# Specialised Medication – Zuclopenthixol Acetate - Clopixol Acuphase® Guideline

## 1. Purpose

This document provides guidance for the safe and appropriate prescription and administration of zuclopenthixol acetate (Clopixol Acuphase®) in adult consumers.

This document should be used in conjunction with appropriate references, including:

- WACHS Medication Prescribing and Administration Policy
- WACHS High Risk Medications Procedure
- Statewide Medication Formulary
- MIMS Product Information

Zuclopenthixol acetate may only be prescribed and administered:

- in a mental health inpatient unit. Approval to use zuclopenthixol acetate in other areas is at the discretion of the regional mental health clinical director or Mental Health Emergency Telehealth Service's consultant psychiatrist
- in a mental health inpatient unit after approval by a consultant psychiatrist (or relevant delegate)
- once efforts to utilise shorter acting parenteral or oral medication(s) have been demonstrated
- where informed consent cannot be obtained, adherence to the WA Health Consent to Treatment Policy, Section 3.7, and *Mental Health Act 2014* (Emergency Psychiatric Treatment) must occur
- by staff who are familiar with this guideline
- in a setting adequately equipped to monitor and respond to adverse events.

## 2. Guideline

### 2.1 Presentation[1]

Zuclopenthixol **acetate** is available as 50 mg/1mL or 100 mg/2 mL glass ampoules (clear, yellow oil) stored at room temperature.

**This product must not be confused with zuclopenthixol decanoate (Clopixol Depot®) 200 mg/mL, a long acting intramuscular antipsychotic injection used for maintenance therapy.**

### 2.2 Indication[1,2,4]

Zuclopenthixol acetate is indicated for treatment of acute psychoses, including mania, and exacerbations of chronic psychoses, particularly when the patient is hostile or aggressive. As the sedative action usually begins at least two hours after administration, it has no place in rapid tranquilisation or acute sedation.

In practice, zuclopenthixol acetate should be reserved as a treatment option for consumers who are displaying symptoms of acute psychosis and acute mania where other treatment modalities have been ineffective or are inappropriate and who:

- have required repeated (i.e. 2 or more) parenteral administration of short acting antipsychotics or sedative drugs to manage agitation and arousal within the last 24 hours and is predicted to require more doses of parenteral medications due to acute agitation
- have displayed acute behavioural disturbances for an extended period of time (24 - 48 hours)
- have had sufficient time for assessment of response and/or side effects of previously injected medications. Allow a minimum of 60 minutes after intramuscular (IM)and 15 minutes after intravenous (IV) administration of other sedative or antipsychotic medications (IV administration of sedatives may occur in the Emergency Department only)
- may have previously received zuclopenthixol acetate and have shown good tolerability and response to it.

Zuclopenthixol acetate must never be used:
- in an attempt to hasten response to other antipsychotics
- as an 'as required' (PRN) medication
- for acute sedation
- as a test dose for zuclopenthixol decanoate long acting injection
- in those who are antipsychotic naïve.

## 2.3 Contraindications[1,2]

Zuclopenthixol acetate must not be used for consumers who:
- have known hypersensitivity to thioxanthenes or any component of the formulation
- are acutely intoxicated with alcohol, opiates or barbiturates
- exhibit a depressed level of consciousness due to any cause
- have circulatory collapse, suspected or established subcortical brain damage
- have blood dyscrasia
- have phaeochromocytoma
- have leukopenia and/or previous agranulocytosis.

The product information must be consulted prior to prescribing for a full list of contraindications.

## 2.4 Precautions[1,2]

Before prescribing, consideration must be given to:
- physical status (including existing medical co-morbidity, dehydration, electrolytes, hypoglycaemia, organic syndromes, delirium, pregnancy status)
- level of consciousness
- possibility of intoxication with any substance
- other prescribed medications including:
  - QT prolonging medications
  - other sedating medications
  - antipsychotic and benzodiazepine medications given in the preceding 24 hours

Allow a minimum of 60 minutes after IM administration of antipsychotic or benzodiazepine medication before administering zuclopenthixol acetate.

Zuclopenthixol acetate use in the following circumstances should only be used if the anticipated benefits outweigh the risks:

- are sensitive to extrapyramidal side effects
- are pregnant
- have hepatic or renal impairment
- have cardiac disease.

The product information must be consulted prior to prescribing for a full list of precautions.

