NOVADOZ
AN MSN COMPANY

SILDENAFIL FOR ORAL SUSPENSION, 10mg/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%).
2	Dosage	What is the recommended dosage?	White to off-white powders containing 1.57 g of sildenafil citrate (equivalent to 1.12 g of sildenafil) in a bottle intended for reconstitution. Following reconstitution with 90 mL of water, the volume of the oral suspension is 112 mL and the oral suspension contains 10 mg/mL sildenafil. A 2 mL oral syringe (with 0.5 mL and 2 mL dose markings) and a press-in bottle adaptor are also provided.
3	Administration	How do I take it?	**Sildenafil Oral Suspension: Dose & Reconstitution Instructions** • **Recommended Dose**: 5 mg or 20 mg three times a day, spaced 4–6 hours apart. Higher doses (>20 mg three times a day) are not recommended. • **Reconstitution**: 1. **Tap** the bottle to release the powder. 2. **Add 60 mL** of water to the bottle, replace the cap, and **shake vigorously** for 30 seconds. 3. **Add another 30 mL** of water (total 90 mL), replace the cap, and **shake vigorously** for 30 seconds. 4. **Attach the bottle adaptor** to the neck of the bottle. 5. **Expiration**: The reconstituted

			suspension is valid for **60 days**.
4	Formulation	Can tablet be crushed?	NO
5	Administration	What do I do if I miss a dose?	If you miss a dose of Sildenafil Oral Suspension continue your prescribed course of therapy, and contact your physician immediately.
6	Administration	Use in Pediatric Population	**Sildenafil for PAH in Paediatric Patients: Study Summary** • **Study Design**: Randomized, double-blind, placebo-controlled, dose-ranging trial with 234 patients (ages 1-17, weight ≥8 kg) for 16 weeks. • **Patient Demographics**: Most had mild to moderate symptoms (WHO Class I-III). One-third had primary PAH, two-thirds had secondary PAH. • **Treatment**: Sildenafil or placebo, three times daily. • **Primary Objective**: Assess Sildenafil's effect on exercise capacity (measured by cardiopulmonary exercise testing in 115 patients). No significant improvement in exercise capacity was observed. • **Mortality Findings**: 42 deaths during the long-term study (median follow-up 4.6 years). The hazard ratio for high vs. low-dose Sildenafil was 3.9 (p=0.007), indicating increased mortality with higher doses. Most deaths occurred before dose titration. • **Conclusion**: Chronic use of Sildenafil for Oral Suspension in children is **not recommended** due to safety concerns.
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 another drug therapy
8	Mechanism	Mechanism of Action	Sildenafil inhibits PDE-5, an enzyme in the pulmonary vasculature that degrades cGMP. By increasing cGMP levels, Sildenafil induces smooth muscle relaxation, leading to **pulmonary vasodilation** in PAH patients and mild systemic vasodilation. • **Selectivity**: Sildenafil is highly selective for PDE-5 (approx. 4,000 times more than PDE-3), which is important for avoiding effects on cardiac contractility. It is less selective for PDE-6 (10-fold), an enzyme in the retina, which may contribute to colour vision abnormalities at higher doses. • **Other Effects**: Sildenafil also inhibits PDE-5 in other tissues, including platelets, contributing to **enhanced platelet anti-aggregatory effects** and mild **peripheral arterial-venous dilation**.
9	Warning	Black Box Warning	None
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	**Sildenafil Use During Pregnancy: Summary** • **Pregnancy Data**: Limited studies (randomized controlled trials, case-control trials, case series) show no clear link between sildenafil use and major birth defects, miscarriage, or adverse maternal/foetal outcomes. • **Animal Studies**: No evidence of embryo-foetal toxicity or teratogenicity at doses up to 32–65 times the recommended human dose. • **Background Risk**: The general background risk for birth defects is 2–4%, and for miscarriage, 15–20%. • **Clinical Considerations**: Untreated pulmonary arterial hypertension (PAH) in

