SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

TRIOGOOD 10

2. QUANTITATIVE AND QUALITATIVE COMPOSITION

Each Hard gelatine capsule contains:

Atorvastatin Calcium USP eq. to Atorvastatin (As pellets)	10 mg
Clopidogrel Bisulphate USP eq. to Clopidogrel (As pellets)	75 mg
Aspirin USP (As enteric coated pellets)	75 mg

For a full list of excipients, see section 6.1.

3. Pharmaceutical form

Hard Gelatin Capsule

Light Green Cap/Clear Body, Size '0' Hard gelatin Capsules containing White, Red and Green Pellets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

TRIOGOOD 10 is a combination drug of blood-thinning agents and cholesterol-lowering agents, primarily taken for the prevention of heart attack and stroke. It also lowers the raised level of cholesterol in our body.

4.2 Posology and method of administration

Posology

The recommended dose is one capsule daily at a set time. Each capsule contains a fixed dose of atorvastatin clopidogrel, and aspirin.

Method of administration

The capsules should be taken with some water. They may be taken with meals.

4.3 Contraindications

Aspirin + Atorvastatin + Clopidogrel is contraindicated in patients with known allergies to aspirin, atorvastatin, clopidogrel, who have asthma, severe kidney or liver issues, heart disease and diabetes.

4.4 Special warnings and precautions for use

Do not consume Triogood 10 if you are allergic to Aspirin + Atorvastatin + Clopidogrel or any of its ingredients in the medication. Do not consume this medicine, Do not take the medication if you have a medical condition causing current bleeding, severe liver disease, or a history of abnormal liver function tests. Avoid this medication if you are pregnant or breastfeeding or have a history of blood clotting disorders, cerebral hemorrhage, or stomach or small intestine ulcers. Consult your doctor if any of these conditions apply to you or if you have any doubts.

Before taking this medicine, it is important to inform your doctor if you have severe respiratory failure, recently used fusidic acid, a history of stroke, or fluid pockets in the brain. Notify your doctor if you have kidney or liver problems, under-active thyroid gland, previous muscle problems, excessive alcohol consumption, liver disease, age over 70, dehydration, high blood pressure, and lack of glucose-6-phosphate dehydrogenase (G6PD). Report to your doctor if you have asthma, inflammatory bowel disease, gout, risk of bleeding, recent brain artery clot, previous allergy to similar medicines, or past non-traumatic brain hemorrhage.

4.5 Interaction with other medicinal products and other forms of interaction

The concurrent use of medications, including antibiotics (clarithromycin), anti-HIV medications (ritonavir, lopinavir, darunavir, atazanavir, and indinavir), antifungal agents (itraconazole), anti-arthritis medications (colchicine), heart-related medications (digoxin), immune-affecting medications, and blood-thinning medications (such as warfarin and heparin), alongside Aspirin + Atorvastatin + Clopidogrel, is not recommended. It is imperative to consult with a doctor before considering the use of any prescription or over-the-counter medications to ensure the safety and efficacy of the combined treatment plan.

4.6 Pregnancy and Lactation:

Pregnancy:

Atorvastatin present in TRIOGOOD 10 is a pregnancy category X drug so it is contraindicated in pregnant women. As it may cause harm to the fetus if administered to a pregnant woman.

Breastfeeding

Triogood 10 is not recommended during breastfeeding.

4.7 Effects on ability to drive and use machines

This combination may affect your ability to drive or operate heavy machinery. Avoid driving if you feel dizzy after taking this combination.

4.8 Undesirable Effects

Atorvastatin

Tabulated list of adverse reactions

Estimated frequencies of reactions are ranked according to the following convention: common (≥ 1/100, < 1/10); uncommon (≥ 1/1,000, < 1/100); rare (≥ 1/10,000, < 1/1,000); very rare (< 1/10,000), not known (cannot be estimated from the available data).

