ONGAB

For the use of a Registered Medical Practitioners or a Hospital or a Laboratory only Abbreviated Prescribing information for Ongab capsule [Pregabalin & Methylcobalamin] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Pregabalin: The active substance, pregabalin, is a gamma-aminobutyric acid analogue [(S)-3-(aminomethyl)-5-methylhexanoic acid]. Pregabalin binds to an auxiliary subunit (α_2 - δ protein) of voltage-gated calcium channels in the central nervous system. **Methylcobalamin:** Methylcobalamin is one of the biologically active form of vitamin B12. It is involved in the synthesis of thymidine from deoxyuridine and promotes the synthesis of DNA and RNA.

INDICATION: Peripheral neuropathy.

DOSAGE AND ADMINISTRATION: Treatment will be started with once daily and the dose may be increased after an interval of 3 to 7 days.

CONTRAINDICATION: Hypersensitivity to the active substance or to any of the excipients.

WARNINGS & PRECAUTIONS: Pregabalin: Diabetic patients-need to adjust hypoglycaemic medicinal products, hypersensitivity reactions-angioedema, dizziness, somnolence, loss of consciousness, confusion, mental impairment, loss of vision, visual blurring or other changes of visual acuity, renal failure, withdrawal symptoms, congestive heart failure, suicidal ideation and behaviour, reduced lower gastrointestinal tract function (e.g. intestinal obstruction, paralytic ileus, constipation), misuse, abuse and dependence and encephalopathy. Methylcobalamin: Should be given with caution in patients suffering from folate deficiency. Megaloblastic anemia is sometimes corrected by treatment with vitamin B12. But this can have very serious side effects. Do not take vitamin B12 if Leber's disease. The treatment of vitamin B12 deficiency can unmask the symptoms of polycythemia vera.

DRUG INTERACTIONS: Pregabalin: Central nervous system influencing medical products- Pregabalin may potentiate the effects of ethanol and lorazepam. Respiratory failure and coma in patients taking pregabalin and other central nervous system (CNS) depressant medicinal products. Pregabalin appears to be additive in the impairment of cognitive and gross motor function caused by oxycodone. **Methylcobalamin:** Serum concentrations may be decreased by use of oral contraceptives. Parenteral chloramphenicol may attenuate the effect of vitamin B12 in anaemia. Folic acid, particularly in large doses, can cover up vitamin B12 deficiency, and cause serious health effects.

ADVERSE REACTIONS: Pregabalin: Nasopharyngitis, Appetite increased, Euphoric mood, irritability, disorientation, insomnia, libido decreased, headache, diplopia, Vertigo, Vomiting, *nausea, diarrhoea*, flatulence, abdominal distension, dry mouth, muscle cramp, arthralgia, back pain, pain in limb, cervical spasm, erectile dysfunction, oedema peripheral, oedema, gait abnormal, fall, feeling drunk, feeling abnormal, fatigue, weight increased. **Methylcobalamin:** Polycythemia vera, itching; transitory exanthema, blood clots, serious allergic reactions.

MARKETED BY



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IN/ ONGAB 150mg, 750 mcg /JUL-17/01/ABPI

(Additional information is available on request)