

GUIDELINES FOR THE USE OF ASENAPINE MALEATE

Summary

Asenapine maleate is an oral antimanic drug for the treatment of adult patients who:

- Are unable to tolerate other antimanic drugs
- Who are NOT non-adherent and for who a depot antipsychotic is not indicated

Asenapine maleate is **not** indicated for schizophrenia, or for unlicensed indications.

Asenapine will only be supplied for named individuals using the Named Patient Request Form appended to this document.

Asenapine maleate may only be initiated by Consultant Psychiatrist

Asenapine maleate may be considered for patients who might otherwise require intramuscular antimanic medication. It might also minimize the need for concurrent benzodiazepine sedation.

Asenapine maleate is indicated for acute mania and is administered by a sublingual tablet, with rapid absorption, within seconds, making it less likely the patient would spit out or palm the tablets. It should not be swallowed as bioavailability is very low by this route (<2%). The sublingual route bypasses the first-pass metabolism, leading to a more rapid onset of action. It must not be chewed or swallowed. Eating and drinking should be avoided for at least 10 minutes following administration, and if taken in combination with other medication, asenapine should be taken last.

Asenapine maleate has been associated with ***anaphylactic reactions***. In the USA, 52 cases in 235000 prescriptions (1:4700), in 87000 patients (1:1740). These reactions have occurred even on the first dose, suggesting cross-reactivity from previous exposure to (as yet unidentified) other drugs. For this reason, the initial dose of asenapine should be given at a venue where medical assistance is available onsite.

Asenapine maleate is **expensive** compared with many other oral antimanic drugs. It costs £102.60 per month (5mg or 10mg twice daily).

1. Prescribing

1.1 Indications – treatment of moderate to severe manic episodes associated with bipolar disorder.

1.2 Dose – Monotherapy – Adult over 18 years – initially 10mg twice daily, reduced to 5mg twice daily according to response

- Combination therapy – Adult over 18 years – initially 5mg twice daily, increased if necessary to 10mg twice daily according to response.

2. Cautions

- 2.1 General cautions for antipsychotics and dementia with Lewy Bodies
- 2.2 Hepatic impairment – no dose adjustment in mild impairment, caution in moderate impairment. Avoid in severe impairment
- 2.3 Renal impairment – use with caution if eGFR is less than 15ml/min
- 2.4 Pregnancy – asenapine should not be used in pregnancy unless necessary and the potential benefits clearly outweigh the risk to the foetus
- 2.5 Breast feeding – asenapine should be avoided
- 2.6 QT interval – asenapine does not affect QT interval, but caution should be exercised when prescribing it to patients with known cardiovascular disease or family history of QT interval prolongation and in concomitant use with other drugs that prolong QT interval.

3. Side effects

Very common side effects include – anxiety, somnolence

Common side effects include – Weight increase, appetite increase, dystonia, akathisia, dyskinesia, Parkinsonism, sedation, dizziness, dysgeusia, oral hypoaesthesia, muscle rigidity, fatigue

Uncommon side effects include – hyperglycaemia, syncope, seizure, dysarthria, orthostatic hypotension, swollen tongue, dysphagia, glossodynia, oral paraesthesia, sexual dysfunction

4. Other considerations

- 4.1 Efficacy and safety have not been established in patients over 65 years. If used, lower doses should be considered, particularly if renal function is impaired. Asenapine has not been studied in people with dementia and should not be used.
- 4.2 Asenapine is not licensed for use in patients under 18 years – no safety or efficacy data is available.
- 4.3 A lower loading and maintenance dose should be used in renal impairment. See manufacturers SPC
- 4.4 No dosage adjustment is required in mild or moderate hepatic impairment. Avoid in severe hepatic impairment.

5. Monitoring

There are no specific monitoring requirements

6. Cost comparison

Drug	Dose	Cost per month
Asenapine	10mg daily or 20mg daily	£51.30 or £102.60
Olanzapine (generic)	10mg daily 15mg daily 20mg daily	£1.59 £1.66 £2.68
Olanzapine orodispersible (generic)	10mg daily 15mg daily 20mg daily	£49.93 £48.79 £79.93
Aripiprazole	10mg daily 15mg daily 20mg daily 30mg daily	£1.28 £1.34 £2.56 £2.62
Aripiprazole Orodispersible	10mg daily 15mg daily 20mg daily 30mg daily	£34.81 £31.94 £69.62 £104.43

Prices from Drug Tariff November 2012

**ASENAPINE MALEATE ORAL TABLETS
NAMED PATIENT REQUEST FORM**

This form must be completed for each patient initiated on asenapine maleate tablets

Patient Name	Date of Birth
Name of Ward/Team	
Name of initiating Consultant	
Signature of initiating consultant	
Name of Head of Psychiatry	
Signature of Head of Psychiatry	

- I understand that the Trust will remain responsible for prescribing and that referral cannot be made to Primary Care for continuation of prescribing
- The patient will have the initial dose of asenapine given at a venue where medical assistance is available on-site

Once approval has been given by the Head of Psychiatry, this form should be sent to Jagdip Bahia (Jagdip.bahia@nhs.net) for authorisation for the drug to be supplied. A prescription should then be sent to the supplier (Lloyds Pharmacy) in the usual way.

Jagdip Bahia
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