PRESCRIBING INFORMATION

Fycompa® (perampanel)

Please refer to the Summary of Product Characteristics (SmPC) before prescribing. ***Presentation:*** Film-coated tablets containing 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, or 12 mg perampanel. Oral suspension containing 0.5 mg perampanel per millilitre (0.5 mg/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). ***Dose and 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 (and >4 years of age):*** Starting dose is 2 mg daily. Dose may be increased based on clinical response and tolerability by increments of 2 mg (no more frequently than weekly, as per half-life considerations described below) to a maintenance dose of up to 8 mg/day. Depending upon individual clinical response and tolerability at a dose of 8 mg/day, the dose may be increased up to 12 mg/day. **Children aged 4-11 years (20 - <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 (<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 4 mg/day to 12 mg/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 elderly patients. Dosage adjustments not required in mild renal impairment. Fycompa 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:*** No data available. ***Contra-Indications:*** Hypersensitivity to perampanel or any excipient. ***Pregnancy:*** Not recommended. ***Lactation:*** Unknown if excreted into breast milk. A decision whether to discontinue breastfeeding or to discontinue/abstain from Fycompa taking into account the benefit of breastfeeding for the child and the benefit of 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. Perampanel may cause dizziness and somnolence and therefore may influence the ability to drive or use machines. At doses of 12 mg/day Fycompa may decrease the effectiveness of progestative-containing hormonal contraceptives. Patients with myoclonic seizures and absence seizures should be monitored while on Fycompa. Other AEDs are known to induce or aggravate these seizure types. There appears to be an increased risk of falls, particularly in the elderly. Aggressive and hostile behaviour has been reported; patients and caregivers should be counselled 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 should be discontinued immediately if symptoms are severe. Caution in patients with a history of substance abuse and the patient should be monitored 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 anti-epileptic medicinal products to enzyme inducing medicinal products 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. Fycompa tablets contain lactose; patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this product. Fycompa oral suspension contains sorbitol (E420); patients with rare hereditary problems of fructose intolerance should not take this product. Caution is advised if combining Fycompa oral suspension with other antiepileptic medicines containing sorbitol. ***Drug Interactions:*** The possibility of decreased efficacy of progestative-containing hormonal contraceptives should be considered for women needing Fycompa 12 mg/day and an additional reliable method (intra-uterine device (IUD), condom) is to be used. Carbamazepine, phenytoin, oxcarbazepine, phenobarbital and topiramate have been shown to increase perampanel clearance and consequently to decrease plasma concentrations of perampanel. Withdrawal of a concomitant CYP450 3A enzyme inducer can be expected to increase plasma concentrations of perampanel and dose reduction of perampanel may be required. Fycompa did not affect in a clinically relevant manner the clearance of clonazepam, levetiracetam, phenobarbital, phenytoin, topiramate, zonisamide, carbamazepine, clobazam, lamotrigine and valproic acid. Fycompa was found to decrease the clearance of oxcarbazepine by 26%. Fycompa (6 mg 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 (once daily for 10 days) increased perampanel AUC by 20% and prolonged perampanel half-life by 15%. Fycompa used in combination with other central nervous system (CNS) depressants such as alcohol can 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 events:*** Adverse reactions most commonly leading to discontinuation of perampanel were dizziness and somnolence. Refer to SmPC for all side effects as listed below. Very common effects (≥1/10): dizziness, somnolence. Common effects (≥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 effects (≥1/1,000 to <1/100): suicidal ideation, suicide attempt. Adverse effects with frequency not known: Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) and Stevens-Johnson Syndrome (SJS). Based on the clinical trial database of 196 adolescents exposed to perampanel from double-blind studies for partial onset seizures and primary generalised tonic-clonic seizures, the overall safety profile in adolescents was similar to that of adults, except for aggression, observed more frequently in adolescents than in adults. Somnolence, irritability, aggression, and agitation were observed more frequently in the paediatric study (180 patients) compared to studies in adolescents and adults.

Legal Category: POM

Basic UK NHS cost:

Fycompa 2 mg: packs of 7 £35.00,
Fycompa 2 mg: packs of 28 £140.00,
Fycompa 4 mg: packs of 28 £140.00,
Fycompa 6 mg: packs of 28 £140.00,
Fycompa 8 mg: packs of 28 £140.00,
Fycompa 10 mg: packs of 28 £140.00,
Fycompa 12 mg: packs of 28 £140.00,
Fycompa oral suspension 0.5 mg/ml: 340 ml bottle £127.50

Marketing authorisation numbers:

Fycompa 2 mg 7 tablets: EU/1/12/776/001,
Fycompa 2 mg 28 tablets: EU/1/12/776/017,
Fycompa 4 mg 28 tablets: EU/1/12/776/003,
Fycompa 6 mg 28 tablets: EU/1/12/776/006,
Fycompa 8 mg 28 tablets: EU/1/12/776/009,
Fycompa 10mg 28 tablets: EU/1/12/776/012,
Fycompa 12 mg 28 tablets: EU/1/12/776/015,
Fycompa oral suspension 0.5 mg/ml:
340 ml bottle: EU/1/12/776/024.

Marketing authorisation holder: Eisai GmbH.

Further Information from: Eisai Ltd,
European Knowledge Centre, Mosquito Way, Hatfield, Hertfordshire, AL10 9SN.

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for the MHRA Yellow Card in the Google Play or Apple App Store, or Ireland: www.hpra.ie. Adverse events should also be reported to Eisai Ltd on +44 (0)845 676 1400/ +44 (0)208 600 1400 or EUmedinfo@eisai.net