



## **PALIPERIDONE (Trevicta®) 3 MONTHLY - Long acting injection (LAI) Guidance for Prescribing and Administration**

### **Paliperidone 1- monthly long acting injection (Xeplion®)**

This is included in the Trust medicines formulary for the maintenance treatment of schizophrenia in:-

- Adult patients stabilised with risperidone or paliperidone (oral paliperidone is not included in HPFT medicines formulary).
- Selected adult patients with schizophrenia and 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 required.

See [prescribing guidance for paliperidone 1-monthly LAI](#).

### **Paliperidone 3-monthly long acting injection (Trevicta®)**

This is now available and is licensed for the maintenance treatment of schizophrenia in adult patients who are clinically stable on paliperidone 1- monthly LAI (Xeplion®)

Paliperidone 3- monthly LAI (Trevicta®) has been approved for use in HPFT on a named patient basis where all the following criteria are met:-

- Is currently receiving paliperidone 1-monthly
- Has received at least six paliperidone 1-monthly injections at the same dose\*
- Patient is clinically stable with well controlled symptoms and a dose change is unlikely to be necessary
- Paliperidone 1-monthly is well tolerated

A named patient request and data collection form (which can be found at the end of this document) should be completed and submitted to [Eric.Tang@hpft.nhs.uk](mailto:Eric.Tang@hpft.nhs.uk) before changing a patient over to paliperidone 3 monthly LAI. A 12 month follow up will be completed.

Patients, who may particularly benefit, include those who are difficult to engage, erratic non-attenders, those with injection site reactions or those who are keen to have a less frequent injection.

As paliperidone 3-monthly LAI has a slow release profile, it is not proposed for acutely unwell patients or those transitioning from oral or other long acting antipsychotic injections.

\*The license for paliperidone palmitate 3-monthly states that it can be used after 4 or more injections of 1-monthly, however the DTC have made a decision that patients must have received a minimum of 6 months treatment at the same dose before changing over. This is to allow clinicians to assess for response and tolerability.

### Assessing response and tolerability before starting paliperidone 3-monthly LAI

It is important to assess that an adequate response has been achieved with paliperidone 1-monthly as dose adjustments with paliperidone 3-monthly can only be made every 3 months and patient response may therefore not be apparent for several months.

Paliperidone plasma levels can be detected for an average of 18 months from the last paliperidone 3-monthly injection. It is therefore essential to assess tolerability to reduce risk of adverse effects before switching to paliperidone 3-monthly LAI. Tolerability should be assessed once steady state is achieved with paliperidone 1- monthly LAI (8 to 12 weeks).

### Other considerations

- Since paliperidone has been detected in plasma up to 18 months after a single dose of the 3 monthly formulation, its use in women of child bearing age who could become pregnant should be considered carefully.
- If paliperidone 3- monthly is discontinued, its prolonged release characteristics must be considered.

Refer to [Summary of Product Characteristics \(SPC\) for Trevicta](#) for full prescribing guidance.

**To avoid confusion with 1-monthly paliperidone LAI prescribe by 3 monthly paliperidone LAI by brand name TREVICTA.**

### Presentation

Trevicta is presented as a pre-filled syringe with 2 needles (a 22G 1½-inch safety needle [0.72 mm x 38.1 mm] and a 22G 1-inch safety needle [0.72 mm x 25.4 mm]).

### Dosing recommendations

Give the first dose of Trevicta when the next dose of 1-monthly paliperidone (Xeplion) would have been due, as per the recommendations below.

| If the last dose of paliperidone 1-monthly was | Initiate Trevicta at the following dose | Volume of Trevicta |
|--|---|--------------------|
| 50mg   | 175mg                                   | 0.875ml            |
| 75mg   | 263mg                                   | 1.315ml            |
| 100mg  | 350mg                                   | 1.75ml             |
| 150mg  | 525mg                                   | 2.625ml            |

The last 6 doses of paliperidone 1- monthly should be the same strength before starting Trevicta. The first dose of Trevicta can be given 7 days before or after the 1-monthly paliperidone due date.

### Dosing interval

Administer Trevicta every 3 months (can be given 2 weeks before or after the 3 monthly due date).

### Supply

Trevicta should be ordered through Polarspeed by the Community Depot Clinic staff. Only one dose per patient should be ordered at a time.

