

## Guidelines for the Safe Use of Clopixol Acuphase<sup>®</sup> (zuclopenthixol acetate)

Presentation	Ampoules containing zuclopenthixol acetate 50 mg per 1 ml					
Indication	Clopixol Acuphase <sup>®</sup> is licensed as "initial treatment of acute psychoses, including mania & exacerbation of chronic psychoses, particularly where duration of effect of 2-3 days is desirable"					
Objectives of care	To alleviate distress and the requirement for repeated administration of rapid tranquillisation (RT) medication for disturbed / violen behaviours					
Place in therapy	<ul> <li>The decision to treat with Acuphase<sup>®</sup> can only be made by a consultant psychiatrist, senior registrar (ST4 or above*) or level 3 non-medical prescriber (NMP) if within their knowledge and competence.</li> <li>The decision to initiate should be made with the full MDT to complete the optimal risk/benefit assessment for the individual, therefore this decision is best made in hours. On call registrars (ST4 or above*) can initiate or prescribe further doses but should seek consultant advice if needed.</li> <li>There is inadequate data &amp; no convincing evidence to support use of Acuphase<sup>®</sup> in acute psychiatric emergency (Cochrane Library)</li> <li>The onset of action of Acuphase<sup>®</sup> is not as rapid as may be believed or required (peaks in 24-36 hours)</li> <li>Acuphase<sup>®</sup> should never be considered as a first-line drug for rapid tranquilisation (RT), unless such practice is in accordance with an advanced directive</li> <li>Acuphase<sup>®</sup> should <u>not</u> be used: <ul> <li>In an attempt to hasten the antipsychotic effect of another therapy</li> <li>As a test dose for zuclopenthixol decanoate depot</li> <li>In community-based settings</li> </ul> </li> <li>*ST4 doctor or above with membership of the Royal College of Psychiatrists (or equivalent professional body of home country).</li> </ul>					
Patient criteria for inclusion	<ul> <li>18 years or over</li> <li>Disturbed / violent behaviours over an extended time period</li> <li>Where RT has been required repeatedly or has been ineffective, i.e., haloperidol and/or sedative drugs (and non-pharmacological de-escalation) should have been used first - See <u>Rapid Tranquilisation Policy</u></li> <li>Prior history of previous use &amp; good response, with use defined in an advance directive</li> </ul>					
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	Approved by         Drug & Therapeutics Committee         Date of Approval         22nd September 2022					

Date of Review

1<sup>st</sup> October 2025

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Patient criteria for exclusion	<ul> <li>Under 18 years of age</li> <li>Intoxication with alcohol / unconscious</li> <li>Antipsychotic naïve or no previous trial of a potent dopamine antagonist e.g. Haloperidol (PO/IM), Risperidone, Zuclopenthixol</li> <li>Accepting oral medication</li> <li>Known sensitivity to EPSEs</li> <li>Pregnancy &amp; breast-feeding</li> <li>Any contra-indications or cautions without a documented assessment of the risks &amp; benefits (see <u>SPC</u> for details)</li> <li>Myasthenia gravis</li> <li>Parkinson's disease</li> <li>Cardiac disease</li> <li>Epilepsy</li> <li>Renal or hepatic impairment</li> </ul>
Alternatives to Acuphase <sup>®</sup>	<ul> <li>Zuclopenthixol is a higher potency dopamine antagonist. If a patient is treatment naïve or if they have not received a medication with potency equal to or higher than risperidone there is a <u>risk of severe EPSEs</u> that may be prolonged due to duration of action (consider discussing with pharmacy).</li> <li>Consider oral Zuclopenthixol 20 mg twice daily and titrating according to response</li> <li>&gt; Oral is a more reversible and a less restrictive option</li> <li>&gt; Each dose peaks in 3-6 hours</li> <li>&gt; Steady state plasma levels are reached in 72 hours; similar plasma levels are achieved with oral compared to Acuphase<sup>®</sup></li> </ul>
Prescribing guidance	<ul> <li>Each dose should be prescribed in the "once only" section of the inpatient prescription chart</li> <li>Dose range: - 50 mg (1 ml) to 150 mg (3 ml); adjusted to the severity of the patient's illness         <ul> <li>Maximum dose per injection for an older patient is 100 mg (2 ml)</li> <li>accumulated dosage must not exceed 400 mg (or 4 injections) in a 2-week period</li> </ul> </li> <li>Prescribe Procyclidine oral and IM when required</li> <li>Review co-prescribed antipsychotics (Oral, IM and depot) - these would usually be discontinued; consider withholding other antipsychotics for the duration of action (2-3 days following administration)</li> <li>Acuphase<sup>®</sup> should be included in HDAT calculations to determine if additional monitoring is required for <u>7 days</u> following administration. 100% BNF max (AMH) = 75 mg / day; 150 mg within any 48-hour periods; 400 mg within any 2-week period</li> </ul>

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Administration	<ul> <li>Allow 30-60 mins to establish response from previously administered IM medications before giving Acuphase<sup>®</sup></li> <li>Administer Acuphase<sup>®</sup> by deep intramuscular injection into the upper outer buttock or lateral thigh</li> <li>Caution is required if considering RT (especially antipsychotics) during treatment with Acuphase<sup>®</sup>, as excessive sedation and/or aggravated adverse events may occur if the patient is exposed to high plasma levels of multiple drugs</li> <li>Administration of other IM medication within 60 minutes of Acuphase<sup>®</sup> should only be considered in exceptional circumstances, and only under the authorisation of a consultant, NMP L3, registrar ST4 or above.</li> </ul>
Physical health Monitoring	<ul> <li>Sedative effects can appear within 2 hours of injection &amp; may peak at 24-36 hours. Significant effects last up to 72 hours but can persist for up to 7 days</li> <li>The patient must be carefully monitored after each injection; this should be documented using NEWS2 documentation.</li> <li>Physical health parameters should normally be monitored as follows:</li> <li>&gt; 15 and 30 minutes after injection, then</li> <li>&gt; At 1, 2, 4, 6, 8, 12, 18, 24, 30, 36, 42 &amp; 48 hours</li> <li>If a patient refuses observations a minimum of respiratory rate and level of alertness should be recorded</li> </ul>
Review and assessing need for further doses	<ul> <li>The decision to prescribe subsequent doses should be made by the consultant following a review of the patient at a suitable time interval after the last dose</li> <li>A dose may be prescribed/authorised by regular consultant, as part of treatment plan, prior to an out of hours period</li> <li>Acuphase<sup>®</sup> should not be viewed as a course of treatment</li> <li>If further doses are required, ideally 2-3 days should be left between administrations to allow assessment of response</li> <li>A minimum interval of 24 hours should be left between doses.</li> <li>The accumulated dosage must not exceed 400 mg (or 4 injections) in a 2-week period</li> <li>Due to the prolonged duration of action, restarting / commencement of oral antipsychotics should be delayed until 2-3 days after the last dose of Acuphase<sup>®</sup></li> </ul>

References:Summary of Product Characteristics – Clopixol Acuphase®. Lundbeck Ltd, last updated 4th July 2022<br/>The Maudsley Prescribing Guidelines, 14th edition, 2021<br/>The Psychotropic Drug Directory 2020/21. Stephen Bazire<br/>Antipsychotic Dosage Ready Reckoner v9.1 (July 2021), POMH-UK

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