## 2.5 Prescribing[1,2]

Zuclopenthixol acetate must be prescribed in accordance with the following:

- Dose range is usually 50-150 mg IM, repeated if necessary, preferably at intervals of 2 to 3 days. In some cases, an additional injection may be given 24 to 48 hours following the first injection.
  - Females and older adults may require lower doses (25-50 mg) with no greater than 100 mg per dose being prescribed for older adult consumers.
- The total cumulative dose permissible in a 2-week period is 400 mg. In addition, the maximum number of injections must not exceed 4.
  - When prescribing it is prudent to also annotate the sequential number of each dose i.e. Dose 1, Dose 2, Dose 3, Dose 4.
  - A long-term treatment plan should be implemented by this time.
- Orders must be charted on the 'once only' section of the Hospital Medication Chart (HMC). It is unacceptable to chart doses in advance or as 'PRN' orders.
- Consumers must be medically reviewed prior to prescribing each dose.
- Treatment should not be referred to as "a course".
- Concomitant psychotropic medication must be reviewed, with consideration of withholding other antipsychotics for the duration of zuclopenthixol acetate therapy and expected action (i.e. up to 72 hours after the last dose).

## 2.6 Administration[1,2]

Zuclopenthixol acetate is administered by deep intramuscular injection into a large muscle (upper outer quadrant of gluteal or lateral thigh).

Administration to a consumer who is physically struggling and resistant to injection is not recommended due to the increased risk of accidental extravasation.

## 2.7 Monitoring[1,2,5]

Administration of zuclopenthixol acetate results in the following profile:

- sedation from 2-4 hours post injection
- peak plasma concentration 24-36 hours post injection
- significant effects may last up to 72 hours
- medication may not be fully eliminated for 7 days.

The following monitoring is recommended:

- baseline temperature (T), blood pressure (BP), heart rate (HR), respiration rate (RR), oxygen saturation (SaO2) and electrocardiogram (ECG)
- monitor T, BP, HR, RR, SaO2
  - every 15 mins for the first hour then
  - 1-hourly for 3 hours then

  - 2-hourly for 4 hours then
  - 4-hourly thereafter for 48 hours
- when patients are asleep (including during the night) RR monitoring should be increased to hourly and documented
- a repeat ECG is recommended at 24 hrs and 48 hrs post injection if possible
- fluid balance to be monitored to ensure adequate hydration levels.

All vital observations are to be recorded on the MR140a WACHS Adult Observation and Response Chart (A-ORC). Abnormal readings must be responded to as per the escalation criteria. Staff must also abide by the WACHS Recognising and Responding to Acute Deterioration (RRAD) Procedure.

More frequent monitoring may be required especially in the following scenarios; in older adult or physically vulnerable consumers, if any concomitant sedating medication has been given, or if appearing asleep/sedated. Alterations to monitoring regimes must be documented by a medical officer in the progress notes and on the A-ORC.

Where the consumer declines to comply with monitoring requirements, this must be documented in the health care record and the prescriber notified.

See Appendix 1 for a table of recommended monitoring

### 2.8 Adverse Effects[2,3]

Access to emergency resuscitation equipment and rescue medications is a requirement of prescribing zuclopenthixol acetate.

The following table outlines potential side effects and their management:

| Side effect | Management |
|---|---|
| Acute dystonic reaction | Give benzatropine 1-2 mg IM stat. Repeat after 20 minutes if required.<br>Oral benzatropine can be given if symptoms are mild and do not affect the airway.<br>Benzatropine is not to be given routinely as a prophylactic measure - prescribe as a PRN medication. |
| Hypotension | Lie patient flat and elevate legs<br>Monitor closely |
| Increased temperature | Medical review (consider neuroleptic malignant syndrome)<br>Withhold antipsychotics, perform ECG, check creatinine kinase levels |
| Cardiac abnormalities – arrhythmia, heart rate of concern, prolonged QTc | Medical review<br>Withhold antipsychotics<br>Monitor closely |
| Respiratory depression<br><br>(or evidence of respiratory distress or obstruction) | Initiate Code Blue Emergency<br>Give oxygen, raise legs, ensure patient is not lying face down<br>Emergency medical assistance and mechanical ventilation required |

| | |
|---|---|
| | Note: If due to benzodiazepine co-prescription, flumazenil may be required. |
| Unable to rouse | Initiate Code Blue Emergency |

## 3. Roles and Responsibilities

**Regional Mental Health Clinical Director** has overall responsibility for:
- ensuring services are delivered in accordance with this procedure
- authorising the use of zuclopenthixol acetate in any area outside of a Mental Health Inpatient Unit (Note: In the event the Regional Mental Health Clinical Director is unavailable, the Consultant Psychiatrist – Mental Health Emergency Telehealth service assumes this responsibility).

