PRESCRIBING INFORMATION
XEPLION® 50 mg, 75 mg, 100 mg & 150 mg prolonged release suspension for injection

ACTIVE INGREDIENT(S): 50 mg, 75 mg, 100 mg or 150 mg paliperidone.

Please refer to Summary of Product Characteristics (SmPC) before prescribing.

INDICATION(S): XEPLION is indicated for maintenance treatment of schizophrenia in adult patients stabilised with paliperidone or risperidone. In selected adult patients with schizophrenia and previous responsiveness to oral paliperidone or risperidone, XEPLION may be used without prior stabilisation with oral treatment if psychotic symptoms are mild to moderate and a long-acting injectable treatment is needed.

DOSEAGE & ADMINISTRATION: Intramuscular injection. Initiation doses (days 1 and 8) must be administered in deltoid muscle for therapeutic concentrations to be rapidly attained. Adults: 150 mg on treatment day 1 and 100 mg one week later (day 8 ± 4), both doses administered in deltoid muscle, using 1½ inch, 22 gauge needle (38.1 mm x 0.72 mm) for patients ≤ 90 kg, or 1-inch, 23 gauge needle (25.4 mm x 0.64 mm) for those < 90 kg. The third dose should be administered one month after the second initiation dose. Recommended monthly maintenance dose is 75 mg (range 50 mg-150 mg) in either deltoid or gluteal muscle. Recommended needle size for maintenance administration of XEPLION into deltoid muscle is as for initiation doses, and for the gluteal muscle is the 1½-inch, 22 gauge needle (38.1 mm x 0.72 mm). To avoid a missed monthly maintenance dose patients may be given injection up to 7 days before to up to the time point.

Consider maintenance doses in upper range for overweight/obese patients. Adjust maintenance dose at monthly intervals as necessary. Alternate injections between left and right sides. Discontinue previous oral antipsychotic if XEPLION treatment at time of initiation does not contribute to core body temperature elevation. Identify all patients on initiation of all antipsychotics. Events of dyskinesia occurs consider discontinuation of all antipsychotics. XEPLION is for use in adults only. Lyophilised powder for XEPLION 75 mg pre-filled, 100 mg pre-filled and 150 mg pre-filled syringes are available.

SIDE EFFECTS: Very common: Insomnia, headache.

Other side effects reported with risperidone are:
- Fatigue and injection site reaction.
- Rash, (injectable risperidone) injection site necrosis and injection site ulcer.

Injection site reactions: mild to moderate pain most commonly reported (tended to lessen in frequency and intensity over time). Weight gain: 12% of XEPLION-treated subjects experienced weight gain of ≥ 7% from baseline to endpoint during 26-week open-label phase of long-term recurrence prevention study. Laboratory tests: Serum prolactin: increases in serum prolactin observed in clinical trial subjects (both genders) with XEPLION. Adverse reactions suggesting increase in prolactin levels reported overall in <1% of subjects.

Class effects: QT prolongation, ventricular arrhythmias, sudden unexplained death, cardiac arrest, and Torsade de pointes may occur with antipsychotics. Cases of venous thromboembolism, including pulmonary embolism and deep vein thrombosis, also reported. Drug withdrawal syndrome in neonates observed with antipsychotics. Frequency unknown. Refer to SmPC for other side effects.

PREGNANCY: Should not be used during pregnancy unless clearly necessary.

LACTATION: Avoid. Not known if secreted in or excreted in human milk.

INTERACTIONS:

<table>
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Potentially harmful interactions:

- Avoid antipsychotic associations with antiarrhythmics, some antihistaminics, some other antipsychotics, some adrenergic antagonist effect, such as XEPLION.
- Concomitant administration of oral paliperidone and paroxetine (a potent CYP2D6 inhibitor) showed no clinically significant effect on paliperidone pharmacokinetics. Co-administration of oral paliperidone once daily with carbamazepine 200 mg twice daily decreases plasma concentration of paliperidone by 37%. Re-evaluate/increase XEPLION dose at carbamazepine initiation. |

Reference(s):

5. Xeplion Summary of Product Characteristics. August 2015

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