SUMMARY OF PRODUCT CHARACTERISTICS

1.Name of the medicinal product:
TRIOGOOD 20 (Aspirin 75mg, Clopidogrel 75mg & Atorvastatin 20mg Capsules)

2.Qualitative and quantitative composition Each hard gelatin capsule contains:
Atorvastatin Calcium USP Eq. to
Atorvastatin (As Pellets) 20mg
Clopidogrel Bisulphate USP Eq. to
Clopidogrel (As Pellets) 75mg
Aspirin USP (As Enteric Coated Pellets).....75mg

For the full list of excipients see section 6.1

3.PHARMACEUTICAL FORM
Capsule

4.CLINICAL PARTICULARS
4.1 Therapeutic indications

The combination of TRIOGOOD 20 is indicated for the treatment of patients with percutaneous coronary intervention (PCI) and myocardial infarction (also known as heart attack which occurs when blood flow to the heart muscle is blocked or interrupted).
Percutaneous coronary intervention (also known as angioplasty with stent) is a non-surgical procedure used among patients with heart problems (such as cardiogenic shock, acute severe heart failure or ischemic symptoms) to unclog blood vessels in the heart that have been narrowed by plaque buildup by placing a stent.

4.2 Posology and method of administration
Take TRIOGOOD 20 as advised by your physician. Swallow TRIOGOOD 20 with a glass of water. Do not crush or chew the medicine. Your doctor will decide the correct dose and duration for you depending upon your age, body weight and disease condition.

4.3 Contraindications
• If you are allergic to atorvastatin, clopidogrel, aspirin capsule ingredients.
• If you are allergic to similar medicines like other salicylates or NSAIDs.
• If you have problems with your liver or kidney.

- If you have any condition that causes bleeding, like a stroke or stomach ulcer.
- If you had or have blood clotting problems.
- If you ever had swelling in the body or an asthmatic attack after taking NSAIDs (medicines used for arthritis or rheumatism and pain).
- If you have gout.
- If you are taking methotrexate used to treat cancer or rheumatoid arthritis.
- If you are taking a combination of glecaprevir and pibrentasvir for the treatment of hepatitis C.
- if you notice any unexplained abnormal blood tests for liver function.
- If you are not using proper contraception methods.
- If you are pregnant or breastfeeding.

4.4 Special warnings and precautions for use

Talk to your doctor if

- Atorvastatin present in TRIOGOOD 20 is a pregnancy category X drug so it is contraindicated in pregnant women.

TRIOGOOD 20 contains Atorvastatin which can cause muscle problems like myopathy and rhabdomyolysis.

- The safety and effectiveness of TRIOGOOD 20 have not been established, so its use should be avoided in pediatric patients or children less than 12 years of age.
- Take TRIOGOOD 20 only when prescribed, it is known to pass on in a limited quantity via breast milk to the child.
- Drive with caution, TRIOGOOD 20 usually causes blurry vision and may affect driving ability.
- TRIOGOOD 20 to be taken with caution, especially if you have a history of liver diseases/ conditions. The dose may have to be adjusted by your doctor.
- TRIOGOOD 20 to be taken with caution, especially if you have a history of kidney diseases /conditions. The dose may have to be adjusted by your doctor.
- Abrupt discontinuation of TRIOGOOD 20 may lead to the occurrence of cardiovascular events like heart attack, stroke and angina (heart-related chest pain). Hence, you should consult a doctor before stopping the dose of TRIOGOOD 20.

4.5 Interaction with other medicinal products and other forms of interaction

Before taking TRIOGOOD 20MG inform to your doctor, if you are taking any of these medicines:

- Other anticoagulants (used for blood thinning) Ex. warfarin, coumarin, heparin, phenindione
- Other cholesterol-lowering medicines (Ex. clofibrate, gemfibrozil, fenofibrate, ezetimibe, colestipol)

- Other non-steroidal anti-inflammatory drugs (Ex. ibuprofen, indomethacin)
- Medicines used to manage HIV infection (Ex. glecaprevir/pibrentasvir, delavirdine, ritonavir with lopinavir and/or atazanavir or sofosbuvir with velpatasvir and voxilaprevir)
- St. john's wort (herbal medicine), selective serotonin reuptake inhibitors (used to manage depression) Ex. fluoxetine, sertraline, paroxetine or fluvoxamine
- Medicines used to manage stomach ulcers such as antacids (Ex. aluminium hydroxide, magnesium hydroxide) and proton-pump inhibitors (Ex. omeprazole or esomeprazole)
- Other medicines used during percutaneous coronary intervention (Ex. abciximab, eptifibatide and tirofiban)
- Antibiotics (used to manage bacterial infections) such as macrolides (Ex. azithromycin, telithromycin, erythromycin, roxithromycin, and clarithromycin) or fusidic acid
- Medicines used to manage epilepsy (Ex. phenytoin, valproic acid, stiripentol)
- Medicines used to manage diabetes (Ex. insulin, glipizide, glimepiride)
- Ciclosporin or tacrolimus (used to manage graft rejection or manage auto-immune disease)
- Azole antifungal agents (used to manage fungal infection) Ex. clotrimazole, fluconazole
- Methotrexate (used to manage cancer or other auto-immune diseases)
- Lithium (used to manage mental illness)
- Corticosteroids (used to manage pain and inflammation) Ex. prednisolone, dexamethasone
- Acetazolamide (used to manage or manage altitude sickness)
- Mifepristone (used to manage pregnancy)
- Metoclopramide (used to manage vomiting)
- Deferasirox (used to manage iron overload)
- Zafirlukst (used to manage asthmatic symptoms)
- Digoxin, amiodarone and verapamil (used to manage abnormal heart rhythm)
- Angiotensin-converting enzyme (ACE) inhibitors such as captopril, enalapril and diuretics such as hydrochlorothiazide (used to manage high blood pressure)
- Rifampin (used to manage tuberculosis)
- Colchicine, probenecid or sulfinpyrazone (used to manage gout)

