

CLOPIDOGREL TABLETS, USP 75 mg

S.No.	Category	Question	Answer
Clinical Particulars			
1	Use/Indication	What is the product indicated for?	<p>Clopidogrel tablets are a P2Y platelet inhibitor indicated for:</p> <ul style="list-style-type: none"> • Acute coronary syndrome: <ul style="list-style-type: none"> – For patients with non-ST-segment elevation ACS (unstable angina [UA]/non-ST-elevation myocardial infarction [NSTEMI]), clopidogrel tablets have been shown to reduce the rate of myocardial infarction (MI) and stroke. – For patients with ST-elevation myocardial infarction (STEMI), clopidogrel tablets have been shown to reduce the rate of MI and stroke. • Recent MI, recent stroke, or established peripheral arterial disease: <ul style="list-style-type: none"> – Clopidogrel tablets have been shown to reduce the rate of MI and stroke.
2	Dosage	What is the recommended dosage?	<p>Acute coronary syndrome:</p> <ul style="list-style-type: none"> – Initiate clopidogrel tablets with a single 300 mg oral loading dose, then continue at 75 mg once daily. – Initiating clopidogrel tablets without a loading dose will delay the establishment of an antiplatelet effect by several days. <p>Recent MI, recent stroke, or established peripheral arterial disease :</p> <ul style="list-style-type: none"> – 75 mg once daily orally without a loading dose.
3	Administration	How do I take it?	<ul style="list-style-type: none"> • Take clopidogrel tablets exactly as your doctor tells you. • Do not change your dose or stop taking clopidogrel tablets without talking to your doctor first. Stopping clopidogrel tablets may increase your risk of heart attack or stroke. • Take clopidogrel tablets with aspirin as instructed by your doctor. • If you take too much clopidogrel tablets, call your doctor or go to the nearest emergency room right away. • Talk with your doctor about stopping your

			clopidogrel tablets before you have surgery. Your doctor may tell you to stop taking clopidogrel tablets at least 5 days before you have surgery to avoid excessive bleeding during surgery.
4	Formulation	Can tablet be crushed?	Do not crush or chew the tablets
5	Administration	What do I do if I miss a dose?	If you miss a dose, take clopidogrel tablets as soon as you remember. If it is almost time for your next dose, skip the missed dose. Take the next dose at your regular time. Do not take 2 doses of clopidogrel tablets at the same time unless your doctor tells you to.
6	Administration	Use in Pediatric Population	Safety and effectiveness in pediatric populations have not been established.
7	Administration	Use in Geriatric Population	No dosage adjustment is necessary in elderly patients.
8	Mechanism	Mechanism of Action	Clopidogrel is an inhibitor of platelet activation and aggregation through the irreversible binding of its active metabolite to the P2Y ₁₂ class of ADP receptors on platelets.
9	Warning	Black Box Warning	<ul style="list-style-type: none"> The effectiveness of clopidogrel depends on its conversion to an active metabolite by the cytochrome P450 (CYP) system, principally CYP2C19. Tests are available to identify patients who are CYP2C19 poor metabolizers. Consider using another platelet P2Y inhibitor in patients identified as CYP2C19 poor metabolizers.
10	Lactation	Use in Lactation	If you are breastfeeding or plan to breastfeed, it is not known if clopidogrel passes into breast milk. You should make a decision with your healthcare provider about whether to avoid or discontinue breastfeeding while continuing clopidogrel tablets.
11	Pregnancy	Use in Pregnancy	If you are pregnant or plan to become pregnant, it is not known whether clopidogrel tablets will harm your unborn baby.
12	Precautions	Is there any interaction between medication and alcohol?	NO
13	Interaction	Is there any interaction with food?	<ul style="list-style-type: none"> CYP2C19 inducers: Increase levels of clopidogrel active metabolite and enhance platelet inhibition. Opioids: Decrease exposure to clopidogrel. Consider using a parenteral antiplatelet agent. Nonsteroidal anti-inflammatory drugs (NSAIDs), warfarin, selective serotonin and serotonin-norepinephrine reuptake inhibitors (SSRIs,

			<p>SNRIs): Increase the risk of bleeding.</p> <ul style="list-style-type: none"> • Other antiplatelet agents: Increase the risk of bleeding due to an additive effect. • Repaglinide (CYP2C8 substrates): Increase substrate plasma concentrations.
14	Storage	What are the storage conditions?	Store clopidogrel tablets at 59°F to 86°F (15°C to 30°C).
15	Dispensing	How to Dispense?	As prescribed by the Physician
16	Contraindication	What are the contraindications of (medication).	<ul style="list-style-type: none"> • Active pathological bleeding, such as peptic ulcer or intracranial haemorrhage • Hypersensitivity to clopidogrel or any component of the product
Pharmaceutical Particulars			
17	Pharmaceutical Form	How is it supplied?	<p>Clopidogrel Tablets USP, 75 mg are available as pink-colored, round-shaped, film-coated tablets debossed with “MC5” on one side and plain on the other side. Tablets are provided as follows:</p> <ul style="list-style-type: none"> • NDC 72205-199-30: Bottles of 30 • NDC 72205-199-90: Bottles of 90 • NDC 72205-199-05: Bottles of 500 • NDC 72205-199-06: Carton of 100 (10 x 10) unit-dose tablets
18	Ingredients	Active and Inactive Ingredients	<p>Active: Clopidogrel bisulfate, USP Inactive: Tablet: hydrogenated castor oil, low substituted-hydroxypropyl cellulose, mannitol, microcrystalline cellulose, and polyethylene glycol 6000, silicon dioxide. Film coating: hypromellose, iron oxide red, iron oxide black, lactose monohydrate, titanium dioxide, and triacetin.</p>
19	Coating	What is the type of coating?	Film-coated tablets
Allergens			
21	Ingredients	Is it Vegetarian?	No (coating material contains lactose)
22	Ingredients	Does it contain Gluten?	No
23	Ingredients	Does it contain Dairy Products?	Yes
24	Ingredients	Does it contain Casein	No
25	Ingredients	Does it contain Whey?	No
26	Ingredients	Does it contain corn?	Yes (Contains starch)

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?	Yes
36	Ingredients	Does it contain Iodine?	No
37	Ingredients	Does it contain latex?	Contains lactose
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?	Yes
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	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)

		formulation of a particular medicine, no longer fills my prescription with Novadoz formulation?	page to learn where to find our products.
52	Miscellaneous	Manufacturer and Distributor	Manufactured by: MSN Life sciences unit-2 Nandigama