

## GUIDELINES FOR THE USE OF PALIPERIDONE PALMITATE INJECTION

### Summary

Paliperidone Palmitate long-acting injection (LAI) is indicated for the maintenance treatment of adult patients with schizophrenia who:

- Have responded to oral risperidone but who are non-compliant

Paliperidone Palmitate LAI is **not indicated** for treatment-resistant schizophrenia, unlicensed indications or for people intolerant of oral risperidone (or oral paliperidone).

KMPT has approved the use of Paliperidone Palmitate LAI for the following unlicensed indications:

- Bipolar prophylaxis where oral risperidone has proven efficacy for the patient but long-term oral medication is not appropriate
- Schizoaffective disorder whose condition has been stabilised with oral risperidone

schizoaffective

Paliperidone Palmitate LAI will only be supplied for named individuals using the Named Patient Request Form appended to this document

Paliperidone LAI may only be initiated by Consultant Psychiatrist.

Paliperidone LAI is intended for **once-monthly injection – i.e once per calendar month, not once every 4 weeks**. It should be given intramuscularly into the deltoid or gluteal muscle. Initial loading doses must be given into the deltoid muscle

Paliperidone LAI requires the administration of two loading doses on day 1 and day 8, but does not require oral supplementation

Paliperidone LAI is **extremely expensive** compared with typical antipsychotic depots and is also more expensive than risperidone LAI. At a dose of 100mg monthly (comparable to 50mg risperidone LAI) it costs more than £3700 per year.

### 1. Prescribing

1.1 Patients must have a history of response to oral risperidone (or oral paliperidone – N.B. not approved in KMPT)

1.2 In KMPT Paliperidone LAI is approved for use in the following indications only:

- Maintenance treatment of adult patients with schizophrenia who have responded to oral risperidone but who are non-compliant (licensed use)
- Bipolar prophylaxis where oral risperidone has proven efficacy for the patient but long-term oral medication is not appropriate (unlicensed use)

1.3 If it is being prescribed for an unlicensed indication, other than those defined above, the request must be approved by the relevant Head of Psychiatry. The Trust's policy on prescribing unlicensed medication should also be followed.

#### 1.4 Paliperidone LAI requires loading dose:

- Day 1 -150mg into deltoid muscle
- Day 8 – 100mg into deltoid muscle
- Day 36 – maintenance dose into deltoid or gluteal muscle

1.5 The recommended maintenance dose is 75mg per month, although some patients may require lower or higher doses within the range 25-100mg, based on efficacy and tolerability.

1.6 The maximum licensed dose of paliperidone LAI is 150mg monthly. However this is equivalent to risperidone LAI 75mg every 2 weeks and in all but extreme cases should not be needed in terms of efficacy.

## 2. Other considerations

2.1 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. Paliperidone has not been studied in people with dementia and should not be used.

2.2 Paliperidone LAI is not licensed for use in patients under 18 years – no safety or efficacy data are available.

2.3 A lower loading and maintenance dose should be used in renal impairment. See manufacturer's summary of product characteristics

2.4 No dosage adjustment is required in mild or moderate hepatic impairment. Avoid in severe hepatic impairment

## 3. Administration

3.1 Two loading doses must be administered on day 1 (150mg) and day 8 (100mg) into the deltoid muscle. The target maintenance dose is 75mg monthly into the deltoid or gluteal muscle.

**3.2 Paliperidone LAI must be administered once each calendar month – i.e. 12 injections per year. It must not be administered every 4 weeks (13 injections per year)**

3.3 Patients on paliperidone LAI need to be scheduled to attend clinic or be visited once per calendar month, not once every 4 weeks

3.4 There is no requirement for specific post injection monitoring over and above that which applies to other depot injections

## 4. Storage

4.1 Paliperidone LAI should be stored in a locked medicine cupboard. There is no requirement for refrigeration

4.2 Paliperidone is supplied in pre-filled syringes. There is no requirement for reconstitution or dilution

## 5. Cost comparison of long-acting antipsychotic injections

Drug	Dose	Cost per year
Paliperidone LAI	50mg monthly (x12)	£2207
	75mg monthly (x12)	£2939
	100mg monthly (x12)	£3769
	150mg monthly (x12)	£4711
Risperidone LAI	25mg every 2 weeks (x26)	£2072
	37.5mg every 2 weeks (x26)	£2894
	50mg every 2 weeks	£3712
Flupentixol decanoate	200mg every 2 weeks (x26)	£364
Fluphenazine decanoate	100mg every 2 weeks (x26)	£234
Haloperidol decanoate	200mg every 4 weeks (x13)	£130
Pipotiazine palmitate	200mg every 4 weeks (x13)	£689
Zuclopenthixol decanoate	500mg every 2 weeks (x26)	£130

## PALIPERIDONE PALMITATE LONG ACTING INJECTION NAMED PATIENT REQUEST FORM

This form must be completed for each patient initiated on paliperidone palmitate LAI

Patient Name			
Date of Birth			
Indication for use (Delete to leave the actual indication only)	<ul style="list-style-type: none"> <li>• Maintenance treatment of adult patients with schizophrenia who have responded to oral risperidone but who are non-compliant (licensed use)</li> <li>• Bipolar prophylaxis where oral risperidone has proven efficacy for the patient but long-term oral medication is not appropriate (unlicensed use)</li> <li>• Schizoaffective disorder whose condition has been stabilised with oral risperidone (unlicensed route)</li> <li>• Other (Use must be approved by the Head of Psychiatry)</li> </ul> Specify indication		
Previous Psychotropic Medication including Dose and Route			
Name of Ward/Team			
Name of Initiating Consultant		Consultant Signature	
Date of Request			
Name of Care Coordinator			
Telephone Number for Care Coordinator			
Has patient ever previously taken Clozapine?	Yes	/	No (Delete as appropriate)
Starting Date and Dose of Paliperidone			

- I confirm that arrangements are in place for the administration of paliperidone palmitate LAI to take place on a **monthly** basis (i.e once per calendar month, not 4-weekly), after initial loading doses have been administered at day 1 and day 8
- I confirm that the patient will be closely monitored for efficacy and tolerability, using Glasgow Antipsychotic Rating 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 and that referral cannot be made to Primary Care for continuation of prescribing
- I confirm that the patient is non-compliant with oral antipsychotic

Please scan and email completed form to: [kmpt.lai-authorisation@nhs.net](mailto:kmpt.lai-authorisation@nhs.net)

### LAI Approval

Pharmacist 1	Signature	Date
Pharmacist 2	Signature	Date
Head of Psychiatry (other unlicensed use only)	Signature	Date

**If the prescribing of Paliperidone LAI is being continued from another Trust please email the clinical lead pharmacist in your locality for approval and this form will not need to be completed.**