**Regional Managers/Inpatient Managers** are to:
- provide orientation and education to relevant WACHS clinicians and staff on the use of this guideline
- ensure adequate equipment and facilities are available to support use of this medication.

**Consultant Psychiatrist or Medical Officer acting under the supervision of a Consultant Psychiatrist**
- Review patient prior to prescribing each dose and thereafter for effect or adverse effects.
- Complete order for medication on the appropriate chart, in the appropriate section.
- Document any modifications to monitoring parameters on the A-ORC.
- Review recorded observations (including ECG) and respond as appropriate.

**Registered Nurse**
- Administer zuclopenthixol acetate in accordance with this guideline and the WACHS Medication Prescribing and Administration Policy.
- Perform and record monitoring requirements.
- Escalate and respond to abnormal monitoring results in accordance with the A-ORC, any chart modifications and this guideline.

**Pharmacist (where available)**
- Endorse medication as suitable to administer.
- Escalate any issues with regards to prescription or administration.
- Provide clinical information regarding prescribing and administration of zuclopenthixol acetate.
- Ensure supply arrangements.

**All staff** are required to work within policies and guidelines to make sure that WACHS is a safe, equitable and positive place to be.

## 4. Monitoring and Evaluation

### 4.1 Monitoring

Managers of clinical areas, health sites and services are responsible for monitoring compliance with this policy.

Clinical incidents involving issues relating to zuclopenthixol acetate are monitored via the Datix Clinical Incident Management reporting processes. SAC 1 events are reviewed by Regional Drug and Therapeutics Committees and the WACHS Safety and Quality Steering Committee.
Any incident that meets the criteria for a notifiable incident as defined by the *Mental Health Act 2014* (WA), must be reported to the Chief Psychiatrist in accordance with the Policy for Mandatory Reporting of Notifiable Incidents to the Chief Psychiatrist.

### 4.2 Evaluation

This guideline is to be reviewed every two (2) years.

Evaluation of this guideline is to be carried out by WACHS Mental Health directorate in consultation with WACHS Pharmacy Service and regional WACHS Health Services.

Policy evaluation methods and tools may include:

- Staff feedback / consultation
- Carer and consumer feedback / consultation
- Survey
- Compliance monitoring
- Benchmarking
- Reporting against organisational targets.

## 5. Compliance

Guidelines are designed to provide staff with evidence-based recommendations to support appropriate actions in specific settings and circumstances. As such, WACHS guidelines should be followed in the first instance. In the clinical context, where a patient's management should vary from an endorsed WACHS guideline, this variation and the clinical opinion as to reasons for variation must be documented in accordance with the Documentation Clinical Practice Standard.

## 6. References

1. Clopixol Acuphase® zuclopenthixol acetate (Approved Product Information) [database on the internet] MIMS Australia [cited 05/10/2022]
2. Taylor D., Barnes T.R.E and Young A.H (2021) The Maudsley Prescribing Guidelines in Psychiatry. 14th Edition. John Wiley & Sons
3. AMH [database on the Internet]. Australian Medicines Handbook Pty.Ltd. 2022 [cited 05/10/2022]. Available from: http://www.amh.net.au
4. Jayakody K, Gibson RC, Kumar A, Gunadasa S. Zuclopenthixol acetate for acute schizophrenia and similar serious mental illnesses. *Cochrane Database of Systematic Reviews* 2012, Issue 4. Art. No:CD000525. DOI: 10.1002/14651858.CD000525.pub3
5. North Metropolitan Health Service Mental Health, Medication Policy: Zuclopenthixol Acetate (Clopixol Acuphase®) Prescribing [cited 05/10/2022]

