SUNITINIB MALATE CAPSULES USP 12.5 mg, 25 mg, 37.5 mg and 50 mg

S.No.	Category	Question	Answer
Clinical Particulars			
1.	Use/Indication	What is the product indicated for?	• Treatment of adult patients with gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib mesylate. • Treatment of adult patients with advanced renal cell carcinoma (RCC). • Adjuvant treatment of adult patients at high risk of recurrent RCC following nephrectomy. • Treatment of progressive, well-differentiated • pancreatic neuroendocrine tumors (pNET) in adult patients with unresectable locally advanced or metastatic disease.
2.	Dosage	What is the recommended dosage?	**GIST and Advanced RCC**: • The recommended dosage is 50 mg orally once daily for the first 4 weeks of each 6-week cycle (Schedule 4/2). **Adjuvant Treatment of RCC**: • The recommended dosage is 50 mg orally once daily for the first 4 weeks of a 6-week cycle (Schedule 4/2) for a maximum of 9 cycles. **pNET:** • The recommended dosage is 37.5 mg orally once daily.
3.	Administration	How do I take it?	❖ Take sunitinib malate capsules exactly the way your healthcare provider tells you. ❖ Take sunitinib malate capsule 1 time each day with or without food. ❖ If you take sunitinib malate capsules for GIST or RCC, you will usually take your medicine for 4 weeks (28 days) and then stop for 2 weeks (14 days). This is 1 cycle of treatment. You will repeat this cycle for as long as your healthcare provider tells you to. ❖ If you take sunitinib malate capsules for pNET, take it 1 time each day until your healthcare provider tells you to stop. ❖ Do not drink grapefruit juice or eat grapefruit during your treatment with sunitinib malate capsules. They may cause you to have too much sunitinib malate capsules in your body. ❖ Your healthcare provider may do blood tests before each cycle of treatment to check you for side effects. ❖ If you miss a dose of sunitinib malate capsules by less than 12 hours, take the missed dose right away. If you miss a dose of sunitinib malate capsules by more than 12 hours, just take your next dose at your regular time. Do

			not make up the missed dose. Tell your healthcare provider about any missed dose. ❖ Call your healthcare provider right away, if you take too much sunitinib malate capsules.
4.	Formulation	Can capsule be crushed?	Sunitinib capsules should be swallowed whole. Do not break, chew, or empty the contents of the capsule, as this may increase drug exposure.
5.	Administration	What do I do if I miss a dose?	• If you miss a dose of sunitinib malate capsules by less than 12 hours, take the missed dose right away. • If you miss a dose of sunitinib malate capsules by more than 12 hours, just take your next dose at your regular time. Do not make up the missed dose. Tell your healthcare provider about any missed dose.
6.	Administration	Use in Pediatric Population	The safety and effectiveness of sunitinib malate in pediatric patients have not been established.
7.	Administration	Use in Geriatric Population	Clinical studies of sunitinib malate did not include sufficient numbers of patients with pNET to determine if patients 65 years of age and older respond differently than younger patients.
8.	Mechanism	Mechanism of Action	Sunitinib is a small-molecule inhibitor targeting multiple receptor tyrosine kinases (RTKs) involved in tumor growth, angiogenesis, and metastasis. It inhibits kinases such as PDGFRα/β, VEGFR1–3, KIT, FLT3, CSF-1R, and RET. Both sunitinib and its primary metabolite show potent activity in biochemical and cellular assays. In preclinical models, sunitinib inhibits RTK phosphorylation, suppresses tumor cell proliferation, reduces angiogenesis, and can lead to tumor regression or reduced metastasis.
9.	Warning	Black Box Warning	Hepatotoxicity may be severe, and in some cases fatal. Monitor hepatic function and interrupt, dose reduce, or discontinue sunitinib malate as recommended.
10.	Lactation	Use in Lactation	Advise women not to breastfeed during treatment with sunitinib malate and for at least 4 weeks after the last dose.
11.	Pregnancy	Use in Pregnancy	Sunitinib malate can cause fetal harm when administered to a pregnant woman.
12.	Interaction	Is there any interaction between medication and other drugs?	• **CYP3A4 Inhibitors**: Consider dose reduction of sunitinib malate when administered with strong CYP3A4 inhibitors. • **CYP3A4 Inducers**: Consider dose increase of sunitinib malate when administered with strong CYP3A4 inducers.
13.	Storage	What are the storage conditions?	Store at 20° to 25°C (**68° to 77°F**); excursions permitted between 15°C to 30°C (**59°F to 86°F**).
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?	• **Sunitinib malate 12.5 mg capsules**: 12.5 mg capsules are supplied as Size "4" hard gelatin capsules with orange opaque body imprinted with "6" and orange opaque cap imprinted with "MS" in white ink. The capsules are available in the following packages: Bottles of 28 capsules: NDC 72205-116-28 • **Sunitinib malate 25 mg capsules**: 25 mg capsules are supplied as Size "3" hard gelatin capsules with orange opaque body imprinted with "7" and caramel opaque cap imprinted with "MS" in white ink The capsules are available in the following packages: Bottles of 28 capsules: NDC 72205-117-28 • **Sunitinib malate 37.5 mg capsules**: 37.5 mg capsules are supplied as Size "3" hard gelatin capsules with yellow opaque body imprinted with "8" and yellow opaque cap imprinted with "MS" in black ink. The capsules are available in the following packages: Bottles of 28 capsules: NDC 72205-118-28 • **Sunitinib malate 37.5 mg capsules:** 50 mg capsules are supplied as Size "2" hard gelatin capsules with caramel opaque body imprinted with "9" and caramel opaque cap imprinted with "MS" in white ink. The capsules are available in the following packages Bottles of 28 capsules: NDC 72205-119-28**.**
17.	Ingredients	Active and Inactive Ingredients	**Active:** Sunitinib malate. **Inactive ingredients**: ❖ croscarmellose ❖ Sodium, ❖ Mannitol, ❖ Magnesium stearate ❖ Pregelatinized starch.
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?	Excipient contains starch
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?	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
Miscellaneous			
42.	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.
43.	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
44.	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.

45.	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.
46.	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.
47.	Miscellaneous	Manufacturer and Distributor	**Manufactured by:** MSN Laboratories Private Limited Telangana – 509 228, INDIA **Distributed by:** Novadoz Pharmaceuticals LLC Piscataway, NJ 08854-3714