4.6 Pregnancy and Breastfeeding

Pregnancy: TRIOGOOD 20 is not recommended for use in pregnant women. However, consult your doctor before taking TRIOGOOD 20. Women of child-bearing potential should use suitable contraceptive method to avoid pregnancy while taking TRIOGOOD 20.

Breastfeeding: TRIOGOOD 20 is not recommended for use in breastfeeding women. Consult your doctor before taking TRIOGOOD 20.

4.8 Undesirable effects

COMMON

- Increased bleeding or bruising
- Hematoma (collection of blood outside the blood vessel)
- Epistaxis (bleeding from the nose)
- Indigestion, diarrhea, stomach pain, nausea, constipation
- Bleeding in the gut
- Dizziness and headache
- Allergic reaction
- Nasopharyngitis (cold)
- Muscle cramps or pain
- Joint pain, back pain, swelling of joints

UNCOMMON

- Tingling or prickling sensation in hands or feet
- Stomach and duodenal ulcer
- Rash, itching
- Blood in urine
- Loss of appetite, burping
- Weight gain
- Nightmare, difficulty falling asleep
- Blurred vision
- Ringing sensation in ears (tinnitus)
- Loss of sensation, altered taste
- Loss of memory
- Hair loss
- Muscle tiredness, fever
- Neck or chest pain
- General discomfort, weakness
- Difficulty breathing

RARE

- Vertigo (spinning sensation)
- Breast enlargement in men (gynecomastia)
- Peripheral neuropathy (weakness, numbness and pain from nerve damage, usually in the hands and feet)
- Asthma attacks, bronchospasm
- Intracranial hemorrhage (bleeding in the brain)

- Cholestasis (a liver disease)

Stop taking TRIOGOOD 20 and consult your doctor immediately if you experience any of the following side effects:
Try not to stop taking this medicine of your own. Stopping TRIOGOOD 20 abruptly may worsen your condition and increase your risk of a future heart attack.

4.8 Overdose
Symptoms of an overdose may include headache, dizziness, nausea, vomiting, abdominal pain, ringing in the ears, hearing problems, confusion. If you experience any of the symptoms or think you have taken too much of this medicine, contact your doctor immediately or visit the nearest hospital

Reporting of suspected adverse reactions:
Healthcare professionals are requested to report any suspected adverse reactions via the national Pharmacovigilance Electronic Reporting Systems to the respective national regulatory authorities.

5.PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic group:
Atorvastatin: HMG-CoA reductase inhibitors, or statins
Clopidogrel: platelet aggregation inhibitors excl. Heparin
Aspirin: Antithrombotic agents, NSAID'S

ATC Code:
Atorvastatin: C10AA05
Clopidogrel: B01AC04
Aspirin: B01AC06

Mechanism of action: TRIOGOOD 20 effectively improves cardiac function and reduces the risk of heart problems, where clopidogrel acts by inhibiting platelet aggregation in the coronary arteries, aspirin acts by blocking the actions of an enzyme called cyclo-oxygenase 1 which is believed to be responsible for catalyzing the synthesis of platelets and atorvastatin acts by inhibiting the action of an enzyme called HMG-CoA reductase, which is required to catalyze the formation of cholesterol, thus preventing clot or plaque formation in the coronary arteries leading to an uninterrupted supply of oxygen and blood to the heart.

5.2 Pharmacokinetic properties

ATORVASTATIN

Absorption: Atorvastatin is readily absorbed after the oral administration. Multiple daily dosages in the form of 2.5-80 mg capsules produce a maximum steady state concentration (Cmax) of 1.95-252 µg/ml within 1-2 h.

Distribution: Mean volume of distribution (Vd) of atorvastatin is approximately 381 | and is ≥ 98% protein bound to the plasma proteins.

Metabolism: Atorvastatin is extensively metabolized to its ortho- and para-hydroxylated derivatives, and to various beta oxidation products. At least 70% of HMG-CoA reductase inhibitory activity has been attributed to the active metabolites of atorvastatin.

