Guidelines for the use of zuclopenthixol acetate (Clopixol Acuphase®) injection

Version 3 – August 2015

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Guidelines for the use of zuclopenthixol acetate (Clopixol Acuphase®) Injection

Introduction

In the past, Acuphase® has often been too widely and possibly inappropriately used, sometimes without full regard being given to the fact that it is a potentially hazardous and toxic preparation with very little published information to support its use. Indeed, the Cochrane Library concludes that there is inadequate data on Acuphase® and no convincing evidence to support its use in acute psychiatric emergency. So far as possible, it should therefore be reserved for the minority of patients who have a prior history of previous use and good response, with use defined in an advance directive. Similarly, as a general rule Acuphase® should not be used for rapid tranquillization unless such practice is also in accordance with an advance directive.

Normally, Acuphase® should never be considered as a first-line drug for rapid tranquillization as its onset of action will often not be rapid enough in these circumstances. In addition, the administration of an oil-based injection carries very high risk in a highly agitated patient.

Acuphase® should never be administered:
- In an attempt to hasten the antipsychotic effect of other therapy
- To a patient who is physically resistant, due to risk of intravasation

Acuphase® should never be used for patients:
- Who will accept oral antipsychotic medication
- Who are antipsychotic naïve
- Who are known to be sensitive to extrapyramidal side effects
- Who are unconscious
- Who are pregnant or are breast-feeding
- Who are known to have cardiac disease or renal or hepatic impairment
- Use outside the inpatient setting is not recommended, as the patient will require close monitoring over a full 24-hour period.

Licensed Use

Acuphase® is licensed as “initial treatment of acute psychoses, including mania and exacerbation of chronic psychoses, particularly where a duration of effect of 2-3 days is desirable”.

It is important to recognise that onset of action is not as rapid as may be believed or required, particularly where rapid tranquillization is needed.

Therefore, Acuphase® should only be used after an acutely psychotic patient has required repeated injections of short-acting antipsychotics such as haloperidol or olanzapine, and/or sedative drugs such as lorazepam, and these have not been effective. (Unless there is an advance directive for its use).
Further to this, Acuphase® should be given only when enough time has elapsed to fully assess the response to previously injected drugs, i.e., at least 15 minutes after IV injections and at least 60 minutes after those administered intramuscularly.

Consideration should be given to zuclopenthixol plasma levels reaching a peak approximately 24-36 hours after administration of an Acuphase® dose. Caution must therefore be applied if consideration is being given to the administration of a short-acting psychotropic IM injection during treatment with Acuphase®, as excessive sedation and/or aggravated adverse events may occur if the patient is exposed to high plasma levels of multiple drugs.

**Dose**

Acuphase® is licensed at a dose of 50mg to 150mg, (1-3ml), repeated if necessary after 2 or 3 days. (Some patients may need an additional injection between 1 and 2 days after the first, although at least 24 hours should be left between doses). The maximum dose per injection for an elderly patient is 100mg (2ml).

**For all patients the accumulated dosage must not exceed 400mg, (or 4 injections), within a 2-week period.**

Acuphase® should not be viewed as a course of treatment and the patient should be carefully reviewed before each dose is prescribed / administered. The maximum licensed duration ensures that a treatment plan is put in place for the patient. More frequent administration or a more prolonged treatment period is not within the terms of the product license and should only occur in very exceptional circumstances.

The patient must be carefully monitored after each injection and a specific recording sheet is available for this purpose and should be retained in the patient’s notes following completion. The exact monitoring frequency is shown on the recording sheet. (See appendix).

If used to good effect and the patient feels that they may benefit from its use in the future, then consideration should be given to the preparation of an advance directive.

**Onset and Duration of Action**

Sedative effects of Acuphase® usually begin to appear within 2 hours of injection and may not reach a peak for another 24 to 36 hours. Significant effects may last for up to 72 hours although full elimination of the drug may not be complete for 7 days.

**Cross-Reference**

This guidance document should be read in conjunction with the Trust’s Rapid Tranquillisation Policy.

**References.**

- Summary of Product Characteristics – Clopixol Acuphase®. Lundbeck Ltd, August 2015
Appendix 1

Zuclopenthixol Acetate (Clopixol Acuphase®) - Record of Post-Administration Observations – version 3

In normal circumstances this monitoring form should be completed and retained in the patient's notes whenever Acuphase® is administered. **If the patient is uncooperative but fully alert and able to walk around then the first column only need be ticked.** If there are occasions when the patient is not fully alert but close monitoring is not possible or is considered inappropriate, this should be clearly documented in the patient's notes.

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<th>Time since administered</th>
<th>Time (24-hr clock)</th>
<th>Wide awake but uncooperative</th>
<th>BP</th>
<th>Temp (°C)</th>
<th>Pulse or oximeter*</th>
<th>Respiration Rate</th>
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*A pulse oximeter reading need only be taken if the patient is asleep or unconscious*