SUMMARY OF PRODUCT CHARACTERISTICS

TRIOGOOD 40 (Aspirin 75 mg, Clopidogrel 75 mg and Atorvastatin 40 mg Capsules)

1. NAME OF THE MEDICINAL PRODUCT

TRIOGOOD 40 (Aspirin 75 mg, Clopidogrel 75 mg and Atorvastatin 40 mg Capsules)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each hard gelatin capsule contains:

Atorvastatin calcium USP equivalent to atorvastatin …… 40 mg

Clopidogrel bisulphate USP equivalent to clopidogrel …… 75 mg

Aspirin (acetylsalicylic acid) USP …… 75 mg

Excipients with known effect:

No excipients with known effect at the quantities present in this product.

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 capsule containing white, red and green pellets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

TRIOGOOD 40 is indicated for the secondary prevention of atherothrombotic events in adult patients with established coronary artery disease including patients who have undergone percutaneous coronary intervention (PCI) or who have had a myocardial infarction (MI), where concurrent treatment with aspirin, clopidogrel and atorvastatin is appropriate and substitution therapy with this fixed-dose combination is clinically suitable.

4.2 Posology and method of administration

Adults

One capsule once daily, taken orally with or without food. The capsule must be swallowed whole and must not be crushed or chewed.

Abrupt discontinuation

Premature discontinuation of TRIOGOOD 40 may increase the risk of cardiovascular events, including stent thrombosis. Patients should not stop therapy without consulting their physician.

Hepatic impairment

Contraindicated in patients with active liver disease or persistent serum transaminase elevations exceeding 3 times the upper limit of normal.

Renal impairment

Use with caution; dose may require adjustment by the treating physician.

Elderly

No specific dose adjustment required, though caution is warranted due to increased susceptibility to adverse effects.

Paediatric population

Not recommended in children and adolescents aged below 18 years.

Method of administration

Oral use. Swallow whole with a glass of water.

4.3 Contraindications

- Hypersensitivity to atorvastatin, clopidogrel, aspirin, other salicylates or any excipients listed in section 6.1.

- Hypersensitivity to NSAIDs including aspirin-induced asthma, urticaria or angioedema.
- Active pathological bleeding (e.g. peptic ulcer, intracranial haemorrhage).
- Active liver disease or persistent serum transaminase elevations exceeding 3 times the upper limit of normal.
- Concomitant use with glecaprevir/pibrentasvir.
- Methotrexate at doses >15 mg/week.
- Pregnancy — atorvastatin is Pregnancy Category X. Aspirin at anti-inflammatory doses should be avoided in the third trimester of pregnancy.
- Women of childbearing potential not using adequate contraception.
- Gout.

4.4 Special warnings and precautions for use

Bleeding risk

Aspirin and clopidogrel both inhibit platelet function and may increase the risk of bleeding at various sites. Concomitant use of anticoagulants, NSAIDs, SSRIs or other antiplatelet agents increases bleeding risk.

Myopathy and rhabdomyolysis

Atorvastatin can cause myopathy and rhabdomyolysis, rarely leading to renal impairment. Patients should report promptly any muscle pain, weakness or cramps, particularly if associated with malaise or fever. Risk is increased with concomitant use of fibrates, ciclosporin, or potent CYP3A4 inhibitors.

Hepatic effects

Liver function tests should be performed before initiation and when clinically indicated. Caution in patients who consume substantial quantities of alcohol.

Gastrointestinal effects

Aspirin can cause GI haemorrhage or ulceration. GI protective therapy should be considered in patients at risk.

Paediatric population

This combination has not been established for use in children and adolescents aged below 18 years.

4.5 Interaction with other medicinal products and other forms of interaction

Anticoagulants (warfarin, coumarin, heparin):

Increased risk of bleeding. Monitor INR and clinical status closely.

Fibrates and other lipid-lowering agents:

Increased risk of myopathy with fibrates. Combined use requires caution.

Strong/moderate CYP3A4 inhibitors (azole antifungals, macrolides, HIV protease inhibitors, diltiazem, verapamil, amiodarone):

Increased atorvastatin plasma concentrations with increased risk of myopathy. Limit atorvastatin dose when co-administered with strong CYP3A4 inhibitors (ciclosporin, clarithromycin, itraconazole, ritonavir).

CYP3A4 inducers (rifampicin, St John's Wort):

Reduced atorvastatin concentrations.

Glecaprevir/pibrentasvir:

Concomitant use is contraindicated — significantly increases atorvastatin exposure.

PPIs (omeprazole, esomeprazole):

May reduce antiplatelet activity of clopidogrel by inhibiting CYP2C19-mediated conversion to active metabolite. Pantoprazole or rabeprazole are preferred.

NSAIDs:

Increased risk of GI bleeding and may antagonise the cardioprotective effects of aspirin.

Antidiabetics (insulin, sulphonylureas):

Aspirin may enhance hypoglycaemic effect.

Alcohol:

Increases risk of GI bleeding and hepatotoxicity.

Digoxin, amiodarone, verapamil:

May increase atorvastatin plasma concentrations. Atorvastatin dose should not exceed 20 mg/day with amiodarone.

4.6 Fertility, pregnancy and lactation

Pregnancy

TRIOGOOD 40 is contraindicated in pregnancy. Atorvastatin is Pregnancy Category X. Aspirin should be avoided in the third trimester. Women of childbearing potential must use effective contraception.

Breast-feeding

Not recommended during breast-feeding. Atorvastatin is excreted in human milk in small amounts. Breast-feeding should be discontinued during treatment.

