TREVICTA PRESCRIBING INFORMATION BASED ON THE EU SUMMARY OF PRODUCT CHARACTERISTICS EU SmPC 13-09-2018:
Trevicta®,175 mg, 263 mg, 350 mg, or 525 mg prolonged release suspension for injection paliperidone.

ACTIVE INGREDIENT(S):
paliperidone.

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

INDICATION(S):
TREVICTA, a 3-monthly injection, is indicated for the maintenance treatment of schizophrenia in adult patients who are clinically stable on 1-monthly paliperidone palmitate injectable product.

DOSAGE & ADMINISTRATION:
Intramuscular administration only. Avoid inadvertent injection into a blood vessel. Patients who are adequately treated with 1-monthly paliperidone palmitate injectable (preferably 4 months or more) and do not require dose adjustment may be switched to TREVICTA.

Adults: Initiate TREVICTA in place of the next scheduled dose of 1 monthly paliperidone palmitate injectable (± 7 days). Base TREVICTA dose on the previous 1 monthly paliperidone palmitate injectable dose using a 3.5 fold higher dose.
Thereafter administer TREVICTA intramuscularly once every 3 months (± 2 weeks). Dose adjustment of TREVICTA can be made every 3 months in increments within the range of 175 mg to 525 mg. Administration: Each injection must be administered only by a health care professional giving the full dose in a single injection and dose must not be divided. Administer dose in either deltoid or gluteal muscle. For deltoid administration, use 1½ inch, 22 gauge needle (0.72 mm x 38.1 mm) in patients ≥ 90 kg, or 1 inch, 22 gauge needle (0.72 mm x 25.4 mm) in patients < 90 kg. For gluteal administration use the 1½ inch, 22 gauge needle (0.72 mm x 38.1 mm). Alternate injections between left and right sides. Inject slowly, deep into the deltoid or gluteal muscle. Use only the needles provided in the TREVICTA pack.

To avoid incomplete administration of TREVICTA, shake the syringe vigorously with the tip up and a loose wrist for at least 15 seconds. Administer within 5 minutes after shaking. If more than 5 minutes pass before injection, shake vigorously again for at least 15 seconds.

In the event of an incompletely injected dose, the dose remaining in the syringe should not be re injected and another dose should not be given since it is difficult to estimate the proportion of the dose actually administered. Closely monitor and manage the patient as clinically appropriate until the next scheduled 3 monthly injection of TREVICTA.

Children: No safety or efficacy data available. Elderly: No safety or efficacy data available for patients > 65 years. Renal impairment: Mild (creatinine clearance ≥ 50 to < 80 ml/min): dose should be adjusted. Stabilise patient using 1-monthly paliperidone palmitate injectable and then transitioned to TREVICTA. Moderate or severe (creatinine clearance < 50 ml/min): Not recommended. Hepatic impairment: Caution in severe hepatic impairment.

Please refer to the SmPC for complete information.

CONTRAINDICATIONS:
Hypersensitivity to paliperidone, risperidone or any of the excipients.

SPECIAL WARNINGS & PRECAUTIONS:
Do not use in acutely agitated or severely psychotic patients. Not recommended in elderly dementia patients. Caution in cardiovascular disease (including family history of QT prolongation) cerebrovascular disease, hypotension, prolactin-dependent tumours, seizures, Parkinson's disease, dementia with Lewy bodies and in conjunction with medicines that prolong the QT interval. May induce orthostatic hypotension. Increases in serum prolactin have been observed. If tardive dyskinesia/extrapyramidal symptoms occurs consider discontinuing all antipsychotics. Caution is warranted in patients receiving both, psychostimulants (e.g., methylphenidate) and paliperidone concomitantly, as extrapyramidal symptoms could emerge when adjusting one or both medications. Gradual withdrawal of stimulant treatment is recommended . Events of leucopenia, neutropenia, and agranulocytosis have been reported with TREVICTA; additional monitoring or cessation of treatment may be required. If Neuroleptic Malignant Syndrome (NMS) occurs, discontinue all antipsychotics, including TREVICTA.

