PRESCRIBING INFORMATION FOR THE UNITED KINGDOM (UK) AND REPUBLIC OF IRELAND (ROI)

Fycompa® (perampanel)

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

Presentation: Film-coated tablets containing 2mg, 4mg, 6mg, 8mg, 10mg, or 12mg perampanel. Oral suspension containing 0.5mg perampanel per millilitre (0.5mg/ml). ***Indication:*** Adjunctive treatment of partial-onset seizures (POS) with or without secondarily generalised seizures in patients from 4 years of age and older. Adjunctive treatment of primary generalised tonic-clonic (PGTC) seizures in patients from 7 years of age and older with idiopathic generalised epilepsy (IGE). ***Dosage and route of administration:*** Dose should be taken orally once daily at bedtime. May be taken with or without food but preferably always under the same conditions. Switching between the tablet and suspension formulation should be done with caution. ***Adults, adolescents, and children ≥30kg* (4-11 years for POS and 7-11 years for PGTC)*:*** Starting dose is 2mg daily. Dose may be increased based on clinical response and tolerability by increments of 2mg (no more frequently than weekly, as per half-life considerations described below) to a maintenance dose of up to 8mg/day. Depending upon individual clinical response and tolerability at a dose of 8mg/day, the dose may be increased up to 12mg/day. **Children aged 4-11 years for POS and 7-11 years for PGTC (20kg to <30kg):** Starting dose is 1mg daily. Dose increase as above in increments of 1mg (no more frequently than weekly) to a maintenance dose of up to 6mg/day. Depending upon individual response, dose may be increased to a maximum of 8mg/day. **Children aged 4-11 years for POS and 7-11 years for PGTC (<20kg):** Starting dose is 1mg daily. Dose increase as above in increments of 1mg (no more frequently than weekly) to a maintenance dose of up to 4mg/day. Depending upon individual response, dose may be increased in increments of 0.5mg/day up to a maximum of 6mg/day. **All patients:** Doses of 4mg/day to 12mg/day have been shown to be effective therapy in partial onset seizures, and up to 8mg/day in primary generalised tonic-clonic seizures. Patients who are taking concomitant medicinal products that do not shorten the half-life of perampanel should be titrated no more frequently than at 2-week intervals. Patients who are taking concomitant medicinal products that shorten the half-life of perampanel should be titrated no more frequently than at 1-week intervals. Withdraw gradually. ***Elderly and patients with renal or hepatic impairment:*** Dosage adjustments not required in the elderly or patients with mild renal impairment. Not recommended in patients with moderate or severe renal impairment or patients undergoing haemodialysis. Caution in mild or moderate hepatic impairment, titration should not be faster than every 2 weeks and maximum daily dosage not exceeding 8mg. Not recommended in severe hepatic impairment. ***Children <4 years with POS and <7 years with PGTC:*** No data available. ***Contra-Indications:*** Hypersensitivity to perampanel or any excipient. ***Pregnancy:*** Should not be used during pregnancy or in women of childbearing potential not using contraception, unless clearly necessary. ***Lactation:*** Unknown if excreted into breast milk. Decide whether to discontinue breastfeeding or discontinue perampanel taking into account the benefit of breastfeeding for the child and therapy for the woman. ***Warnings and Precautions:*** Patients and their carers should monitor for signs of suicidal ideation and behaviours and seek medical advice should such signs emerge. Severe cutaneous adverse reactions (SCARs) including drug reaction with eosinophilia and systemic symptoms (DRESS) and Stevens-Johnson Syndrome (SJS) have been reported. At time of prescription patients should be advised of the signs and symptoms and monitored closely for skin reactions. Withdraw perampanel immediately and consider alternative treatment if these signs and symptoms appear. Perampanel should not be restarted at any time if a serious reaction such as SJS or DRESS develops on perampanel treatment. May cause dizziness and somnolence and therefore may influence the ability to drive or use machines. Doses of 12mg/day may decrease the effectiveness of progestative-containing hormonal contraceptives. Additional forms of non-hormonal contraception are recommended. Patients with myoclonic seizures and absence seizures should be monitored. There appears to be an increased risk of falls, particularly in the elderly. Aggressive, hostile and abnormal behaviour including homicidal ideation have been reported; counsel patients and caregivers to alert a healthcare professional immediately if significant changes in mood or patterns of behaviour are noted; the dosage of perampanel should be reduced if such symptoms occur and