

Trust Prescribing and Administration Guidance

Drug	Paliperidone Palmitate Long-Acting Injection
Approving Committee	Medicines Optimisation Committee
Date of approval	April 2021, updated August 2021
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Review Date	April 2024

Following a review of the evidence for the use of the long acting injection paliperidone palmitate the Trust Medicines Management Committee has made the following recommendations:

- Despite an apparent lack of clinical advantage over risperidone long-acting injection, paliperidone palmitate has several practical advantages and may be considered as a useful alternative to current treatments.
- Where there is a locally commissioned service (LCS) in place the administration of aripiprazole depot antipsychotic injections may take place under an **AMBER** shared care agreement to enable stable patients with schizophrenia to be prescribed and administered these injections through their primary care prescriber (GP).
- Where there is no LCS in place, or if a practice has not signed up to the LCS, the drug remains as **RED** status and prescriptions will be issued by the provider.
- Fuller details are available via the Surrey PAD ([Link](#))
- To mitigate the clinical and financial risk that the use of paliperidone long acting injection poses, the Medicines Management Committee recommended the managed prescribing of paliperidone palmitate in the Trust.
- All **new** initiations of paliperidone palmitate must be approved prior to initiation by the Chief pharmacist, other senior pharmacist, or member of the Trust Medicines Optimisation Committee.

Clinicians, wishing to initiate paliperidone palmitate treatment **MUST**

- Note the above points regarding use of paliperidone within SABP and partnership organisations.
- Complete the request for approval of the initiation of treatment (link) (Trustweb toolkit → Clinical Hub → Pharmacy → Pharmacy charts and forms)
- ensure they are familiar with the prescribing recommendations found in the Summary of Product Characteristics (SPC):
- [Xeplion prolonged-release suspension for injection - Summary of Product Characteristics \(SmPC\) - \(emc\)](#)
- ensure the patient can tolerate oral risperidone prior to initiation of long acting treatment, and that it is effective.
- ensure that all staff involved in the administration are competent in deltoid administration

1. Key Points

- 1.1 Paliperidone long acting injection (LAI) is **licensed / indicated** for the maintenance treatment of adult patients with schizophrenia, whose condition has been stabilised with oral risperidone or paliperidone. (*Note – oral paliperidone is not included in the Trust Formulary*). In selected patients with previous responsiveness to oral risperidone (or paliperidone), paliperidone LAI may be used without prior stabilisation with oral treatment if psychotic symptoms are mild to moderate and a long-acting injectable treatment is needed.
- 1.2 Paliperidone LAI is **not indicated** for treatment-resistant schizophrenia, unlicensed indications or people intolerant to oral risperidone or paliperidone.
- 1.3 Paliperidone LAI may only be **newly prescribed** by doctors of specialist registrar grade or above. Other grades may not initiate therapy or adjust dose without direct instruction from their consultant.
- 1.4 Paliperidone LAI is intended for **once-monthly injection (i.e. once per calendar month, rather than 4-weekly)**, by intramuscular route into the deltoid or gluteal muscle. However, initial loading doses **must** be given into the deltoid muscle. (See manufacturer's guidance, www.medicines.org.uk).
- 1.5 Paliperidone LAI requires the administration of **two loading doses**, (on day 1 and on day 8), but does not require any oral supplementation.
- 1.6 Where an individual is switching treatment from another depot medication, the loading doses are unlikely to be needed. Seek advice from pharmacy.
- 1.7 Paliperidone LAI is **extremely expensive** when compared to conventional antipsychotic depots and is also more expensive than risperidone LAI in terms of procurement cost. At 100mg per month, it costs approximately £3,800 per patient year. (**See section 6**)

2. Prescribing Treatment

- 2.1 Generally, people who will receive paliperidone LAI should have a history of response and tolerability to oral risperidone (or oral paliperidone). (See 1.1 above).
- 2.2 Recommended Dosing Schedule:

