of life pathway documented, complications should be managed in accordance with their individualised plan. CPR or PACE calls may not be appropriate. The Medical Emergency Treatment Limitation Section on the reverse side of the Resuscitation Plan form should be completed with specific instructions for the management of any opioid-related complications.

**Storage requirements**

HYDROmorphone products must be supplied from pharmacy in a distinctive container with clear labelling to distinguish them from morphine. They must remain in this distinctive container during storage on the ward. HYDROmorphine must be stored separately from morphine, for example in a separate safe or on a different shelf. Where space permits, clear shelf labelling should be applied utilising tall man lettering.

HYDROmorphine products must not be stored in clinical areas where use is infrequent. Review of storage areas should be undertaken on a six-monthly basis.

Where practicable HYDROmorphine should be supplied from pharmacy on an individual patient basis and the patient’s medication chart clinically reviewed by a pharmacist prior to supply.

Any dispensed products that are no longer required should be removed from clinical areas at the earliest opportunity.

Efforts should be made to ensure that, where possible, only one strength of the injection (10mg/mL OR 2mg/mL) is held in clinical areas at any time. Where both strengths need to be held to meet patient needs, clear labelling and education strategies must be in place to mitigate the risk of product selection error.

The 50mg in 1mL injection must not be stocked in SESLHD facilities. Where high doses may be required, manufactured pre-filled syringes should be used.
Pharmacist review

Pharmacists should prioritise patients prescribed HYDROmorphine for clinical review during business hours. Within each SESLHD facility, mechanisms should be in place to assist pharmacists with identification of these patients.

When clinically reviewing a HYDROmorphine order, the pharmacist is responsible for ensuring the appropriateness of the drug, formulation, dose, route and frequency in the context of the individual patient’s parameters. The pharmacist should also ensure that all prescribing requirements (above) have been met.

Once satisfied with the order, the pharmacist should annotate the medication chart in the pharmacy section with “verified”, their initials and the date. In electronic systems, the HYDROmorphine order should be electronically verified, and the words “Pharmacist verified” added to the order comments.

Additional Resources


Basis of Protocol:

MIMS
AMH
Therapeutic Guidelines
NSW Health Safety Alert 001/17 HYDROmorphine: High risk medicine
NSW Health Safety Alert 004/17 HYDROmorphine (high-risk medicine): Changes to Dilaudid® injectable preparations

Groups consulted in development of this protocol

POWH High Risk Medicines – Narcotics Working Party
SESLHD Medication Safety Pharmacists Network
SESLHD facility Drug and Therapeutics Committees (or equivalent)

**AUTHORISATION**

| Author (Name) | Chi Tran  
| Katie Kerr | Position  
| POWH Senior Pharmacist – Projects  
| SESLHD QUM Lead Pharmacist | Department  
| Pharmacy Department  
| Medical Executive Directorate | Department Contact  
| Katie.kerr@health.nsw.gov.au |
### GOVERNANCE

<table>
<thead>
<tr>
<th>Enactment date</th>
<th>June 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expiry date:</td>
<td>30 June 2018</td>
</tr>
<tr>
<td>Ratification date by SESLHD Drug and QUM Committee</td>
<td>1 June 2017</td>
</tr>
<tr>
<td>Chairperson, Drug and QUM Committee</td>
<td>Dr James Mackie</td>
</tr>
<tr>
<td>Version Number</td>
<td>1</td>
</tr>
</tbody>
</table>