

## PRESCRIBING INFORMATION

### Ongentys® (opicapone)

Please refer to the SPC before prescribing. **Presentation:** Capsules containing 50 mg of opicapone. **Indication:** Adjunctive therapy to preparations of levodopa/DOPA decarboxylase inhibitors (DDCI) in adult patients with Parkinson's disease and end-of-dose motor fluctuations who cannot be stabilised on those combinations. **Dosage and administration:** The recommended dose is 50 mg of opicapone. It should be taken once daily at bedtime at least one hour before or after levodopa combinations. Ongentys is to be administered as an adjunct to levodopa treatment and enhances the effects of levodopa. Hence, it is often necessary to adjust levodopa dosage by extending the dosing intervals and/or reducing the amount of levodopa per dose within the first days to first weeks after initiating the treatment with opicapone according to the clinical condition of the patient. If one dose is missed, the next dose should be taken as scheduled. The patient should not take an extra dose to make up for the missed dose. **Elderly patients:** No dose adjustment is needed for elderly patients. Caution must be exercised in patients  $\geq$  85 years of age as there is limited experience in this age group. **Patients with renal impairment:** No dose adjustment is necessary in patients with renal impairment, as opicapone is not excreted by the kidney. **Patients with hepatic impairment:** No dose adjustment is necessary in patients with mild hepatic impairment (Child- Pugh Class A). There is limited clinical experience in patients with moderate hepatic impairment (Child- Pugh Class B). Caution must be exercised in these patients and dose adjustment may be necessary. There is no clinical experience in patients with severe hepatic impairment (Child-Pugh Class C), therefore, Ongentys is not recommended in these patients. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. Pheochromocytoma, paraganglioma, or other catecholamine secreting neoplasms. History of neuroleptic malignant syndrome and/or non-traumatic rhabdomyolysis. Concomitant use with monoamine oxidase (MAO-A and MAO-B) inhibitors (e.g. phenelzine, tranylcypromine and moclobemide) other than those for the treatment of Parkinson's disease. **Pregnancy:** Ongentys is not recommended during pregnancy and in women of childbearing potential not using contraception. **Lactation:** Breast-feeding should be discontinued during treatment with Ongentys. **Warnings and precautions:** Opicapone enhances the effects of levodopa. To reduce levodopa-related dopaminergic adverse reactions (e.g. dyskinesia, hallucinations, nausea, vomiting and orthostatic hypotension), it is often necessary to adjust the daily dose of levodopa by extending the dosing intervals and/or reducing the amount of levodopa per dose within the first days to first weeks after initiating treatment with Ongentys, according to the clinical condition of the patient. Patients and care-givers should be made aware that impulse control disorders including pathological gambling, increased libido, hypersexuality, compulsive spending or buying, binge eating and compulsive eating can occur in patients treated with dopamine agonists and/or other dopaminergic treatments. Patients should be monitored regularly for the development of impulse control disorders and review of treatment is recommended

if such symptoms develop. Increases in liver enzymes were reported in studies nitrocatechol inhibitors of catechol-O-methyltransferase (COMT). For patients who experience progressive anorexia, asthenia and weight decrease within a relatively short period of time, a general medical evaluation including liver function should be considered. **Excipients:** Ongentys contains lactose. Patients with rare hereditary problems of galactose intolerance, the total lactase deficiency or glucose-galactose malabsorption should not take this medicinal product. **Drug interactions:** Concomitant use of opicapone with MAO inhibitors (e.g. phenelzine, tranylcypromine and moclobemide) other than those for the treatment of Parkinson's disease is contraindicated. Concomitant use of opicapone and MAO inhibitors for the treatment of Parkinson's disease, e.g. rasagiline (up to 1 mg/day) and selegiline (up to 10 mg/day in oral formulation or 1.25 mg/day in buccal absorption formulation), is permissible. There is no experience with opicapone when used concomitantly with the MAO-B inhibitor safinamide. Therefore, their concomitant use should be considered with appropriate caution. Opicapone may interfere with the metabolism of medicinal products containing a catechol group that are metabolised by COMT, e.g. rimiterole, isoprenaline, adrenaline, noradrenaline, dopamine, dopexamine or dobutamine, leading to potentiated effects of these medicinal products. Careful monitoring of patients being treated with these medicinal products is advised when opicapone is used. Concomitant use with tricyclic antidepressants and noradrenaline re-uptake inhibitors (e.g. venlafaxine, maprotiline and desipramine) should be considered with appropriate caution. Particular consideration should be given to medicinal products metabolised by CYP2C8 and their co-administration must be avoided. Particular consideration should be given to medicinal products transported by OATP1B1 and their concomitant use should be considered with appropriate caution. **Adverse events:** Refer to the SPC for all side effects. Very common side effects ( $\geq$  1/10): Dyskinesia. Common side effects ( $\geq$  1/100 to  $<$  1/10): Abnormal dreams, Hallucination, Hallucination visual, Insomnia, Dizziness, Headache, Somnolence, Orthostatic hypotension, Constipation, Dry mouth, Vomiting, Muscle spasms, Blood creatine phosphokinase increased. Uncommon side effects ( $\geq$  1/1,000 to  $<$  1/100): Decreased appetite, Hypertriglyceridaemia, Anxiety, Depression, Hallucination auditory, Nightmares, Sleep disorder, Dysgeusia, Hyperkinesia, Syncope, Dry eye, Ear congestion, Palpitations, Hypertension, Hypotension, Dyspnoea, Abdominal distention, Abdominal pain, Abdominal pain upper, Dyspepsia, Muscle twitching, Musculoskeletal stiffness, Myalgia, Pain in extremity, Chromaturia, Nocturia, Weight decreased. **Legal Category:** POM. **Basic UK NHS cost:** Ongentys pack of 30: £93.90. **Marketing authorisation numbers:** PLGB 21566/0004 EU/1/15/1066/003. **Marketing authorisation holder:** Bial-Portela & Ca., S.A., A Avenida da Siderurgia nacional 4745-457 Coronado (S. Romao e S. Mamede) – Portugal. **Further Information from:** Bial Pharma UK Ltd., Admiral House, St. Leonard's Road, Windsor, SL4 3BL, UK. **Job code:** UK/ON/2021/016(1). **Date of preparation:** October 2021.

#### Adverse events should be reported.

Reporting forms and information can be found at [www.yellowcard.mhra.gov.uk](http://www.yellowcard.mhra.gov.uk) or in Ireland: [www.hpra.ie](http://www.hpra.ie).

Adverse events should also be reported to BIAL on +44 (0)1628 531171 or [bial@pharmalex.com](mailto:bial@pharmalex.com)