Deferasirox Oral Granules,90mg 180 mg and 360 mg

S.No.	Category	Question	Answer
Clinical Particulars			
1	Use/Indication	What is the product indicated for?	Deferasirox oral granules is an iron chelator indicated for the treatment of chronic iron overload due to blood transfusions in patients 2 years of age and older. The treatment of chronic iron overload in patients 10 years of age and older with non-transfusion-dependent thalassemia (NTDT) syndromes, and with a liver iron (Fe) concentration (LIC) of at least 5 mg of iron per gram of liver dry weight (mg Fe/g dw) and a serum ferritin greater than 300 mcg/L. Limitations of Use: The safety and efficacy of deferasirox oral granules when administered with other iron chelation therapy have not been established.
2	Dosage	What is the recommended dosage?	**Transfusional Iron Overload:** Initial dose for patients with estimated glomerular filtration rate (eGFR) greater than 60 mL/min/1.73 m^2 is 14 mg per kg (calculated to nearest whole sachet content for granules) once daily. **NTDT Syndromes:** Initial dose for patients with eGFR greater than 60 mL/min/1.73 m^2 is 7 mg per kg (calculated to nearest whole sachet content for granules) once daily. See full prescribing information for information regarding monitoring, administration, and dose reductions for organ impairment.
3	Administration	How do I take it?	Take deferasirox oral granules exactly as your healthcare provider tells you. You may take deferasirox oral granules on an empty stomach or with a light meal. Sprinkle the prescribed dose of granules onto soft food such as yogurt or applesauce immediately prior to use and administered orally. Deferasirox oral granules should be taken once a day, preferably at the same time each day. Do not take deferasirox oral granules with aluminum-containing antacid products. See full prescribing information for information regarding monitoring, administration, and dose reductions for organ impairment.
4	Administration	What do I do if I miss a dose?	Patients who miss a dose of Deferasirox oral granules should take their next scheduled dose.

			Always contact your physician for further queries.
5	Administration	Use in Pediatric Population	The safety and effectiveness of deferasirox have been established in pediatric patients 2 years of age and older for the treatment of transfusional iron overload. Exercise caution in pediatric patients with eGFR between 40 and 60 mL/minute/1.73 m^2
7	Administration	Use in Geriatric Population	Monitor elderly patients for early signs or symptoms of adverse reactions that may require a dose adjustment. Elderly patients are at increased risk for toxicity due to the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. Dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range.
8	Mechanism	Mechanism of Action	Deferasirox is an orally active chelator that is selective for iron (as Fe^{3+}). It is a tridentate ligand that binds iron with high affinity in a 2:1 ratio. Although deferasirox has very low affinity for zinc and copper, there are variable decreases in the serum concentration of these trace metals after the administration of deferasirox. The clinical significance of these decreases is uncertain.
9	Warning	Black Box Warning	RENAL FAILURE, HEPATIC FAILURE, and GASTROINTESTINAL HEMORRHAGE. DEFERASIROX THERAPY REQUIRES CLOSE PATIENT MONITORING, INCLUDING LABORATORY TESTS OF RENAL AND HEPATIC FUNCTION. See full prescribing information for complete boxed warning.
10	Lactation	Use in Lactation	Advise women not to breastfeed during treatment with deferasirox oral granules. Before taking deferasirox oral granules tell your healthcare provider if you are breastfeeding or plan to breastfeed. It is not known if deferasirox passes into breast milk and can harm baby. You and your healthcare provider should decide if you would take deferasirox oral granules or breastfeed. You should not do both.
11	Pregnancy	Use in Pregnancy	Deferasirox should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Before taking deferasirox oral granules tell your healthcare provider if you are pregnant or plan to become pregnant. It is not known if deferasirox oral granules can harm your unborn baby. Hormonal forms of birth control may not be as effective if used during treatment with deferasirox oral granules. You could become pregnant. Talk to your healthcare provider about other birth control options that you can use during this time. Tell your healthcare provider right away if you become pregnant during treatment with deferasirox oral granules.
12	Precautions	Is there any interaction between medication and alcohol?	None.

