SUMMARY OF PRODUCT CHARACTERISTICS
DUOGOOD (Aspirin 75 mg / Clopidogrel 75 mg Film-Coated Tablets)

1. NAME OF THE MEDICINAL PRODUCT

DUOGOOD (Clopidogrel Bisulphate USP 75 mg / Aspirin USP 75 mg Film-Coated Tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains clopidogrel bisulphate USP equivalent to clopidogrel 75 mg and aspirin (acetylsalicylic acid) USP 75 mg.

Excipients with known effect:

Contains lactose monohydrate (96.12 mg per tablet) and propylene glycol. Contains Sunset Yellow FCF. For warnings, see section 4.4.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet.

Orange, round, biconvex film-coated tablet, debossed and scored on one side and plain on the other. The score line is intended only to facilitate breaking for ease of swallowing, not to divide into equal doses.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

DUOGOOD is indicated for the secondary prevention of atherothrombotic events in adult patients already taking both clopidogrel and acetylsalicylic acid (ASA), as a fixed-dose combination for continuation of therapy in: Non-ST segment elevation acute coronary syndrome (NSTE-ACS: unstable angina or non-Q-wave MI) including patients undergoing stent placement following PCI; ST segment elevation acute myocardial infarction (STEMI) in medically treated patients eligible for thrombolytic therapy.

4.2 Posology and method of administration

One tablet once daily. DUOGOOD is for continuation of therapy in patients already initiated on separate clopidogrel and ASA. If a dose is missed and <12 hours after regular scheduled time: take immediately; if >12 hours, take the next dose at the regular scheduled time. Not recommended for children and adolescents under 18 years.

Renal impairment

Not to be used in patients with severe renal impairment (CrCl <30 ml/min). Use with caution in mild to moderate renal impairment.

Hepatic impairment

Not to be used in patients with severe hepatic impairment. Use with caution in moderate hepatic disease.

Method of administration

Oral. May be given with or without food.

4.3 Contraindications

- Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.
- Severe hepatic impairment.
- Active pathological bleeding such as peptic ulcer or intracranial haemorrhage.
- Due to ASA: hypersensitivity to NSAIDs and syndrome of asthma, rhinitis and nasal polyps; patients with pre-existing mastocytosis.
- Severe renal impairment (CrCl <30 ml/min).
- Third trimester of pregnancy.

4.4 Special warnings and precautions for use

Bleeding and haematological disorders
Due to the risk of bleeding, blood cell count and/or other appropriate testing should be performed if clinical symptoms suggestive of bleeding arise. DUOGOOD should be used with caution in patients at risk of increased bleeding from trauma, surgery, or other pathological conditions, and in patients receiving other agents associated with bleeding risk. Concomitant use with oral anticoagulants is not recommended.

CYP2C19 pharmacogenetics
Clopidogrel is partly metabolised by CYP2C19 to its active metabolite. Patients who are poor CYP2C19 metabolisers form less active metabolite and have smaller effects on platelet function. Concomitant use of strong or moderate CYP2C19 inhibitors should be discouraged.

Aspirin-related cautions
Patients with a history of asthma or allergic disorders are at increased risk. Children under 18 years: possible association with Reye's syndrome. G6PD deficiency: risk of haemolysis. Gout: low-dose ASA increases urate concentrations.

Gastrointestinal effects
Use with caution in patients with a history of peptic ulcer or gastroduodenal haemorrhage. GI bleeding — which may be fatal — can occur.

Lactose and Sunset Yellow FCF
This product contains lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. Contains Sunset Yellow FCF (E110), which may cause allergic reactions.

4.5 Interaction with other medicinal products and other forms of interaction

Oral anticoagulants: Concomitant administration is not recommended (increased bleeding risk). Glycoprotein IIb/IIIa inhibitors, heparin, thrombolytics, NSAIDs (including COX-2 inhibitors): increased bleeding risk; use with caution. SSRIs: increased bleeding risk. PPIs (especially omeprazole and esomeprazole): reduce clopidogrel active metabolite by 40–45%; concomitant use is discouraged. Pantoprazole or lansoprazole may be used. CYP2C8 substrates (e.g. repaglinide, paclitaxel): clopidogrel increases exposure via CYP2C8 inhibition by its glucuronide metabolite; use with caution. Uricosurics, methotrexate (>20 mg/week), valproic acid: interactions via ASA. Opioid agonists: may delay and reduce clopidogrel absorption.