Hypersensitivity reactions can occur even in patients who have previously tolerated oral risperidone or oral paliperidone. Rarely, cases of anaphylactic reaction after injection with 1-monthly paliperidone palmitate injectable have been reported in patients who have previously tolerated oral risperidone or oral paliperidone. Hyperglycaemia, diabetes mellitus, and exacerbation of pre-existing diabetes has been reported. Appropriate clinical monitoring in diabetics and those with risk factors for diabetes is advisable.
Monitor patients for symptoms of hyperglycaemia and patients with diabetes mellitus should be monitored regularly for worsening of glucose control. Advise of potential for weight gain, monitor weight regularly. Paliperidone has been reported to induce priapism. Caution in patients experiencing conditions which may contribute to core body temperature elevation. Identify all possible risk factors for VTE before and during treatment and take preventive measures. Antiemetic effects (observed in paliperidone preclinical studies) may mask signs and symptoms of overdosage with certain medicines, such as intestinal obstruction, Reye's syndrome, and brain tumour.

Intraoperative floppy iris syndrome (IFIS) observed during cataract surgery in patients treated with medicines with alpha1a-adrenergic antagonist effect, such as TREVICTA.This medicinal product is essentially sodium-free.

SIDE EFFECTS:
Very common side effects: insomnia. Common side effects: upper respiratory tract infection, urinary tract infection, influenza, hyperglycaemia, weight increased, weight decreased, decreased appetite, agitation, depression, anxiety, parkinsonism, akathisia, sedation/somnolence, dystonia, dizziness, dyskinesia, tremor, headache, tachycardia, hypertension, cough, nasal congestion, abdominal pain, vomiting, nausea, constipation, diarrhoea, dyspepsia, toothache, transaminases increased, musculoskeletal pain, back pain, arthralgia, amenorrhoea, pyrexia, asthenia, fatigue, injection site reaction, galactorrhoea, hyperprolactinaemia
Please refer to the SmPC for other side effects.

PREGNANCY:
Should not be used during pregnancy unless clearly necessary. Neonates exposed to antipsychotics during the third trimester of pregnancy are at risk of adverse reactions including extrapyramidal and/or withdrawal symptoms that may vary in severity and duration following delivery.

LACTATION:
Should not be used while breastfeeding.

INTERACTIONS:
Caution with medicines that prolong QT interval e.g., class IA and class III antiarrhythmics, some antihistaminics, some antibiotics, some other antipsychotics, some antimalarials. Potential for TREVICTA to affect other medicines: Caution in conjunction with: other centrally acting medicines e.g., anxiolytics, antipsychotics, hypnotics, opiates, alcohol; medicines known to lower seizure threshold i.e., phenothiazines, butyrophenones, tricyclics, SSRIs, tramadol, mefloquine; medicines capable of inducing orthostatic hypotension (an additive effect may be observed when TREVICTA is co-administered); levodopa and other dopamine agonists (paliperidone may antagonize their effect - use the lowest effective dose of each treatment if this combination must be prescribed e.g., end-stage Parkinson's disease). Interaction of TREVICTA with lithium is unlikely. Potential for other medicines to affect TREVICTA: 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 TREVICTA dose at carbemazepine initiation. No clinically significant interaction expected between valproate and TREVICTA. Caution when TREVICTA is co-administered with risperidone or oral paliperidone for extended periods of time. Limited safety data for concomitant use of TREVICTA with other antipsychotics. The combined use of psychostimulants with paliperidone can lead to extrapyramidal symptoms upon change of either or both treatments.

LEGAL CLASSIFICATION:
Prescription only medicine.

MARKETING AUTHORISATION NUMBER(S):
1/138116; 1/138216 ;1/138316 ;1/138416

MARKETING AUTHORISATION HOLDER:
Janssen Cilag International NV Turnhoutseweg 30, B-2340 Beerse, Belgium.

Prescribing information generation date or last revised: 05-12-2018
Based on 13-09-2018 EU SmPC

For complete information, please refer to the SmPC