GUIDELINES FOR PRESCRIBING LURASIDONE FOR BIPOLAR

Summary

- In the UK Lurasidone is only licensed for the treatment of schizophrenia in patients aged 18 years and over. It is not indicated for Treatment Resistant Schizophrenia or any stages of bipolar illness.
- In the U.S.A it is also approved for depressive episodes associated with Bipolar I Disorder (bipolar depression), as monotherapy and as adjunctive therapy with lithium or valproate.
- The 13th edition of the Maudsley Guidelines recommends Lurasidone as a treatment for bipolar depression and prophylaxis if it was effective in an acute episode
- In KMPT Lurasidone is approved for third-line use after two previous antipsychotics or mood stabilisers have been tried. It can be used to treat an episode of depression as monotherapy or in combination with lithium or valproate. It may be continued as prophylaxis if it was effective in an acute episode.
- Lurasidone may only be initiated by a Consultant Psychiatrist, who must have gained the approval from the relevant Head of Psychiatry, using the named-patient form in this guideline.
- Lurasidone should be given once daily, with a meal. If taken without food, the plasma levels achieved will be significantly lower, which will reduce the efficacy
- The USA SPC states: 'The recommended starting dose of LATUDA is 20 mg given once daily as monotherapy or as adjunctive therapy with lithium or valproate. Initial dose titration is not required. LATUDA has been shown to be effective in a dose range of 20 mg per day to 120 mg per day as monotherapy or as adjunctive therapy with lithium or valproate. The maximum recommended dose, as monotherapy or as adjunctive therapy with lithium or valproate, is 120 mg per day. In the monotherapy study, the higher dose range (80 mg to 120 mg per day) did not provide additional efficacy on average, compared to the lower dose range (20 to 60 mg per day)'.

1. Prescribing

1.1 Lurasidone is approved for third-line use after two previous antipsychotics or mood stabilisers have been tried. It can be used to treat an episode of depression as monotherapy or in combination with lithium or valproate. It may be continued as prophylaxis if it was effective in an acute episode.

1.2 There is no specific guidance when switching to lurasidone from other antipsychotics or mood stabilisers. Guidance should be sought from a pharmacist

1.3 There is no specific guidance when switching to lurasidone from a long-acting antipsychotic injection. Guidance should be sought from a pharmacist

1.4 Lurasidone is available as 18.5mg, 37mg and 74mg tablets in the UK and the suggested dose for depressive episodes associated with bipolar I is therefore 18.5mg – 74mg

2. Other dosing recommendations

2.1 Dose recommendations for elderly patients with normal renal function are the same as younger adults. There are limited data to support the use of higher doses in the elderly and no data for 148mg dose. Caution is required if treating elderly patients with higher doses. Lurasidone should not be used in patients with dementia.

2.2 Lurasidone is not licensed for use in patients under 18 years of age

2.3 No dosage adjustment is required in patients with mild renal impairment. In moderate and severe renal impairment, the recommended starting dose is 18.5mg. In moderate impairment the maximum dose should not exceed 74mg once daily and in severe impairment, should not exceed 37mg once daily.

2.4 No dosage adjustment is required in patients with mild hepatic impairment. In moderate and severe hepatic impairment, the recommended starting dose is 18.5mg. In moderate impairment the maximum dose should not exceed 74mg once daily and in severe impairment, should not exceed 37mg once daily.

2.5 Concomitant treatment with a potent CYP3A4 inducer or inhibitor such as carbamazepine, phenytoin, rifampicin, St John's Wort, clarithromycin, ketoconazole, itraconazole or protease-inhibitors is contra-indicated.

2.6 Concomitant treatment with a moderate CYP3A4 inhibitor such as amiodarone, diltiazem, erythromycin, fluconazole or verapamil, the starting dos should be reduced to 18.5mg and the maximum dose should not exceed 74mg

2.7 There are limited data regarding the use of lurasidone during pregnancy, therefore it should not be used unless the potential benefits clearly outweigh the risks. It is not known whether lurasidone is excreted in breast milk, therefore it should not be used during breast feeding unless the potential benefits clearly outweigh the risks.

2.8 Patients on higher doses than 111mg daily who miss more than 3 doses should be restarted at 111mg once daily and titrated upwards based on tolerability and clinical response. For doses 111mg and below, patients can be restarted on their previous dose without titration.

3. Administration

3.1 Lurasidone are film-coated and should be swallowed whole in order to mask the bitter taste

3.2 Lurasidone should be taken once daily, with a meal, at or around the same time each day to aid compliance. Lurasidone may not be suitable for people with erratic eating habits or who are unwilling to take the tablets with a meal

3.3 Lurasidone must be taken with a meal, otherwise levels of absorption are reduced, optimal plasma levels will not be reached and efficacy may be compromised.

4. Cost

Lurasidone is very expensive compared with generic oral antipsychotics. The patent has expired on aripiprazole and generic versions are available, although the drug tariff price has not yet reduced significantly

Drug	**Dose**	**Cost per 28 days** (Drug Tariff June 2015)
Lurasidone	37mg once daily 55.5mg (37+18.5) once daily 74mg once daily 111mg (74+37) once daily 148mg (74+74)once daily	£91 £181 £91 £181 £181
Aripiprazole	10mg once daily 15mg once daily 20mg once daily 30mg once daily	£88.93 £88.93 £177.85 £177.85
Olanzapine	10mg once daily 15mg once daily 20mg once daily	£1.59 £1.67 £1.96
Quetiapine IR	150mg twice daily 200mg twice daily 300mg twice daily	£2.50 £3.03 £3.96
Risperidone	1mg twice daily 2mg twice daily	£2.88 £1.57

LURASIDONE NAMED PATIENT REQUEST FORM

This form must be completed for each patient initiated on lurasidone

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 confirm that lurasidone is being used to treat bipolar depression and the patient has already tried at least 2 mood stabilisers or antipsychotics
- I confirm that I have discussed with the patient and/ or carer the need to take lurasidone with a meal
- I confirm that the patient will be closely monitored for efficacy and tolerability, using the Glasgow Antipsychotic Side effect Scale (GASS), and that a full assessment will be carried out at 3 months, 6 months and regularly thereafter
- I understand that the Trust will remain responsible for prescribing until the patient is stabilised on the drug, and only at that point may the GP be approached to take over prescribing responsibility, although they are not obliged to do so

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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