## Administration

- Administer intramuscularly into either the deltoid or gluteal muscle.
- Select appropriate needle depending on administration site and patient weight. 22G 1½ needles must be used for gluteal administrations regardless of body weight.
- **IMPORTANT: Vigorously shake** the syringe with a loose wrist for at least **15 seconds** within the 5 minutes prior to administration. This is to ensure homogeneous suspension and prevention of incomplete administration.
- If more than 5 minutes pass before injection then shake vigorously again for at least 15 seconds to re-suspend.
- See also [Trevicta administration video guide](#)

## What if a dose of Trevicta is missed?

| If the scheduled dose is missed and the time since last injection is: | Action   |
|---|--|
| > 3½ months up to 4 months  | Trevicta should be administered as soon as possible and then resume the 3-monthly injection schedule.  |
| 4 months to 9 months  | Use the recommended re-initiation regimen shown in the table below.  |
| > 9 months  | Re-initiate treatment with 1-monthly paliperidone palmitate injectable as described in the prescribing information for that product. Trevicta can then be resumed after the patient has been adequately treated with 1-monthly paliperidone palmitate injectable preferably for four months or more. |

## Recommended re-initiation regimen after missing 4 to 9 months of TREVICTA

| If the last dose of TREVICTA was: | Administer 1-monthly paliperidone palmitate injectable, two doses one week apart (into deltoid muscle) |        | Then administer TREVICTA (into deltoid or gluteal muscle) |
|-----------------------------------|--|--------|---|
|                                   | Day 1  | Day 8  | 1 month after day 8                                       |
| 175 mg                            | 50 mg  | 50 mg  | 175 mg  |
| 263 mg                            | 75 mg  | 75 mg  | 263 mg  |
| 350 mg                            | 100 mg   | 100 mg | 350 mg  |
| 525 mg                            | 100 mg   | 100 mg | 525 mg  |

## Pharmacokinetics

The release of the active substance starts as early as day 1 and lasts for at least 18 months.

Trevicta is the palmitate ester prodrug of paliperidone. It has an extremely low solubility in water and therefore dissolves slowly after intramuscular injection before being hydrolysed to paliperidone and absorbed into the systemic circulation. Following a single intramuscular dose, the plasma concentration of paliperidone gradually rises to reach maximum plasma concentrations at a median of 30-33 days.

## Storage

Store in a locked medicines cupboard. Trevicta does not need refrigeration.

## Further information

See SPC or manufacturer's product literature. For other information contact pharmacy team.

**References**

Trevicta Summary of Product Characteristics. Janssen-Cilag Ltd.22nd September 2016

Bazire S. Psychotropic Drug directory 2016

**Paliperidone 3 monthly Long Acting Injection (LAI) Named Patient Request and Data Collection Form**

The named patient request form for Paliperidone 3 monthly LAI has been adapted in order to gather information that will support a short clinical audit.

The aims of this short clinical audit are to evaluate:

- Any factors that contributed to the decision making on prescribing Paliperidone 3 monthly LAI
- The number of patients remaining on Paliperidone 3 monthly LAI 12 months after initiation and any factors leading to discontinuation

1. Requesting consultant details

Name:

Clinic base address and tel no:

Email:

2. Patient details

Name:

D.O.B:

Gender:

Paris ID:

3. Patients current medication

- (a) Has the patient been receiving their **current** Paliperidone monthly LAI dose for at least 6 months? Yes  No
- (b) What is their current Paliperidone monthly LAI dose? \_\_\_\_\_
- (c) Is the patient tolerating their Paliperidone monthly LAI medication? Yes  No
- (d) Is the patient prescribed any additional antipsychotic medication? Yes  No
- If yes please specify medications \_\_\_\_\_
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4. Paliperidone 3 monthly request

- (a) What are the factors that have led to the choice of Paliperidone 3 monthly as the preferred option in this patient? (more than one option can be ticked)

- Patient is stable and 3 monthly injections is a good option
- Patient is difficult to engage
- Patient is erratic at attending depot clinic appointments
- Patient suffers from injection site reactions
- Patient is keen to have less frequent injections
- Other \_\_\_\_\_

5. Has the patient been involved in the decision making to prescribe Paliperidone 3 monthly LAI? Yes  No

Please return completed form to Eric Tang at [Eric.tang@hpft.nhs.uk](mailto:Eric.tang@hpft.nhs.uk)

## Questionnaire post 12 months

At 12 months, the consultant will be contacted and Paris notes reviewed to ascertain:

1. Is the patient still on Paliperidone 3 monthly LAI? Yes  No

If no what antipsychotic medications are they prescribed now (if any)?

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If no what were the reasons Paliperidone 3 monthly LAI was discontinued?

- Patient's mental state deteriorated
- Patient missed appointments
- Injections were too far apart and unable to maintain contact with patient
- Other (please specify) \_\_\_\_\_

2. If yes is the patient maintained on the same dose as when initiated? Yes  No

If no what dose are they on now? \_\_\_\_\_

If no why was the dose changed? \_\_\_\_\_