Elimination: Atorvastatin and its metabolites are primarily eliminated in the bile, and the drug does not undergo any enterohepatic circulation. The mean plasma elimination half- life of atorvastatin is approximately 14 h, but the half-life of its inhibitory activity for HMG-CoA reductase is 20-30 h due to the contribution from the active metabolites. Less than 2% of a dose of atorvastatin is excreted in urine following oral administration.

CLOPIDOGREL

Absorption: After single and repeated oral doses of 75 mg per day, clopidogrel is rapidly absorbed. Mean peak plasma levels of unchanged clopidogrel (approximately 2.2-2.5 ng/ml after a single 75 mg oral dose) occurred approximately 45 minutes after dosing. Absorption is at least 50%, based on urinary excretion of clopidogrel metabolites. Distribution: Clopidogrel and the main circulating (inactive) metabolite bind reversibly in vitro to human plasma proteins (98% and 94% respectively).
The binding is non- saturable in vitro
over a wide concentration range.

Metabolism: Clopidogrel is extensively metabolised by the liver. In vitro and in vivo, clopidogrel is metabolised according to two main metabolic pathways: one mediated by esterases and leading to hydrolysis into its inactive carboxylic acid derivative (85% of circulating metabolites), and one mediated by multiple cytochromes P450. Clopidogrel is first metabolised to a 2-oxo-clopidogrel intermediate metabolite. Subsequent metabolism of the 2-oxo-clopidogrel intermediate metabolite results in formation of the active metabolite, a thiol derivative of clopidogrel. The active metabolite is formed mostly by CYP2C19 with contributions from several other CYP enzymes, including CYP1A2, CYP2B6 and CYP3A4. The active thiol metabolite which has been isolated in vitro, binds rapidly and irreversibly to platelet receptors, thus inhibiting platelet aggregation.

After a single oral dose of 75 mg, clopidogrel has a half-life of approximately 6 hours. The elimination half-life of the main circulating (inactive) metabolite was 8

Elimination: hours after single and repeated administration.

ASPIRIN (ACETYLSALICYLIC ACID)

Absorption: Following absorption, the ASA in Aspirin 75mg & Clopidogrel 75mg Capsule is hydrolyzed to salicylic acid with peak plasma levels of salicylic acid occurring within 1 hour of dosing, such that plasma levels of ASA are essentially undetectable 1.5-3 hours after dosing. **Distribution:** ASA is poorly bound to plasma proteins and its apparent volume of distribution is low. Its metabolite, salicylic acid, is highly bound to plasma proteins, but its binding is concentration dependent (nonlinear). At low concentrations (<100 micrograms/ml), approximately 90% of salicylic acid is bound to albumin. Salicylic acid is widely
distributed to all tissues and fluids in the body, including the central nervous system, breast milk, and foetal tissues.

Metabolism: Salicylic acid is primarily conjugated in the liver to form salicyluric acid, a phenolic glucuronide, an acyl glucuronide, and a number of minor metabolites. Salicylate metabolism is saturable and total body clearance decreases at higher serum concentrations due to the limited ability of the liver to form both salicyluric acid and phenolic glucuronide.

Elimination: At high ASA doses, the elimination of salicylic acid follows zero-order kinetics (i.e., the rate of elimination is constant in relation to plasma concentration), with an apparent halflife of 6 hours or higher. Renal excretion of unchanged active substance depends upon urinary pH. As urinary pH rises above 6.5, the renal clearance of free salicylate increases from <5% to 80%. Following therapeutic doses, approximately 10% is found excreted in the urine as salicylic acid, 75% as salicylic acid, 10% phenolic- and 5% acyl-glucuronides of salicyluric acid.

5.3 Preclinical safety data

Not Known

6.PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Excipient	Specification
Light Green Cap/Clear Body Size '0' Hard Gelatin Capsules	IH

6.2
Incompatibilities
Not applicable.

6.3 Shelf life
36 months

6.4 Special precautions for storage
Store at a temperature not exceeding 30°C. Protect from light & moisture.

6.5 Nature and contents of container
1 Alu-Alu Blister of 10 Capsules, such 3 Blisters packed in Printed Carton with Insert

6.6 Special precautions for disposal and other handling
Not applicable

7. Marketing Authorisation Holder and Manufacturer
Marketing Authorization Holder
NATIONAL PHARMACY LTD.
P.O. BOX 17843-00500,
NAIROBI, KENYA

Manufacturer:
ZAIN PHARMA LIMITED
Plot No: 209/13741, Colchester Park,
Go-Down No.1, 2, 3, Off Mombasa Road,
Behind Nice And Lovely House,
P.O. Box: 100167-00101, Nairobi, Kenya

8. Marketing Authorisaton Number
H2026/CTD11883/25348

9. Date of First Registration/Renewal
February 18 2026
10. Date of Revision of Text
February 18 2026