Day 1	-	150mg into the deltoid muscle.
Day 8 (+/- 4 days)	-	100mg into the deltoid muscle.
Day 36 (+/- 7 days)	-	Maintenance dose into deltoid or gluteal muscle
- 2.3 The recommended maintenance dose is 75mg per month although some people may benefit from lower or higher doses, within the range 50mg – 100mg, based on efficacy and tolerability.
- 2.4 A maintenance (maximum) dose of 150mg per month is also within the terms of the Product Licence. However, it should be noted that this dose is equivalent to administering risperidone Consta® at a dose of 75mg fortnightly and in all but extreme cases should not be necessary in terms of efficacy.

3. Other Dosing Recommendations / Considerations

- 3.1 **The elderly:** Efficacy and safety in patients over 65 years of age have not been established. If used, lower doses should be considered particularly if renal function is diminished. The product has not been studied in elderly patients with dementia and should not be used.
- 3.2 **Children & Adolescents:** The product is **not licensed** for use in patients less than 18 years of age. No efficacy or safety data are available.
- 3.3 **Renal impairment:** Lower loading and maintenance doses should be used. Note that an adjusted dose is recommended for individuals with a creatinine clearance of <80mL/min. The manufacturer does not recommend treatment for individuals with a creatinine clearance of <50mL/min. Manufacturer's data should be referred to before prescribing.
- 3.4 **Hepatic impairment:** No dosage adjustment is required in mild or moderate impairment. Use in severe impairment should be avoided.

4. Administration

- 4.1 **The two loading doses of paliperidone LAI, one on day 1 and one on day 8, must be administered into the deltoid muscle.** If administered into the gluteal muscle, plasma levels will not rise quickly enough and oral supplementation may then be required. (Paliperidone LAI is intended for administration without oral supplementation).
- 4.2 Following the two loading doses of 150mg (day 1) and 100mg (day 8), the target maintenance dose is 75mg per month.
- 4.3 **Paliperidone LAI is not intended for 4-weekly administration. Instead it requires maintenance doses to be administered 12 times a year – i.e. once each calendar month.** Administering paliperidone LAI every 4 weeks, (i.e. 13 times a year), does not provide any greater efficacy and will greatly increase costs.
- 4.4 **People receiving paliperidone LAI need to be scheduled to attend clinic or to be visited for injection, once each calendar month.** For example, administration could be scheduled for a certain day each month – e.g. the first Tuesday of each month or the second Thursday, etc. Applying this sort of schedule will mean that most doses are 4 weeks apart, but occasionally will be 5 weeks apart, dependent on the month. However, this will not affect efficacy.
- 4.5 Following administration of paliperidone LAI there is no requirement for any enhanced level of patient monitoring. People receiving paliperidone LAI should be monitored for post-injection events in the same way as for traditional depot injections.

5. Missed doses

- 5.1 Where a scheduled dose is missed, the manufacturer's advice should be followed. There is specific guidance offered around the situations where the 2nd initiation dose is missed.
- 5.2 Where people stabilised on maintenance treatment miss their scheduled dose, the monthly maintenance dose may be given up to 2 weeks after the due date, followed by injections at monthly intervals.
- 5.3 Where people stabilised on treatment miss their scheduled dose by more than 2 weeks but less than 6 months, an adjusted re-initiation schedule is required.
- 5.4 Where there has been a break in treatment of greater than 6 months, the standard loading doses will be required.

6. Storage

- 6.1 Packs of paliperidone LAI should be stored in a locked medicines cabinet; there is no requirement for fridge storage.
- 6.2 Paliperidone LAI is supplied in pre-filled syringes; there is no need for any reconstitution or dilution.

Reference:

Paliperidone Long-Acting Injection (Xeplion®): Guidelines for Prescribing and Administration (March 2013)

Jed Hewitt, Chief Pharmacist Sussex Partnership NHS Foundation Trust

Summary of product Characteristics, Xepilon. Janssen Cilag Ltd. Last updated September 2018. Available via www.medicines.org.uk