13	Interaction	Is there any interaction with food?	None.
14	Side effects	What are the common side effects?	In patients with transfusional iron overload, the most frequently occurring (greater than 5%) adverse reactions are diarrhea, vomiting, nausea, abdominal pain, skin rashes, and increases in serum creatinine. In deferasirox-treated patients with NTDT syndromes, the most frequently occurring (greater than 5%) adverse reactions are diarrhea, rash, and nausea. See full prescribing information for complete information regarding adverse reactions.
15	Storage	What are the storage conditions?	Store deferasirox oral granules at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature]. Protect from moisture.
16	Dispensing	How to Dispense?	As prescribed by the Physician
17	Contraindication	What are the contraindications of (medication).	Deferasirox oral granules were contraindicated patients with: • Estimated GFR less than 40 mL/min/1.73 m^2. • Patients with poor performance status. • Patients with high-risk myelodysplastic syndrome (MDS). • Patients with advanced malignancies. • Patients with platelet counts less than 50 x 10^9/L. • Known hypersensitivity to deferasirox or any component of deferasirox.
Pharmaceutical Particulars			
18	Pharmaceutical Form	How is it supplied?	Deferasirox oral granules 180 mg are white to almost white granules in sachet. They are available in cartons of 30 sachets……. (NDC 72205-075-30). Deferasirox oral granules 360 mg are white to almost white granules in sachet. They are available in cartons of 30 sachets……. ….. (NDC 72205-076-30).
19	Ingredients	Active and Inactive Ingredients	**Active ingredient:** Deferasirox **Inactive ingredients:** Colloidal silicon dioxide, croscarmellose sodium, hydrogenated castor oil, lactose monohydrate, low substituted hydroxy propyl cellulose, microcrystalline cellulose, poloxamer (188), povidone (K30) and sodium stearyl fumarate.
Allergens			
	Ingredients	Is it Vegetarian?	No, Lactose produced from Milk source from healthy cows is used as inactive ingredient
21	Ingredients	Does it contain Gluten?	No
22	Ingredients	Does it contain Dairy Products?	Yes, Lactose produced from Milk source from healthy cows is used as inactive ingredient
23	Ingredients	Does it contain Casein	No
24	Ingredients	Does it contain Whey?	No

25	Ingredients	Does it contain corn?	No
26	Ingredients	Does it contain rye?	No
27	Ingredients	Does it contain sugar?	No
28	Ingredients	Does it contain Oats?	No
29	Ingredients	Does it contain wheat?	No
30	Ingredients	Does it contain spelt?	No
31	Ingredients	Does it contain barley?	No
32	Ingredients	Does it contain rennet?	No
33	Ingredients	Does it contain starch?	Yes
34	Ingredients	Does it contain povidone?	Yes
35	Ingredients	Does it contain Iodine?	Croscarmellose sodium is a
36	Ingredients	Does it contain latex?	No
37	Ingredients	Does it contain alcohol?	Yes, Deferasirox API Contains NMT 300 PPM which is very minute and negligible quantity
38	Ingredients	Does it contain dyes?	No
39	Ingredients	Does it contain flavor?	No
40	Ingredients	Does it contain Lactose?	Yes, lactose produced from Milk source from healthy cows is used as inactive ingredient
41	Ingredients	Does it contain Nuts?	No
42	Ingredients	Does it contain Preservatives?	No
43	Ingredients	Does it contain Soy products?	No
44	Ingredients	Does it contain peanut?	No
45	Ingredients	Does it contain nickel?	No
Miscellaneous			
46	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 Laboratories Private Limited Telangana – 509 228, INDIA **Distributed by:** MSN Pharmaceuticals Inc. Piscataway, NJ 08854-3714 Issued on: 12/2019