rollumilast (roh-floo-mi-last)

Dexilias, Ducal

Classification
Therapeutic: COPD agents
Pharmacologic: phosphodiesterase inhibitors

Pregnancy Category C

Indications
To reduce the risk of exacerbations in severe COPD patients that have a history of chronic bronchitis with exacerbations.

Action
Roflumilast and one active metabolite (roflumilast N-oxide) act as selective inhibitors of phosphodiesterase 4 (PDE4), responsible for breaking down 3', 5'-adenosine monophosphate (cAMP). Resulting intracellular accumulation of cAMP in lung tissue. Reduces cells (neutrophils, eosinophils and total cells) in sputum.

Therapeutic Effects: Decrease exacerbations in COPD patients.

Pharmacokinetics
Absorption: Well absorbed following oral administration.
Distribution: Parent drug and metabolites probably enter breast milk.
Protein Binding: Roflumilast—99%; roflumilast N-oxide—97%.
Metabolism and Excretion: Mostly metabolized (87.5%), primarily by CYP3A4 and CYP1A2 enzyme systems. One metabolite, roflumilast N-oxide in pharmacologically active. Inactive metabolites excreted in urine.
Half-life: Roflumilast—17 hr; roflumilast N-oxide—30 hr.

TIME/ACTION PROFILE (blood levels)

<table>
<thead>
<tr>
<th>ROUTE</th>
<th>ONSET</th>
<th>PEAK</th>
<th>DURATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>PO</td>
<td>unknown</td>
<td>1 (4–13†)</td>
<td>24 hr</td>
</tr>
</tbody>
</table>

†For roflumilast N-oxide.

Contraindications/Precautions
Contraindicated in: Acute bronchospasm; Moderate to severe hepatic impairment; Concurrent use of strong inducers of CYP3A4 and CYP1A2 enzyme systems; Lactation: Avoid breast feeding.

Use Cautiously in: History of depression/suicidal thoughts; OB: Use only if potential maternal benefit justifies potential risk to the fetus. Ped: Safety and effectiveness not established.

Adverse Reactions/Side Effects
CNS: anxiety, depression, dizziness, headache, insomnia.

Interactions
Drug-Drug: Strong inducers of the CYP3A4 and CYP1A2 enzyme systems, including: rifampicin, phenobarbital, carbamazepine, and phenytoin. Blood levels and effectiveness; concurrent use should be avoided. Blood levels and risk of adverse reactions may be increased by concurrent use of inhibitors of the CYP3A4 enzyme system and dual inhibitors of the CYP3A4 and CYP1A2 enzyme systems including erythromycin, ketoconazole, fluvoxamine, and simvastatin. Gastrointestinal and ethinyl estradiol may also increase levels and risk of adverse reactions; risk should be considered.

Route/Dosage
PO (Adults): 500 mcg once daily.

NURSING IMPLICATIONS

Assessment
● Assess respiratory status periodically during therapy.
● Monitor weight regularly. If unexplained or clinically significant weight loss occurs, evaluate weight loss and consider discontinuation of roflumilast.
● Assess mental status (orientation, mood, behavior) before and periodically during therapy. Assess for suicidal tendencies.
● Monitor for signs and symptoms of hypersensitivity reactions (angioedema, urticaria, rash). Discontinue therapy and treat symptomatically if symptoms occur.

Potential Nursing Diagnoses
Ineffective airway clearance

Implementation
● PO: Administer without regard to food.

NURSING DIAGNOSES
Ineffective airway clearance

INTERVENTIONS
● PO: Administer without regard to food.
Patient/Family Teaching

● Instruct patient to take roflumilast as directed. Advise patient to read Medication Guide before starting therapy and with each Rx refill; new information may be available.
● Inform patient that roflumilast is not a bronchodilator and should not be used for treating sudden breathing problems.
● Advise patient to monitor weight regularly. If weight loss occurs, notify health care professional; may require discontinuation of therapy.
● Advise patient and family to notify health care professional if thoughts about suicide or dying, attempts to commit suicide, trouble sleeping, new or worse depression, new or worse anxiety, acting on dangerous impulses, or other unusual changes in behavior or mood or signs and symptoms of hypersensitivity reactions occur.
● Instruct patient to notify health care professional of all Rx or OTC medications, vitamins, or herbal products being taken and to avoid concurrent use of Rx, OTC, and herbal products without consulting health care professional.
● Advise female patient to notify health care professional if pregnancy is planned or suspected or if breast feeding.

Evaluation/Desired Outcomes

● in the number of flare-ups or the worsening of COPD symptoms (exacerbations).

Why was this drug prescribed for your patient?