Eltrombopag Tablets 12.5mg,25mg,50mg and 75mg.

S.No.	Category	Question	Answer
Clinical Particulars			
1. 1	Use/Indication	What is the product indicated for?	Eltrombopag tablets are a thrombopoietin receptor agonist indicated for: • Persistent or chronic immune thrombocytopenia (ITP) in adults and children ≥1 year with an insufficient response to corticosteroids, immunoglobulins, or splenectomy. • Thrombocytopenia in chronic hepatitis C patients to enable initiation and maintenance of interferon-based therapy. • First-line treatment of severe aplastic anemia (SAA) in adults and children ≥2 years, in combination with standard immunosuppressive therapy. • Severe aplastic anemia in patients with an insufficient response to immunosuppressive therapy.
2. 2	Dosage	What is the recommended dosage?	• Persistent/Chronic ITP: Start at 50 mg once daily for adults and children ≥6 years, and 25 mg once daily for children 1–5 years. Adjust to maintain platelet count ≥50 × 10^9/L. Maximum dose: 75 mg/day. • Chronic Hepatitis C-associated Thrombocytopenia: Start at 25 mg once daily. Adjust to achieve the platelet count needed for antiviral therapy. Maximum dose: 100 mg/day. • First-line Severe Aplastic Anemia: Start at 2.5 mg/kg (ages 2–5 years), 75 mg (ages 6–11 years), or 150 mg (≥12 years) once daily with standard immunosuppressive therapy. Adjust as needed. • Refractory Severe Aplastic Anemia: Start at 50 mg once daily and adjust to maintain platelet count ≥50 × 10^9/L. Maximum dose: 150 mg/day. • Dose adjustments: Lower starting doses are recommended for patients with hepatic impairment and those of East-/Southeast-Asian ancestry.
3. 3	Administration	How do I take it?	• Take eltrombopag exactly as prescribed. Swallow tablets whole; do not split, chew, crush, or mix with food or liquids. • Take on an empty stomach or with a low-calcium meal (≤50 mg calcium), at least 2 hours before or 4 hours after calcium-rich foods or products.

			• If you miss a dose, take the next scheduled dose. Do not take more than one dose in a day. • Do not stop or change the dose without consulting your healthcare provider. • Contact your healthcare provider immediately if you take too much. • Regular platelet count monitoring is required, and patients with severe aplastic anemia (SAA) may also require bone marrow monitoring. Report any unusual bruising or bleeding during or after treatment.
4.	Administration	Use in Pediatric Population	• Approved use: Eltrombopag is approved for children ≥1 year with persistent or chronic ITP and children ≥2 years with treatment-naïve severe aplastic anemia (with h-ATG and cyclosporine). • Not established: Safety and efficacy have not been established in: • Children <1 year with ITP. • Pediatric patients with chronic hepatitis C-associated thrombocytopenia. • Pediatric patients with refractory severe aplastic anemia. • Safety, efficacy, and pharmacokinetics in pediatric patients with ITP have been evaluated in clinical trials involving children aged 1 year and older.
5.	Administration	Use in Geriatric Population	In clinical studies, some older patients (65 years and above) were included, but only a small number were 75 years or older. Overall, there were no significant differences in safety or effectiveness of eltrombopag between older patients and younger patients.
6.	Mechanism	Mechanism of Action	Eltrombopag is a medicine that stimulates the body to make more platelets. It works by activating a receptor in the bone marrow, which helps cells grow and develop into platelet-producing cells, increasing platelet count.
7.	Warning	Black Box Warning	Boxed Warning: Risk of Hepatic Decompensation and Hepatotoxicity • In patients with chronic hepatitis C, eltrombopag used in combination with interferon and ribavirin may increase the risk of hepatic decompensation. • Eltrombopag may also increase the risk of severe and potentially life-threatening hepatotoxicity. Monitor hepatic function and discontinue treatment as recommended.
8.	Lactation	Use in Lactation	Advise women not to breastfeed during treatment with eltrombopag.
9.	Pregnancy	Use in Pregnancy	It is unknown whether eltrombopag may harm an unborn baby. Inform your healthcare provider if you are pregnant or become pregnant during treatment. Females of reproductive potential should use effective contraception during treatment and for at least 7 days after the last dose.

