

ROFSHIELD

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only

Abbreviated Prescribing information for Rofshield (Roflumilast tablets 500mcg) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: - Roflumilast is a PDE₄ inhibitor, a non-steroid, anti-inflammatory active substance designed to target both the systemic and pulmonary inflammation associated with COPD.

INDICATION: - For the treatment of chronic obstructive pulmonary disease

DOSAGE AND ADMINISTRATION: The recommended dose is 500 micrograms (one tablet) once daily. Roflumilast may need to be taken for several weeks to achieve its effect.

CONTRAINDICATION: Contraindicated in patients who have hypersensitivity to the active substance or to any of the excipients and moderate or severe hepatic impairment (Child-Pugh B or C).

WARNINGS & PRECAUTIONS: Roflumilast is not indicated as rescue medicinal product for the relief of acute bronchospasms. Decrease in body weight, roflumilast is associated with an increased risk of psychiatric disorders such as insomnia, anxiety, nervousness and depression, while adverse reactions like diarrhoea, nausea, abdominal pain and headache mainly occur within the first weeks of therapy and mostly resolve on continued treatment.

DRUG INTERACTIONS: CYP1A2/3A4 inhibitor enoxacin and the CYP1A2/2C19/3A4 inhibitors cimetidine and fluvoxamine, resulted in increases of the total PDE₄ inhibitory activity, strong cytochrome P450 enzyme inducers (e.g. phenobarbital, carbamazepine, phenytoin) may reduce the therapeutic efficacy of roflumilast.

ADVERSE REACTIONS: Hypersensitivity, angioedema, weight decreased, decreased appetite, gynaecomastia, insomnia, anxiety, suicidal ideation and behavior, depression, nervousness, panic attack, headache, tremor, vertigo, dizziness, palpitations, diarrhoea, nausea, abdominal pain, gastritis, vomiting, gastro-oesophageal reflux disease, dyspepsia, gamma-GT increased, aspartate aminotransferase (AST) increased, rash, urticaria, muscle spasms and weakness, myalgia, back pain, blood creatine phosphokinase (CPK) increased, malaise, asthenia and fatigue.

MARKETED BY:



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(Additional information is available on request)