System Organ Class	Frequency	Undesirable effects
Infections and infestations	Common	nasopharyngitis

Blood and the lymphatic system disorders	Rare	thrombocytopenia
Immune system disorders	Common	allergic reactions
	Very rare	anaphylaxis
Metabolism and nutrition disorders	Common	hyperglycaemia
	Uncommon	hypoglycaemia, weight gain, anorexia
Psychiatric disorders	Uncommon	nightmare, insomnia
Nervous system disorders	Common	headache
	Uncommon	dizziness, paraesthesia, hypoesthesia, dysgeusia, amnesia
	Rare	peripheral neuropathy
	Not known	myasthenia gravis
Eye disorders	Uncommon	vision blurred
	Rare	visual disturbance
	Not known	ocular myasthenia
Ear and labyrinth disorders	Uncommon	tinnitus
	Very rare	hearing loss
Respiratory, thoracic and mediastinal disorders	Common	pharyngolaryngeal pain, epistaxis
Gastrointestinal disorders	Common	constipation, flatulence, dyspepsia, nausea, diarrhoea
	Uncommon	vomiting, abdominal pain upper and lower, eructation, pancreatitis
Hepato-biliary disorders	Uncommon	hepatitis
	Rare	cholestasis
	Very rare	hepatic failure
Skin and subcutaneous tissue disorders	Uncommon	urticaria, skin rash, pruritus, alopecia
	Rare	angioneurotic oedema,
		dermatitis bullous including erythema multiforme, StevensJohnson syndrome and toxic epidermal necrolysis, lichenoid drug reaction

Musculoskeletal, connective tissue disorders	Common	myalgia, arthralgia, pain in extremity, muscle spasms, joint swelling, back pain
	Uncommon	neck pain, muscle fatigue
	Rare	myopathy, myositis, rhabdomyolysis, muscle rupture, tendonopathy, sometimes complicated by rupture
	Very rare	lupus-like syndrome
	Not known	immune mediated necrotizing myopathy (see section 4.4)
Reproductive system and breast disorders	Very rare	gynecomastia
General disorders and administration site conditions	Uncommon	malaise, asthenia, chest pain, peripheral oedema, fatigue, pyrexia
Investigations	Common	liver function test abnormal, blood creatine kinase increased
	Uncommon	white blood cells urine positive
Vascular disorders	Rare	Vasculitis

Clopidogrel

Tabulated list of adverse reactions
Adverse reactions that occurred either during clinical studies or that were spontaneously reported are presented in the table below. Their frequency is defined using the following conventions: common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000), not known (cannot be estimated from the available data). Within each system organ class, adverse reactions are presented in order of decreasing seriousness.

System Organ Class	Common	Uncommon	Rare	Very rare, not known*
Blood and the lymphatic system disorders		Thrombocytopenia, leucopenia, eosinophilia	Neutropenia, including severe	Thrombotic thrombocytopenic purpura (TTP) (see

			neutropenia	section 4.4), aplastic anaemia, pancytopenia, agranulocytosis, severe thrombocytopenia, acquired haemophilia A, granulocytopenia, anaemia
Cardiac disorders				Kounis syndrome (vasospastic allergic angina / allergic myocardial infarction) in the context of a hypersensitivity reaction due to clopidogrel*
Immune system disorders				Serum sickness, anaphylactoid reactions, cross- reactive drug hypersensitivity among thienopyridines (such as ticlopidine, prasugrel) (see section 4.4)*, insulin autoimmune syndrome, which
				can lead to severe hypoglycemia, particularly in patients with HLA DRA4 subtype (more frequent in the Japanese population)*

Psychiatric disorders				Hallucinations, confusion
Nervous system disorders		Intracranial bleeding (some cases were reported with fatal outcome), headache, paraesthesia, dizziness		Taste disturbances, ageusia
Eye disorders		Eye bleeding (conjunctival, ocular, retinal)		
Ear and labyrinth disorders			Vertigo	
Vascular disorders	Haematoma			Serious hemorrhage, hemorrhage of operative wound, vasculitis, hypotension
Respiratory, thoracic and mediastinal disorders	Epistaxis			Respiratory tract bleeding (haemoptysis, pulmonary hemorrhage), bronchospasm, interstitial pneumonitis, eosinophilic pneumonia

Gastrointestinal disorders	Gastrointestinal hemorrhage, diarrhoea, abdominal pain, dyspepsia	Gastric ulcer and duodenal ulcer, gastritis, vomiting, nausea, constipation, flatulence	Retroperitoneal hemorrhage	Gastrointestinal and retroperitoneal hemorrhage with fatal outcome, pancreatitis, colitis (including ulcerative or lymphocytic colitis), stomatitis

Hepato-biliary disorders				Acute liver failure, hepatitis, abnormal liver function test
Skin and subcutaneous tissue disorders	Bruising	Rash, pruritus, skin bleeding (purpura)		Bullous dermatitis (toxic epidermal necrolysis, Stevens Johnson Syndrome, erythema multiforme, acute generalised exanthematous pustulosis (AGEP)), angioedema, drug-induced hypersensitivity syndrome, drug rash with eosinophilia and systemic symptoms (DRESS), rash erythematous or exfoliative, urticaria, eczema, lichen planus
Reproductive systems and breast disorders			Gynaecomastia	
Musculoskeletal, connective tissue and bone disorders				Musculo-skeletal bleeding (haemarthrosis), arthritis, arthralgia, myalgia
Renal and urinary disorders		Haematuria		Glomerulonephritis, blood creatinine increased
General disorders and administration site conditions	Bleeding at puncture site			Fever

Investigations		Bleeding time prolonged, neutrophil count decreased, platelet count decreased		

* Information related to clopidogrel with frequency "not known".