## 7. Definitions

Nil

## 8. Document Summary

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|---|---|
| **Coverage** | WACHS wide |
| **Audience** | Medical, nursing and pharmacy staff working in acute care settings where zuclopenthixol acetate may be prescribed and administered |
| **Records Management** | Clinical: Health Record Management Policy |
| **Related Legislation** | • *Mental Health Act 2014* (WA)<br>• *Medicines and Poisons Act 2014* (WA) |
| **Related Mandatory Policies / Frameworks** | • Clinical Governance, Safety and Quality Framework<br>• Mental Health Framework<br>• MP 0122/19 - Clinical Incident Management Policy<br>• MP 0175/22 - Consent to Treatment Policy<br>• MP 0131/20 - High Risk Medication Policy<br>• MP 0078/18 - Medication Chart Policy<br>• MP 139/20 - Medicines Handling Policy<br>• MP 0104/19 - Medication Review Policy<br>• MP 0171/22 - Recognising and Responding to Acute Deterioration Policy<br>• MP 0077/18 - Statewide Medicines Formulary Policy |
| **Related WACHS Policy Documents** | • Adults with Impaired Decision Making Capacity Procedure<br>• Clinical Observation and Assessments Clinical Practice Standard<br>• Documentation Clinical Practice Standard<br>• High Risk Medications Procedure<br>• Medication Prescribing and Administration Policy<br>• Recognising and Responding to Acute Deterioration (RRAD) Policy<br>• Recognising and Responding to Acute Deterioration (RRAD) Procedure |
| **Other Related Documents** | • WA Health Guidelines for Managing Specific High Risk Medications Relevant to the Organisation<br>• WA Chief Psychiatrist Policy for Mandatory Reporting of Notifiable Incidents to the Chief Psychiatrist |
| **Related Forms** | • MR140A WACHS Adult Observation and Response Chart<br>• MR170A National Inpatient Medication Chart – Adult Short Stay<br>• MR171 National Inpatient Medication Chart – Adult Long Stay |
| **Related Training Packages** | High Risk Medications: Introduction (HRMINT EL2) |
| **Aboriginal Health Impact Statement Declaration (ISD)** | ISD Record ID: 2158 |
| **National Safety and Quality Health Service (NSQHS) Standards** | 4.01, 4.03, 4.04, 4.11, 4.13, 4.15, 5.01, 5.11, 5.12, 5.13, 5.33, 5.34, 8.04-8.13 |

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| **Aged Care Quality Standards** | N/A |
| **National Standards for Mental Health Services** | 1.2, 1.3, 1.6, 2.4, 6.8, 6.9, 8.4, 8.7, 10.5.1, 10.5.2, 10.5.3, 10.5.5, 10.5.6, 10.5.7, 10.5.8, 10.5.10 |

## 9. Document Control

| Version | Published date | Current from | Summary of changes |
|---|---|---|---|
| 2.00 | 30 June 2023 | 30 June 2023 | • Title Change<br>• Expanded scope to include indication, contraindications and precautions, prescribing, administration and management of adverse reactions<br>• Clarification of jurisdiction and authority to prescribe<br>• Further detailing of roles and responsibilities |

## 10. Approval

| | |
|---|---|
| **Policy Owner** | Executive Director Mental Health |
| **Co-approver** | Executive Director Clinical Excellence<br>Executive Director Nursing and Midwifery |
| **Contact** | Director of Psychiatry – Clinical Governance, Mental Health |
| **Business Unit** | WACHS Mental Health |
| **EDRMS #** | ED-CO-18-50025 |



**This document can be made available in alternative formats on request.**

## Appendix 1: Recommended monitoring post zuclopenthixol acetate (Acuphase®) injection*

| Time point | Observations | Date/Time | Initials | Comments |
|---|---|---|---|---|
| Baseline | T, HR, BP, RR, O2 sat, ECG | | | |
| Acuphase® administered | - | | | |
| 15mins | T, HR, BP, RR, O2 sat | | | |
| 30mins | T, HR, BP, RR, O2 sat | | | |
| 45mins | T, HR, BP, RR, O2 sat | | | |
| 60mins | T, HR, BP, RR, O2 sat | | | |
| 2 hours | T, HR, BP, RR, O2 sat | | | |
| 3 hours | T, HR, BP, RR, O2 sat | | | |
| 4 hours | T, HR, BP, RR, O2 sat | | | |
| 6 hours | T, HR, BP, RR, O2 sat | | | |
| 8 hours | T, HR, BP, RR, O2 sat | | | |
| 12 hours | T, HR, BP, RR, O2 sat | | | |
| 16 hours | T, HR, BP, RR, O2 sat | | | |
| 20 hours | T, HR, BP, RR, O2 sat | | | |
| 24 hours | T, HR, BP, RR, O2 sat ECG | | | |
| 28 hours | T, HR, BP, RR, O2 sat | | | |
| 32 hours | T, HR, BP, RR, O2 sat | | | |
| 36 hours | T, HR, BP, RR, O2 sat | | | |
| 40 hours | T, HR, BP, RR, O2 sat | | | |
| 44 hours | T, HR, BP, RR, O2 sat | | | |
| 48 hours | T, HR, BP, RR, O2 sat ECG | | | |

**When patients are asleep (including during the night) RR monitoring should be increased to hourly**

***This table can be used as a prompt – all observations must be documented on the A-ORC**