Roflumilast Tablets, 250 mcg and 500 mcg

S. No.	Category	Question	Answer
Clinical Particulars			
1	Use/Indication	What is the product indicated for?	Roflumilast Tablets are a selective phosphodiesterase 4 inhibitor indicated as a treatment to reduce the risk of COPD exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations. Limitations of Use: • Roflumilast Tablets are not a bronchodilator and is not indicated for the relief of acute bronchospasm. • Roflumilast Tablets 250 mcg is a starting dose, for the first 4 weeks of treatment only and is not the effective (therapeutic) dose
2	Dosage	What is the recommended dosage?	• Starting treatment with a dose of Roflumilast Tablet 250 mcg once daily for 4 weeks and increasing to Roflumilast Tablet 500 mcg once daily thereafter may reduce the rate of treatment discontinuation in some patients. • Roflumilast 250 mcg per day is not the effective (therapeutic) dose.
3	Administration	How do I take it?	Roflumilast tablets can be taken with or without food.
4	Administration	Use in Pediatric Population	COPD does not normally occur in children. The safety and effectiveness of Roflumilast Tablets in pediatric patients have not been established
5	Administration	Use in Geriatric Population	No adjustment of dosage in geriatric patients is warranted.
6	Mechanism	Mechanism of Action	Roflumilast and its active metabolite re selective inhibitors of phosphodiesterase 4 (PDE4). Roflumilast and roflumilast N-oxide inhibition of PDE4 (a major cyclic-3′,5′-adenosinemonophosphate (cyclic AMP)-metabolizing enzyme in lung tissue) activity leads to accumulation of intracellular cyclic AMP. While the specific mechanism(s) by which Roflumilast Tablets exerts its therapeutic action in COPD patients is not well defined, it is thought to be related to the effects of increased intracellular cyclic AMP in lung cells.
7	Warning	Warnings and precautions	**R**oflumilast tablets should not be used for the relief of acute bronchospasm.
8	Lactation	Use in Lactation	There is no information regarding the presence of Roflumilast Tablets in human milk, the effects on the breastfed infant, or the effects on milk production. Roflumilast and/or its metabolites are excreted into the milk of lactating rats. Excretion of Roflumilast and/or its metabolites into human milk is probable. Roflumilast Tablets should not be used by women who are nursing.

9	Pregnancy	Use in Pregnancy	Roflumilast Tablets should not be used during labor and delivery. There are no human studies that have investigated effects of Roflumilast Tablets on preterm labor or labor at Term.
10	Storage	What are the storage conditions?	Store Roflumilast tablets at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F).
11	Dispensing	How to Dispense?	This package is not for household dispensing. If dispensed for outpatient use, a well closed, light-resistant, child-resistant container should be utilized.
12	Contraindication	What are the contraindications of (medication)?	Moderate to severe liver impairment (Child-Pugh B or C)
Pharmaceutical Particulars			
13	Pharmaceutical Form	How Supplied	Roflumilast Tablets 250 mcg are supplied as white to off-white, round, flat face bevel edged, uncoated tablets, debossed with “R” on one side and “0.25” on the other side. Roflumilast 250 mcg Tablets are available: • Blister pack of 28: NDC 72205-201-32 • 2×10 Unit Dose: NDC 72205-201-24 • Roflumilast Tablets 500 mcg are supplied as white to off-white, round, flat face bevel edged, uncoated tablets, debossed with “R” on one side and “0.5” on the other side • Roflumilast 500 mcg Tablets are available: • Bottles of 30: NDC 72205-200-30 • Bottles of 90: NDC 72205-200-90 • 10X10UnitDose:NDC72205-200-06
14	Ingredients	Active and Inactive	**Active ingredient:** Roflumilast **Inactive ingredients:** lactose monohydrate, magnesium stearate, polysorbate 80 and pregelatinized starch.
Allergens			
15	Ingredients	Does it contain Gluten?	No
16	Ingredients	Does it contain alcohol?	API contains solvents within the limits as per ICH
17	Ingredients	Does it contain dyes?	No
18	Ingredients	Does it contain Lactose?	Lactose used as diluent in the FP products and sourced from Cow’s milk
19	Ingredients	Does it contain Nuts?	No
20	Ingredients	Does it contain Preservatives?	No
21	Ingredients	Does it contain Soy products?	No
22	Ingredients	Does it contain peanut?	No
23	Ingredients	Does it contain Corn?	Starch used which is derived from maize starch

24	Ingredients	Does it contain any animal products?	Lactose sourced from cow's milk
25	Ingredients	Does it contain any Wheat?	Starch used which is derived from maize starch
Miscellaneous			
26	Miscellaneous	May I know the product availability?	Novadoz Pharmaceuticals products are only available through pharmacies, wholesalers, and other authorized distributors. See our ADR (authorized distributors of record) page at NovadozPharma.com to learn more about where to find our products.
27	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
28	Miscellaneous	Do you have any patient's assistance program?	Novadoz Pharmaceuticals does not offer patient assistance programs at this time. The company that produces the brand version of your product may or may not offer such a program. Please check for access & eligibility requirements with that company
29	Miscellaneous	Why does my pharmacy, that used to fill your generic formulation of a particular medicine, no longer fills my prescription with Novadoz formulation?	Please check with your pharmacy as to why your prescription is not a Novadoz Pharmaceuticals product. You may refer to NovadozPharma.com ADR (authorized distributor of record) page to learn where to find our products
30	Miscellaneous	May I know where is this product manufactured?	**Manufactured by**: MSN Laboratories Private Limited Telangana – 509 228, INDIA **Distributed by**: Novadoz Pharmaceuticals LLC Piscataway, NJ 08854-3714