Aspirin

Side effects are grouped on the basis of System Organ Class. Within each system organ class the frequencies are defined as: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000) and not known (cannot be estimated from the available data)

Blood and lymphatic system disorders	*Common:* Increased bleeding tendencies. *Rare:* Thrombocytopenia, granulocytosis, aplastic anaemia. *Not known:* Cases of bleeding with prolonged bleeding time such as epistaxis, gingival bleeding. Symptoms may persist for a period of 4–8 days after acetylsalicylic acid discontinuation. As a result there may be an increased risk of bleeding during surgical procedures. Existing (haematemesis, melaena) or occult gastrointestinal bleeding, which may lead to iron deficiency anaemia (more common at higher doses).
Immune system Disorders	*Rare:* Hypersensitivity reactions, angio-oedema, allergic oedema, anaphylactic reactions including shock.
Metabolism and digestive system disorders	*Not known:* Hyperuricemia.
Nervous system disorders	*Rare:* Intracranial haemorrhage *Not known:* Headache, vertigo.
Ear and labyrinth disorders	*Not known:* Reduced hearing ability; tinnitus.

Vascular disorders	*Rare:* Hemorrhagic vasculitis.
Respiratory, thoracic and mediastinal disorders	*Uncommon:* Rhinitis, dyspnoea. *Rare:* Bronchospasm, asthma attacks.
Reproductive System and mammary disorders	*Rare:* Menorrhagia
Gastrointestinal disorders	*Common:* Dyspepsia. nausea, *Rare:* Severe gastrointestinal haemorrhage, vomiting. *Not known:* Gastric or duodenal ulcers and perforat diarrhoea.
Hepatobiliary disorders	*Not known:* Hepatic insufficiency
Skin and subcutaneous tissue disorders	*Uncommon:* Urticaria. *Rare:* Steven-Johnsons syndrome, Lyells syndrome, purpura, erythema nodosum, erythema multiforme.
Renal and urinary tract disorders	*Not known:* Impaired renal function, salt and water retention.

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorisation of the medicinal product is important as it allows continued monitoring of the benefit–risk balance of the medicinal product. Healthcare professionals are requested to report any suspected adverse reactions to the marketing authorisation holder or, where applicable, via the national reporting system.

4.9 Overdose
Overdose of this combination can cause dizziness and buzzing in the ears. Inform your doctor regarding these effects and follow the advice accordingly.
If you forget to take this combination, take it as soon as you remember. But avoid repeating the dose.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group:
Aspirin: Antithrombotic agents
Clopidogrel: Platelet aggregation inhibitors
Hydrochlorothiazide: HMG-CoA reductase inhibitors (statins)
ATC code: C10BX

TRIOGOOD 10 is a combination drug of blood-thinning agents and cholesterol-lowering agents, primarily taken for the prevention of heart attack and stroke. It also lowers the raised level of cholesterol in our body.

Aspirin

is effective to reduce inflammation, relieve pain, reduce fever, and thin blood to prevent clots. Aspirin inhibits the action of enzymes in the body to achieve these results.

Clopidogrel:

This active form is a platelet inhibitor that irreversibly binds to $P2Y_{12}$ ADP receptors on platelets. This binding prevents ADP binding to $P2Y_{12}$ receptors, activation of the glycoprotein GPIIb/IIIa complex, and platelet aggregation. A 75mg oral dose of clopidogrel is 50% absorbed from the intestine.

Atorvastatin:

Pharmacodynamics. Atorvastatin and its active metabolites are all pharmacologically active. The liver is the main target organ of action, being the principal site of cholesterol synthesis and LDL clearance. The extent of LDL reduction depends on the dose of the drug rather than on the plasma drug concentration.

5.2 Pharmacokinetic properties

Aspirin

Aspirin is used in the treatment of mild to moderate pain, inflammation, and fever. It is also used as an antiplatelet agent to prevent myocardial infarction, stroke and transient ischemic episodes.

