

21 - Examples of acceptable use of drugs outside t

Examples of acceptable use of drugs outside their licences/labels

Prescribing psychotropics CHAPTER 14 The advice is largely echoed by more recent publications from the American Psychiatric Association¹⁷ (who note that off-label prescribing should be reimbursed) and the Royal Australian and New Zealand College of Psychiatrists¹⁸ who emphasise shared decision-making and the presumption of capacity. Examples of acceptable use of drugs outside their licences/labels Table 14.5 gives examples of common unlicensed uses of drugs in psychiatric practice. These examples would all fulfil the Bolam and Bolitho criteria in principle. An exhaustive list of unlicensed uses is impossible to prepare as the evidence base is constantly changing and because the expertise and experience of prescribers vary. A particular strategy may be justified in the hands of a specialist in psychopharmacology based in a tertiary referral centre but be much more difficult to justify if initiated by someone with a special interest in psychotherapy who rarely prescribes. Note that some drugs do not have a UK licence for any indication. Two commonly prescribed examples in psychiatric practice are immediate-release formulations of melatonin (used to treat insomnia in children and adolescents) and pirenzepine (used to treat clozapine-induced hypersalivation). Awareness of the evidence base and documentation of potential benefits, adverse effects and patient consent are especially important here. Table 14.5 Examples of common unlicensed uses of drugs in psychiatric practice. Drug/drug group Unlicensed use(s) Further information Second-generation antipsychotics Psychotic illness other than schizophrenia Licensed indications vary markedly, and in most cases are unlikely to reflect real differences in efficacy between drugs. Clozapine Bipolar disorder Substantial evidence to support efficacy when standard treatments have failed to control symptoms Cyproheptadine Akathisia Some evidence to support efficacy in this distressing and difficult to treat adverse effect of antipsychotics Fluoxetine/sertraline Generalised anxiety disorder Substantial supporting evidence Ketamine (racemate) Refractory depression Substantial evidence with both racemate and S-isomer Melatonin (circadin) Insomnia in children Licence covers adults >55 years only. Probably preferable to unlicensed formulations of melatonin. Naltrexone Self-injurious behaviour in people with learning

disabilities Limited evidence base Acceptable in specialist hands Sodium valproate Treatment and prophylaxis of bipolar disorder Established clinical practice Evidence from other valproate preparations

Revision #1

Created 2026-01-04 20:18:36 UTC by Omar Ayman

Updated 2026-01-04 20:18:36 UTC by Omar Ayman