discontinuation should be considered if symptoms are severe. Caution in patients with a history of substance abuse and monitor the patient for symptoms of perampanel abuse. Patients should be closely monitored for tolerability and clinical response when adding or removing cytochrome P450 inducers or inhibitors or switching from concomitant non-inducer antiepileptic drugs (AEDs) to enzyme inducing AEDs and vice versa, since perampanel plasma levels can be decreased or increased; the dose of perampanel may need to be adjusted accordingly. Cases of hepatotoxicity (mainly increases in hepatic enzymes) have been reported in combination with other AEDs. If raised hepatic enzymes are observed, monitoring of liver function should be considered. Tablets contain lactose; patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this product. Oral suspension contains sorbitol (E420), benzoic acid (E210) and sodium benzoate (E211); patients with hereditary fructose intolerance (HFI) should not take this product. Caution is advised if combining oral suspension with other AEDs containing sorbitol. Benzoic acid and benzoates can displace bilirubin from albumin, which may increase bilirubinaemia. Increased bilirubinaemia may increase neonatal jaundice that could develop into kernicterus. ***Drug Interactions:*** The possibility of decreased efficacy of progestative-containing hormonal contraceptives should be considered for women needing 12mg/day and an additional reliable method is to be used. Carbamazepine, phenytoin, oxcarbazepine, phenobarbital and topiramate have been shown to increase perampanel clearance and consequently to decrease the plasma concentration of perampanel. Take this effect into account and manage when adding or withdrawing these AEDs from a patient's treatment regimen. Perampanel did not affect in a clinically relevant manner the clearance of clonazepam, levetiracetam, phenobarbital, phenytoin, topiramate, zonisamide, carbamazepine, clobazam, lamotrigine and valproic acid but decreased the clearance of oxcarbazepine by 26%. Perampanel (6mg once daily for 20 days) decreased midazolam AUC by 13% in healthy subjects (CYP3A substrate effect). Strong inducers of cytochrome P450 such as rifampicin and hypericum are expected to decrease perampanel concentrations. Felbamate may reduce perampanel concentrations. CYP3A4 inhibitor ketoconazole (400mg once daily for 10 days) increased perampanel AUC by 20% and prolonged perampanel half-life by 15%. Perampanel used in combination with other central nervous system (CNS) depressants such as alcohol may increase levels of anger, confusion, and depression. The effects of perampanel on tasks involving alertness and vigilance such as driving ability were additive or supra-additive to the effects of alcohol. ***Adverse reactions:*** Refer to SmPC in relation to adverse reactions. *Very common* (≥1/10): dizziness, somnolence. *Common* (≥1/100 to <1/10): decreased appetite, increased appetite, aggression, anger, anxiety, confusional state, ataxia, dysarthria, balance disorder, irritability, diplopia, vision blurred, vertigo, nausea, back pain, gait disturbance, fatigue, weight increased, fall. *Uncommon* (≥1/1,000 to <1/100): suicidal ideation, suicide attempt, hallucinations, psychotic disorder. *Adverse reactions with frequency not known*: Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) and Stevens-Johnson Syndrome (SJS). ***Legal Category:*** POM ***Basic UK NHS cost:*** 2mg tablets: packs of 7 £35.00, packs of 28 £140.00, 4mg tablets: packs of 28 £140.00, 6mg tablets: packs of 28 £140.00, 8mg tablets: packs of 28 £140.00, 10mg tablets: packs of 28 £140.00, 12mg tablets: packs of 28 £140.00, Oral suspension 0.5mg/ml: 340 ml bottle £127.50. ***Marketing authorisation numbers: MHRA*** 2mg tablets: PLGB 33967/0013, 4mg tablets: PLGB 33967/0014, 6mg tablets: PLGB 33967/0015, 8mg tablets: PLGB 33967/0016, 10mg tablets: PLGB 33967/0011, 12mg tablets: PLGB 33967/0012, Oral suspension 0.5mg/ml: 340 ml bottle: PLGB 33967/0010. ***EMA*** 2mg 7 tablets: EU/1/12/776/001, 2mg 28 tablets: EU/1/12/776/017, 4mg 28 tablets: EU/1/12/776/003, 6mg 28 tablets: EU/1/12/776/006, 8mg 28 tablets: EU/1/12/776/009, 10mg 28 tablets: EU/1/12/776/012, 12mg 28 tablets: EU/1/12/776/015, Oral suspension 0.5mg/ml: 340 ml bottle: EU/1/12/776/024. ***Marketing authorisation holder:*** MHRA: Eisai Europe Limited (MHRA approvals). EMA: Eisai GmbH (EMA approvals). ***Further Information from:*** Eisai Ltd, European Knowledge Centre, Mosquito Way, Hatfield, Hertfordshire, AL10 9SN. ***Date of preparation****:* January 2025. UK-FYC-25-00001

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or by searching for the MHRA Yellow Card in the Google Play or Apple App Store.
For Republic of Ireland: www.hpra.ie. Adverse events should also be reported to Eisai Ltd on +44 (0)208 600 1400 or EUmedinfo@eisai.net