Fertility

No clinical data on effect of this combination on human fertility. Animal studies with individual components have not demonstrated fertility impairment at clinically relevant exposures.

4.7 Effects on ability to drive and use machines

May rarely cause dizziness or visual disturbances (atorvastatin). Patients experiencing such effects should not drive or operate machinery.

4.8 Undesirable effects

Summary of the safety profile

The adverse reaction profile reflects those of atorvastatin, clopidogrel and aspirin. Most common: bleeding events, dyspepsia, nausea, abdominal pain, diarrhoea, headache and musculoskeletal pain. Serious reactions include major bleeding, myopathy/rhabdomyolysis, severe hepatotoxicity, TTP and severe hypersensitivity reactions.

Tabulated list of adverse reactions

Frequencies: common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare/very rare/not known.

System Organ Class	Common	Uncommon	Rare / Not Known
Blood and lymphatic disorders	Haematoma, epistaxis, bruising	Leukopenia	Thrombocytopenia; TTP (not known)
Nervous system disorders	Headache, dizziness	Paraesthesia, memory loss	Peripheral neuropathy (rare)
Gastrointestinal disorders	Dyspepsia, nausea, diarrhoea, abdominal pain, GI bleeding	Gastric/duodenal ulcer	Intracranial haemorrhage (rare); pancreatitis (rare)
Hepatobiliary disorders			Hepatotoxicity, jaundice, cholestasis (rare)
Musculoskeletal disorders	Myalgia, arthralgia, back pain	Muscle weakness, cramps	Myopathy, rhabdomyolysis (rare)
Skin disorders		Rash, pruritus	Angioedema, urticaria (not known)
Respiratory disorders	Nasopharyngitis	Dyspnoea	Asthma, bronchospasm (rare)
Immune system disorders		Hypersensitivity	Anaphylaxis (not known)
General disorders		Fatigue, asthenia	Chest pain (not known)

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the National Regulatory Authority.

4.9 Overdose

Symptoms may include headache, dizziness, nausea, vomiting, abdominal pain, tinnitus, confusion and increased bleeding. Rhabdomyolysis has been reported in atorvastatin overdose. No specific antidote. Provide symptomatic and supportive treatment. Monitor renal function. For aspirin overdose, alkalinisation of urine may enhance salicylate elimination.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Combined cardiovascular agents. ATC codes: Atorvastatin C10AA05; Clopidogrel B01AC04; Aspirin B01AC06.

Aspirin

Aspirin irreversibly inhibits COX-1, preventing thromboxane A2 synthesis and inhibiting platelet aggregation. At 75 mg, aspirin provides selective antiplatelet effects with minimal COX-2 inhibition.

Clopidogrel

Clopidogrel is a prodrug requiring CYP2C19-mediated hepatic activation. The active thiol metabolite irreversibly inhibits the ADP P2Y12 receptor on platelets, inhibiting ADP-induced platelet aggregation. The combination of aspirin and clopidogrel provides dual antiplatelet coverage addressing different platelet activation pathways.

Atorvastatin

Atorvastatin is a competitive inhibitor of HMG-CoA reductase, the rate-limiting enzyme in cholesterol biosynthesis. By reducing hepatic cholesterol synthesis, atorvastatin upregulates LDL receptors, increasing LDL-C clearance from the bloodstream. At least 70% of HMG-CoA reductase inhibitory activity is attributable to active metabolites.

5.2 Pharmacokinetic properties

Atorvastatin

Rapidly absorbed after oral administration; Cmax reached within 1–2 hours. Absolute bioavailability approximately 14% due to first-pass metabolism. Volume of distribution approximately 381 litres; ≥98% protein bound. Extensively metabolised to ortho- and para-hydroxylated derivatives. Primarily excreted in bile; mean plasma half-life approximately 14 hours; inhibitory half-life 20–30 hours due to active metabolites.

Clopidogrel

Rapidly absorbed after 75 mg oral dose; peak plasma levels approximately 45 minutes after dosing. Absorption ≥50%. Extensively metabolised via esterases (85% to inactive carboxylic acid derivative) and CYP enzymes (CYP2C19) to produce the active thiol metabolite. Half-life approximately 6 hours for clopidogrel; 8 hours for the main circulating metabolite.

Aspirin

Rapidly hydrolysed to salicylic acid; peak salicylic acid levels within 1 hour. Salicylic acid approximately 90% protein bound at low concentrations. Conjugated in liver to salicyluric acid, phenolic glucuronide and acyl glucuronide. At therapeutic doses, half-life 2–3 hours.

5.3 Preclinical safety data

Preclinical safety data for the individual components are well established. No specific preclinical studies were conducted with this fixed-dose combination. The combined safety profile is expected to reflect the individual components. Atorvastatin has not demonstrated mutagenic or clastogenic potential in standard genotoxicity assays.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

The following excipients are present in the hard gelatin capsule:

Light green cap/clear body, size '0' hard gelatin capsule (IH)

Note: The submitted SmPC lists only the capsule shell. The applicant should provide a complete list of all excipients present in the pellets for PPB registration.

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 and moisture. Keep out of the reach and sight of children.

6.5 Nature and contents of container

1 ALU-ALU blister of 10 capsules; 3 such blisters packed in printed carton with package insert. Pack size: 30 capsules.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

ZAIN PHARMA LTD.

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 AUTHORISATION NUMBER (PPB REGISTRATION NUMBER)

H2025/CTD12491/26434

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

08.12.2025

10. DATE OF REVISION OF THE TEXT

08.12.2025