			pregnant women poses risks such as heart failure, stroke, preterm delivery, and maternal/foetal death.
12	Precautions	Is there any interaction between medication and alcohol?	Sildenafil (50 mg) did not potentiate the hypotensive effect of alcohol in healthy volunteers with mean maximum blood alcohol levels of 0.08%.
13	Interaction	Is there any interaction with food?	No
14	Side effects	What are the common side effects?	• **low blood pressure.** Low blood pressure may cause you to feel faint or dizzy. Lie down if you feel faint or dizzy. • **more shortness of breath than usual.** Tell your doctor if you get shorter of breath after you start Sildenafil for Oral Suspension. More shortness of breath than usual may be due to your underlying medical condition. • **decreased eyesight or loss of sight in one or both eyes (NAION).** If you notice a sudden decrease or loss of eyesight, talk to your doctor right away. • **sudden decrease or loss of hearing.** If you notice a sudden decrease or loss of hearing, talk to your doctor right away. It is not possible to determine whether these events are related directly to this class of oral medicines, including Sildenafil for Oral Suspension, or to other diseases or medicines, to other factors, or to a combination of factors. • **heart attack, stroke, irregular heartbeats, and death.** Most of these happened in men who already had heart problems. • **erections that last several hours.** If you have an erection that lasts more than 4 hours, get medical help right away. If it is not treated right away, priapism can permanently damage your penis.
15	Storage	What are the storage conditions?	• Store reconstituted oral suspension below 30°C (86°F) or in a refrigerator between 2°C to 8°C (36°F to 46°F).

			• Do not freeze Sildenafil for Oral Suspension • Throw away (discard) Sildenafil for Oral Suspension after 60 days. • **Keep Sildenafil for Oral Suspension and all medicines away from children.**
16	Dispensing	How to Dispense?	As prescribed by the Physician
17	Contraindication	What are the contraindications of (medication).	Sildenafil is contraindicated in patients with: • **Concomitant use of organic nitrates** (due to increased risk of hypotension). • **Concomitant use of riociguat** (due to potentiation of hypotensive effects). • **Known hypersensitivity to sildenafil** or any component of the product (including risk of anaphylactic reactions).
Pharmaceutical Particulars			
18	Pharmaceutical Form	How is it supplied?	**Form**: Amber glass bottle containing 1.57 g sildenafil citrate (equivalent to 1.12 g sildenafil) as a white to off-white powder. **After Reconstitution**: The suspension volume is 112 mL, with a concentration of 10 mg sildenafil per mL. **Supplied With**: A 2 mL oral dosing syringe (marked for 0.5 mL and 2 mL doses) and a press-in bottle adaptor.
19	Ingredients	Active and Inactive Ingredients	**Active:** sildenafil citrate **Inactive**: sorbitol, citric acid anhydrous, sucralose, sodium citrate dihydrate, xanthan gum, titanium dioxide, sodium benzoate, colloidal silicon dioxide anhydrous, and grape flavor.
20	Coating	What is the type of coating?	None
Allergens			
21	Ingredients	Is it Vegetarian?	yes
22	Ingredients	Does it contain Gluten?	No
23	Ingredients	Does it contain Dairy Products?	No
24	Ingredients	Does it contain Casein	No
25	Ingredients	Does it contain Whey?	No

26	Ingredients	Does it contain corn?	No
27	Ingredients	Does it contain rye?	No
28	Ingredients	Does it contain sugar?	No
29	Ingredients	Does it contain Oats?	No
30	Ingredients	Does it contain wheat?	No
31	Ingredients	Does it contain spelt?	No
32	Ingredients	Does it contain barley?	No
33	Ingredients	Does it contain rennet?	No
34	Ingredients	Does it contain starch?	No
35	Ingredients	Does it contain Iodine?	No
36	Ingredients	Does it contain latex?	No
37	Ingredients	Does it contain alcohol?	No
38	Ingredients	Does it contain dyes?	No
39	Ingredients	Does it contain flavor?	No
40	Ingredients	Does it contain Lactose?	No
41	Ingredients	Does it contain Nuts?	No
42	Ingredients	Does it contain Preservatives?	Yes
43	Ingredients	Does it contain Soy products?	No
44	Ingredients	Does it contain peanut?	No
45	Ingredients	Does it contain nickel?	No
46			
Miscellaneous	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.

47	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
48	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.
49	Miscellaneous	How do I report an adverse drug effect or reaction to Novadoz medication?	To report suspected adverse reactions, contact Novadoz Pharmaceuticals LLC at 1-855-668-2369 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
50	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.
51	Miscellaneous	Manufacturer and Distributor	**Manufactured by:** **MSN Pharmaceuticals Inc** **20 Duke Road, Piscataway-08854, NJ, USA** **Distributed by:** **Novadoz Pharmaceuticals LLC** **Piscataway, NJ 08854-3714** **TEL: 855-NOVADOZ (668-2369)**