4.6 Fertility, pregnancy and lactation

Pregnancy
DUOGOOD should not be used during the first two trimesters unless clearly necessary. Contraindicated during the third trimester (ASA component). No clinical data on clopidogrel in pregnancy.

Breast-feeding
Breast-feeding should be discontinued during treatment.

Fertility
No fertility data available with DUOGOOD. Clopidogrel showed no effect on animal fertility.

4.7 Effects on ability to drive and use machines

DUOGOOD has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Bleeding is the most common reaction — including major and fatal bleeding. GI haemorrhage and haematoma are common. Epistaxis, haematuria and eye bleeding are uncommon. Other adverse reactions include thrombocytopenia, leucopenia, TTP (very rare), rash and pruritus (uncommon), and hypersensitivity reactions. See the full list in the submitted SmPC.

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

Clopidogrel: May lead to prolonged bleeding time and bleeding complications. Platelet transfusion may reverse the effects. ASA: Moderate intoxication causes dizziness, headache, tinnitus, confusion and GI symptoms.

Severe intoxication involves acid-base disturbances, hyperthermia, convulsions, hallucinations and hypoglycaemia. Treatment is symptomatic; alkalising urine and haemodialysis are options for severe cases.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antithrombotic agents; platelet aggregation inhibitors excl. heparin. ATC code: B01AC30.

Clopidogrel is a prodrug metabolised by CYP450 enzymes to an active thiol metabolite that irreversibly inhibits the P2Y12 ADP receptor on platelets, blocking ADP-mediated platelet activation and GPIIb/IIIa complex activation. Platelet function recovery occurs at a rate consistent with platelet turnover (approximately 7–10 days). ASA irreversibly inhibits COX-1 and COX-2, blocking thromboxane A2 synthesis and platelet aggregation. The combination provides synergistic antiplatelet activity.

5.2 Pharmacokinetic properties

Clopidogrel: Rapidly absorbed; absolute bioavailability approximately 50%. Extensively metabolised; active metabolite formed primarily by CYP2C19 with contributions from CYP1A2, CYP2B6 and CYP3A4. Half-life of main circulating (inactive) metabolite approximately 8 hours. Approximately 50% excreted in urine and 46% in faeces. ASA: Hydrolysed to salicylic acid in plasma; peak salicylic acid approximately 1 hour post-dose. Salicylic acid highly protein-bound (~90%); half-life approximately 2 hours. Eliminated as salicyluric acid, glucuronides and unchanged salicylate in urine.

5.3 Preclinical safety data

Clopidogrel: No evidence of carcinogenic effect in mice or rats. No genotoxicity in standard assays. No effect on fertility. Not teratogenic in rats or rabbits. ASA: Not genotoxic or clastogenic. Not a tumour promoter. Teratogenic in several laboratory animals at prostaglandin-synthesis-inhibiting doses.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate (96.12 mg per tablet; excipient with known effect), povidone K-30, croscarmellose sodium, sodium starch glycolate, magnesium stearate, purified talc, colloidal anhydrous silica, hydroxypropyl methylcellulose (HPMC), propylene glycol, Sunset Yellow FCF (E110; film-coat; excipient with known effect), titanium dioxide (E171).

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. Keep out of the reach and sight of children.

6.5 Nature and contents of container

10 tablets per ALU-ALU blister; 3 such blisters packed in a carton with package insert. Pack size: 30 tablets.

6.6 Special precautions for disposal and other handling

No special requirements. Any unused 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)

H2026/CTD12273/25346

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

12.04.2026

10. DATE OF REVISION OF THE TEXT

12.04.2026