

Sildenafil for Oral Suspension, 10 mg/mL.

S.No.	Category	Question	Answer
Clinical Particulars			
1.	Use/Indication	What is the product indicated for?	Sildenafil is a phosphodiesterase-5 (PDE-5) inhibitor indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group I) in adults to improve exercise ability and delay clinical worsening. Studies establishing effectiveness were short-term (12 to 16 weeks), and included predominately patients with NYHA Functional Class II–III symptoms. Etiologies were idiopathic (71%) or associated with connective tissue disease (25%). (1)
2.	Dosage	What is the recommended dosage?	Oral suspension: 5 mg or 20 mg three times a day, 4–6 hours apart see full prescribing information for reconstitution instructions for the Powder for Oral Suspension (2.1, 2.3)
3.	Administration	How do I take?	Take Sildenafil for Oral Suspension 3 times a day about 4 to 6 hours apart. Do not mix Sildenafil for Oral Suspension with other medicine or flavoring. Shake well for at least 10 seconds before each dose. Do not take more than one dose of Sildenafil for Oral Suspension at a time.
4.	Administration	What do I do if I miss a dose?	If you miss a dose, take it as soon as you remember. If it is close to your next dose, skip the missed dose, and take your next dose at the regular time
5.	Side effects	What are the most common and possible side effects?	Nosebleed, headache, upset stomach, getting red or hot in the face (flushing), trouble sleeping, as well as fever, erection increased, respiratory infection, nausea, vomiting, bronchitis, pharyngitis, runny nose, and pneumonia in children.
6.	Administration	Use in Pediatric Population	Pediatric use information is approved for Pfizer's LYRICA (pregabalin) Capsules and Oral Solution products. However, due to Pfizer's marketing exclusivity rights, this drug product is not labeled with that pediatric information.
7.	Administration	Use in Geriatric Population	Clinical studies of Sildenafil for Oral Suspension did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.
8.	Mechanism	Mechanism of Action	Sildenafil is an inhibitor of cGMP specific phosphodiesterase type-5 (PDE-5) in the smooth muscle of the pulmonary vasculature, where PDE-5 is responsible for degradation of cGMP. Sildenafil, therefore, increases cGMP within pulmonary vascular smooth muscle cells resulting in relaxation. In patients with PAH, this can lead to vasodilation of the pulmonary vascular bed

			and, to a lesser degree, vasodilatation in the systemic circulation. Studies in vitro have shown that sildenafil is selective for PDE-5. Its effect is more potent on PDE-5 than on other known phosphodiesterases (10-fold for PDE6, greater than 80-fold for PDE1, greater than 700-fold for PDE2, PDE3, PDE4, PDE7, PDE8, PDE9, PDE10, and PDE11). The approximately 4,000-fold selectivity for PDE-5 versus PDE3 is important because PDE3 is involved in control of cardiac contractility. Sildenafil is only about 10-fold as potent for PDE-5 compared to PDE6, an enzyme found in the retina and involved in the phototransduction pathway of the retina. This lower selectivity is thought to be the basis for abnormalities related to color vision observed with higher doses or plasma levels.
9.	Warning	Black Box Warning	No Black Box warning
10.	Lactation	Use in Lactation	Limited published data from a case report describe the presence of sildenafil and its active metabolite in human milk. There is insufficient information about the effects of sildenafil on the breastfed infant and no information on the effects of sildenafil on milk production. Limited clinical data during lactation preclude a clear determination of the risk of sildenafil to an infant during lactation.
11.	Pregnancy	Use in Pregnancy	Pregnant women with untreated pulmonary arterial hypertension are at risk for heart failure, stroke, preterm delivery, and maternal and fetal death.
12.	Storage	What are the storage conditions?	Recommended storage for Sildenafil for Oral Suspension: Store below 30°C (86°F) in the original package in order to protect from moisture.
13.	Dispensing	How to Dispense?	As prescribed by the Physician
14.	Contraindication	What are the contraindications of (medication)?	Concomitant use of organic nitrates in any form, either regularly or intermittently, because of the greater risk of hypotension. Concomitant use of riociguat. known hypersensitivity to sildenafil or any component of the tablet, injection, or oral suspension. hypersensitivity, including anaphylactic reaction, anaphytic shock and anaphylactoid reaction.
Pharmaceutical Particulars			
15.	Pharmaceutical Form	How Supplied	Sildenafil for Oral Suspension is supplied in amber glass bottles. Each bottle contains white to off-white powders containing 1.57 g of sildenafil citrate (equivalent to 1.12 g sildenafil). Following constitution, the volume of the oral suspension is 112 mL (10 mg sildenafil/mL). A 2 mL oral dosing syringe (with 0.5 mL and 2 mL dose markings) and a press-in bottle adaptor are also provided.
16.	Ingredients	Active and Inactive	Active ingredient: sildenafil citrate Inactive ingredients: sorbitol, citric acid anhydrous, sucralose, sodium citrate dihydrate, xanthan gum, titanium dioxide, sodium benzoate, colloidal silicon dioxide anhydrous, and grape flavor
Allergens			
17.	Ingredients	Does it contain Gluten?	No
18.	Ingredients	Does it contain alcohol?	No
19.	Ingredients	Does it contain dyes?	No
20.	Ingredients	Does it contain Lactose?	No

21.	Ingredients	Does it contain Nuts?	No
22.	Ingredients	Does it contain Preservatives?	No
23.	Ingredients	Does it contain Soy products?	No
24.	Ingredients	Does it contain peanut?	No
25.	Ingredients	Does it contain any derivatives from tree nuts or any other type of nuts?	No
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?	<p>Manufactured by: MSN pharmaceuticals Inc. Piscataway, NJ 08854.</p> <p>Distributed by: Novadoz Pharmaceuticals LLC Piscataway, NJ 08854-3714 TEL: 855-NOVADOZ (668-2369)</p>