Aspirin is absorbed rapidly from the stomach and intestine by passive diffusion. Aspirin is a prodrug, which is transformed into salicylate in the stomach, in the intestinal mucosa, in the blood and mainly in the liver. Salicylate is the active metabolite responsible for most anti-inflammatory and analgesic effects (but acetylsalicylate is the active moiety for the antiplatelet-aggregating effect). Gastrointestinal intolerance to salicylate observed in some patients has prompted the development of formulations with enteric coating.

Salicylate distributes rapidly into the body fluid compartments. It binds to albumin in the plasma. With increasing total plasma salicylate concentrations, the unbound fraction increases. Salicylate may cross the placental barrier and distributes into breast milk.

As mentioned above, aspirin is rapidly biotransformed into the active metabolite, salicylate. Therefore, aspirin has a very short half-life. Salicylate, in turn, is mainly metabolized by the liver. This metabolism occurs primarily by hepatic conjugation with glycin or glucuronic acid, each involving different metabolic pathways. The

predominant pathway is the conjugation with glycin, which is saturable. With low doses of aspirin approximately 90% of salicylate is metabolized through this pathway. As the maximum capacity of this major pathway is reached, the other pathways with a lower clearance become more important. Therefore, the half-life of salicylate depends on the major metabolic pathway used at a given concentration and becomes longer with increasing dosage. Salicylate is said to follow nonlinear kinetics at the
upper limit of the dosing range. Studies have shown that there is much inter-subject variation with respect to the relative contribution of the different salicylate metabolic pathways.

Urinary excretion of unchanged salicylate accounts for 10% of the total elimination of salicylate. Excretion of salicylate results of glomerular filtration, active proximal tubular secretion through the organic acid transporters and passive tubular reabsorption. Urinary excretion is markedly pH dependant and as the urinary pH rises from 5 to 8, the amount of free ionized salicylate excreted increases from 3% of the total salicylate dose to more than 80% (by ion trapping in the urine). Salicylate metabolites are also excreted in the urine.

Clopidogrel
Clopidogrel active metabolite ($clopidogrel_{AM}$) concentration in samples collected on day 9 pre-dose and at specified times through 24 h post-dose were determined and used to determine the peak plasma concentration (C_{max}) and the area under the plasma concentration-time curve from time 0 to the time of last quantifiable concentration (AUC_t).

Atovarstatin
Atorvastatin presents a dose-dependent and non-linear pharmacokinetic profile. It is very rapidly absorbed after oral administration. After the administration of a dose of 40 mg, its peak plasma concentration of 28 ng/ml is reached 1-2 hours after initial administration with an AUC of about 200 ng·h/ml.

5.3 Preclinical safety data
Aspirin

it has been studied to assess its toxicity, pharmacokinetics, and potential adverse effects. These studies typically evaluate organ toxicity, reproductive effects, genotoxicity, and carcinogenicity. Aspirin has a well-established safety profile when used at recommended doses, but like any medication, it can have side effects such as gastrointestinal irritation, bleeding, and allergic reactions. Preclinical studies help provide insight into the potential risks associated with aspirin use.

Metformin
Metformin has been shown to have a generally favorable safety profile in preclinical studies, with the most common side effects being gastrointestinal issues like diarrhea and nausea. Additionally, metformin has been found to have potential

benefits beyond its antidiabetic effects, such as anti-inflammatory and anti-cancer properties, as observed in preclinical research.

Atorvastatin
The most common adverse effects seen with the therapeutic use of atorvastatin include constipation, flatulence, upset stomach, and abdominal pain. of atorvastatin has been associated with changes in liver function and muscle aches or weakness

6. PHARMACEUTICAL PARTICULARS

6.1 Incompatibilities
Not applicable.

6.2 Shelf life
36 months.

6.3 Special precautions for storage
Store below 30°C. Protect from light and moisture.

6.4 Nature and contents of container
10 Capsules are packed in Alu-Alu blister pack. Such 3 blister packs are packed in printed and laminated carton along with insert. Pack such cartons in shipper box. Seal shipper
box with BOPP tape. Affix one label on each shipper box.

6.5 Special precautions for disposal and other handling:
Not applicable

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS
Marketing Authorisation Holder:
Pro-Med Pharmaceuticals Ltd
Old Mombasa Road, Behind Nice & Lovely Go downs,
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8. MARKETING AUTHORISATION NUMBER
H2026/CTD11882/25347

9. DATE OF FIRST REGISTRATION/RENEWAL REGISTRATION

18/02/2026

10. DATE OF REVISION OF THE TEXT
18/02/2026