10.	Precautions	Using alcohol	None
11.	Interaction	Is there any interaction with other medication?	▪ Polyvalent cations: Take eltrombopag at least 2 hours before or 4 hours after antacids, dairy products, mineral supplements, or other products containing calcium, iron, magnesium, aluminum, zinc, or selenium, as they reduce eltrombopag absorption. ▪ OATP1B1/BCRP substrates: Use caution with drugs such as rosuvastatin, atorvastatin, methotrexate, irinotecan, and imatinib. Monitor for increased drug exposure; dose adjustment (e.g., rosuvastatin) may be required. ▪ Protease inhibitors: No dose adjustment is required with lopinavir/ritonavir, boceprevir, or telaprevir. ▪ Peginterferon alfa-2a/2b: No dose adjustment is required when coadministered. ▪ Laboratory tests: Eltrombopag may interfere with bilirubin and creatinine test results, potentially causing false readings. Inform the laboratory if the patient is receiving eltrombopag.
12.	Precautions	What should I avoid while taking medication	Avoid situations and medicines that may increase your risk of bleeding.
13.	Storage	What are the storage conditions?	Store eltrombopag tablets at room temperature between 68°F to 77°F (20°C to 25°C). Keep eltrombopag tablets in the bottle given to you.
14.	Dispensing	How to Dispense?	As prescribed by the Physician
15.	Contraindication	What are the contraindications of (medication).	None
Pharmaceutical Particulars			
16.	Pharmaceutical Form	How is it supplied?	**12.5 mg Tablets:** The 12.5 mg tablets are off-white to light grey colored, round, biconvex, film-coated tablets, debossed with "ME" on one side and "12" on the other side, and are available in bottles of 30: NDC 72205-156-30. **25 mg Tablets:** The 25 mg tablets are light orange to orange colored, round, biconvex, film-coated tablets, debossed with "ME" on one side and "13" on the other side, and are available in bottles of 30: NDC 72205-157-30. **50 mg Tablets:** The 50 mg tablets are light blue to blue colored, round, biconvex, film-coated tablets, debossed with "ME" on one side and "14" on the other side, and are available in: • Bottles of 14: NDC 72205-158-19 • Bottles of 30: NDC 72205-158-30

			75 mg Tablets: The 75 mg tablets are brown colored, round shaped, biconvex, film-coated tablets, debossed with "ME" on one side and "15" on the other side, and are available in bottles of 30: NDC 72205-159-30.
17.	Ingredients	Active and Inactive Ingredients	**Active:** Eltrombopag olamine **Inactive:** Magnesium stearate, mannitol, microcrystalline cellulose 102, povidone K30, sodium starch glycolate type A, hypromellose 2910 (6 mPa·s), titanium dioxide, polyethylene glycol 3350, ferric oxide red, ferric oxide yellow, ferrosoferric oxide.
Allergens			
18.	Ingredients	Is it Vegetarian?	Yes
19.	Ingredients	Does it contain Gluten?	No
20.	Ingredients	Does it contain Dairy Products?	No
21.	Ingredients	Does it contain Casein	No
22.	Ingredients	Does it contain Whey?	No
23.	Ingredients	Does it contain corn?	No
24.	Ingredients	Does it contain rye?	No
25.	Ingredients	Does it contain sugar?	No
26.	Ingredients	Does it contain Oats?	No
27.	Ingredients	Does it contain wheat?	No
28.	Ingredients	Does it contain spelt?	No
29.	Ingredients	Does it contain barley?	No
30.	Ingredients	Does it contain rennet?	No
31.	Ingredients	Does it contain starch?	No
32.	Ingredients	Does it contain Iodine?	No
33.	Ingredients	Does it contain latex?	No
34.	Ingredients	Does it contain alcohol?	Yes; API contains solvents within the limits as per ICH
35.	Ingredients	Does it contain dyes?	No
36.	Ingredients	Does it contain flavor?	No
37.	Ingredients	Does it contain Lactose?	No
38.	Ingredients	Does it contain Nuts?	No
39.	Ingredients	Does it contain Preservatives?	No
40.	Ingredients	Does it contain Soy products?	No
41.	Ingredients	Does it contain peanut?	No
42.	Ingredients	Does it contain nickel?	No
Miscellaneous			

43.	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.
44.	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
45.	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.
46.	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.
47.	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.
48.	Miscellaneous	Manufacturer and Distributor	**Manufactured by:** **MSN laboratories Private Limited** Telangana -509 228, INDIA **Distributed by:** **Novadoz Pharmaceuticals LLC** Piscataway, NJ 08854-3714