

Off-label Use of Atropine Eye Drops for Clozapine-Induced Hypersalivation

SA Health staff are advised against the use of off-label atropine eye drops for the treatment of clozapine-induced hypersalivation.

A 2014 coroner's investigation into the accidental death of a patient was attributed to accidental ingestion of a toxic quantity of atropine eye drops prescribed off-label for sublingual administration. Expert toxicology opinion determined that the concentration of atropine found in the patient was 50-100 times the expected therapeutic dose. In addition, it was noted that:

- the plastic eye drop bottle was very easy to empty with a gentle squeeze
- the dose taken by the deceased was at least 6-8 mL of the solution
- higher systemic exposure is expected from sublingual administration of atropine eye drops compared with oral administration (tablets) due to bypassing of first-pass metabolism and therefore toxicity is expected to be seen at lower sublingual doses than oral ones

TGA and SA Health Response:

The Therapeutic Goods Administration (TGA) circulated a Medicines Safety Update (Vol 9, number 3, August-September 2018) warning to health professionals to exercise extreme caution when considering off-label prescribing of atropine eye drops for hypersalivation.

Atropine eye drops are not approved by the TGA for use sublingually to treat hypersalivation and are only listed on the SA Health Medicines Formulary for use in eye examinations and procedures.

Use of atropine eye drops for hypersalivation in SA Health public hospitals and health services for an individual patient must therefore be approved by the relevant Local Health Network Quality Use of Medicines or Drug and Therapeutics Committee (individual patient use (IPU) request), prior to commencement.

Alternative Treatment Option(s)

Hyoscine hydrobromide tablets are listed on the SA Medicines Formulary for clozapine patients with hypersalivation which is consistent with The Maudsley Prescribing Guidelines in Psychiatry (available via SALUS).

SA Health will subsidise prescriptions written by SA Health prescribers, dispensed in SA Health hospital pharmacy.

Prescribers are to be mindful of:

- dose: 300 microgram sucked or chewed up to three times a day, when required
- possible anticholinergic/antimuscarinic side effects including constipation
- potential ongoing cost to consumers as this indication is off-label and therefore not reimbursed under PBS
- ensuring an adequate treatment plan is in place
- other alternatives listed in The Maudsley Prescribing Guidelines that may be considered for individual consumers (will require IPU request)

For more information

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