

TICAGRELOR TABLETS 60mg, 90mg

S.No.	Category	Question	Answer
Clinical Particulars			
1	Use/Indication	What is the product indicated for?	Ticagrelor tablets are a P2Y₁₂ platelet inhibitor indicated for the following: 1. Acute Coronary Syndrome (ACS) or History of Myocardial Infarction (MI): - To reduce the risk of cardiovascular (CV) death, myocardial infarction, and stroke in patients with ACS or a history of MI. - Demonstrated superior efficacy to clopidogrel when used for at least the first 12 months following an ACS event. - Also reduces the risk of stent thrombosis in patients treated with coronary stenting for ACS. 2. Coronary Artery Disease (CAD) Without Prior MI or Stroke: - To reduce the risk of a first myocardial infarction or stroke in patients with coronary artery disease at high risk for atherothrombotic events. - While not limited to patients with type 2 diabetes mellitus (T2DM), efficacy was established in this population. 3. Acute Ischemic Stroke or High-Risk Transient Ischemic Attack (TIA): - To reduce the risk of stroke in patients presenting with: - Acute ischemic stroke (NIH Stroke Scale score ≤ 5), or - High-risk TIA.
2	Dosage	What is the recommended dosage?	1. Acute Coronary Syndrome (ACS) or History of Myocardial Infarction (MI): Initiation: Administer a 180 mg oral loading dose of ticagrelor. Maintenance (First Year): Continue with 90 mg twice daily.

			• Long-term Maintenance (After One Year): Reduce to 60 mg twice daily. 2. Coronary Artery Disease (CAD) Without Prior Stroke or MI: • Maintenance Dose: Administer 60 mg twice daily. 3. Acute Ischemic Stroke: • Initiation: Administer a 180 mg loading dose of ticagrelor. • Short-term Maintenance: Continue with 90 mg twice daily for up to 30 days.
3	Administration	How do I take it?	✓ Take ticagrelor exactly as prescribed by your healthcare provider. ✓ Your provider will tell you how many tablets to take and when to take them. ✓ Always take ticagrelor with a daily dose of aspirin (usually 75–100 mg), unless your provider advises otherwise. ✓ Ticagrelor can be taken with or without food. ✓ Take ticagrelor twice a day, at the same times each day, to maintain consistent levels in your body. ✓ If you miss a dose, just take your next dose at the regular time. Do not double up or take two doses at once unless directed by your provider. ✓ If you accidentally take too much, call your healthcare provider, contact Poison Control, or go to the nearest emergency room immediately.
4	Formulation	Can tablet be crushed?	• If you are unable to swallow the tablet(s) whole: ○ Crush the tablet(s) and mix with a small amount of water. ○ Drink all the water right away. ○ Refill the glass with water, stir well, and drink all the water again to ensure you get the full dose. • Ticagrelor tablets may also be given through certain nasogastric (NG) tubes: ○ Ask your healthcare provider for specific instructions on how to properly administer ticagrelor through an NG tube.
5	Administration	What do I do if I miss a dose?	If you miss a dose, just take your next dose at the regular time. Do not double up or take two doses at once unless directed by your provider.
6	Administration	Use in Pediatric Population	Ticagrelor is not approved for use in pediatric patients. Its safety and effectiveness have not been established, and it was not effective in a study of children with sickle cell disease.

7	Administration	Use in Geriatric Population	Ticagrelor has been studied in older adults, including patients aged ≥ 65 and ≥ 75 years. No overall differences in safety or effectiveness were observed compared to younger patients.
8	Mechanism	Mechanism of Action	Ticagrelor and its major metabolite reversibly interact with the platelet P2Y ₁₂ ADP receptor to prevent signal transduction and platelet activation. Ticagrelor and its active metabolite are approximately equipotent.
9	Warning	Black Box Warning	▪ Ticagrelor, like other antiplatelet agents, can cause serious or fatal bleeding. ▪ Do not use ticagrelor in patients with: ▪ Active pathological bleeding, or ▪ A history of intracranial hemorrhage. ▪ Do not initiate ticagrelor in patients scheduled for urgent coronary artery bypass graft (CABG) surgery. ▪ If bleeding occurs, manage it without discontinuing ticagrelor when possible, as stopping the medication may increase the risk of cardiovascular events.
10	Lactation	Use in Lactation	Breastfeeding not recommended
11	Pregnancy	Use in Pregnancy	• Available data from case reports do not show a known risk of major birth defects, miscarriage, or adverse outcomes with ticagrelor use during pregnancy. • Tell your healthcare provider if you are pregnant or planning to become pregnant. It is not known if ticagrelor tablets will harm your unborn baby, so you and your provider should decide together whether to use this medication during pregnancy.
12	Precautions	Is there any interaction with other medications?	➤ Avoid use with strong CYP3A inhibitors or CYP3A inducers. ➤ Opioids: Decreased exposure to ticagrelor. Consider use of parenteral anti-platelet agent. ➤ Patients receiving more than 40 mg per day of simvastatin or lovastatin may be at increased risk of statin-related adverse effects. ➤ Rosuvastatin plasma concentrations may increase. Monitor for statin-related adverse effects. ➤ Monitor digoxin levels with initiation of or any change in ticagrelor.
13	Interaction	Is there any interaction with food?	NO
14	Storage	What are the storage conditions?	❖ Store at 25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) ❖ Keep ticagrelor tablets and all medicines out of the reach of children.
17	Dispensing	How to Dispense?	As prescribed by the Physician
18	Contraindication	What are the contraindications of (medication).	▪ History of intracranial hemorrhage. ▪ Active pathological bleeding. ▪ Hypersensitivity to ticagrelor or any component of the product.
Pharmaceutical Particulars			
18	Pharmaceutical Form	How is it supplied?	Ticagrelor tablets, 90 mg is supplied as a round, biconvex, yellow, film-coated tablets debossed with “M” on one side and “90” on other side: Packaging and NDC Codes:

			• Bottles of 60 – NDC 72205-368-60 • Bottles of 100 – NDC 72205-368-91 • Bottles of 180 – NDC 72205-368-18 • Bottles of 1,000 – NDC 72205-368-99 • 100-count Hospital Unit Dose – NDC 72205-368-11
19	Ingredients	Active and Inactive Ingredients	Active: Ticagrelor tablets Inactive: croscarmellose sodium, dibasic calcium phosphate, hydroxypropyl cellulose, magnesium stearate and mannitol. The tablets are film-coated with a coating material containing hydroxypropyl methylcellulose, iron oxide red, iron oxide yellow, polyethylene glycol 400, talc and titanium dioxide.
20	Coating	What is the type of coating?	Film-coated tablets
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
36	Ingredients	Does it contain Iodine?	No
37	Ingredients	Does it contain latex?	No
38	Ingredients	Does it contain alcohol?	Yes (API contains solvents within the limits as per ICH)
39	Ingredients	Does it contain dyes?	No
40	Ingredients	Does it contain flavor?	No
41	Ingredients	Does it contain Lactose?	No
42	Ingredients	Does it contain Nuts?	No
43	Ingredients	Does it contain Preservatives?	No

44	Ingredients	Does it contain Soy products?	No
45	Ingredients	Does it contain peanut?	No
46	Ingredients	Does it contain nickel?	No
Miscellaneous			
47	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.
48	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
49	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.
50	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.
51	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.
52	Miscellaneous	Manufacturer and Distributor	Manufactured by: MSN Laboratories Private Limited, Unit – II, Formulations Division, Nandigama Distributed by: Novadoz Pharmaceuticals LLC Piscataway, NJ 08854-3714