COAPROVEL® Abridged Prescribing Information

NAME AND PRESENTATIONS: CoAprovel® 150/12.5 mg tablets contain irbesartan 150 mg and hydrochlorothiazide 12.5 mg. CoAprovel® 300/12.5 mg, CoAprovel® 300/25 mg tablets contain irbesartan 300 mg and hydrochlorothiazide 12.5 mg and 25 mg respectively. **THERAPEUTIC INDICATIONS:** Treatment of essential hypertension. This fixed dose combination is indicated in adult patients whose blood pressure is not adequately controlled on irbesartan or hydrochlorothiazide alone. **POSOLOGY AND METHOD OF ADMINISTRATION:** CoAprovel can be taken once daily, withor without food. Dose titration with the individual components (i.e. irbesartan and hydrochlorothiazide) may berecommended. When clinically appropriate direct change from monotherapy to the fixed combinations may beconsidered: CoAprovel 150 mg/12.5 mg may be administered in patients whose blood pressure is not adequately controlled with hydrochlorothiazide or irbesartan 150 mg alone. CoAprovel 300 mg/12.5 mg may be administered in patients insufficiently controlled by irbesartan300 mg or by CoAprovel 150 mg/12.5 mg. CoAprovel 300 mg/25 mg may be administered in patients insufficiently controlled by CoAprovel 300mg/12.5 mg. Doses higher than 300 mg irbesartan/25 mg hydrochlorothiazide once daily are not recommended. When necessary, CoAprovel may be administered with another antihypertensive medicinal product. Renal impairment: Due to hydrochlorothiazide component, CoAprovel is not recommended for patients with severe renal dysfunction (CrCl < 30ml/min). No dosage adjustment is necessary with mild to moderate renal impairment (CrCl ≥ 30 ml/min). Hepatic impairment: Not indicated in patients with severe hepatic impairment. Thiazides should be used with caution in patients with impaired hepatic function. No dosage adjustment is necessary with mild to moderate hepatic impairment. Elderly: No dosage adjustment. Paediatric population: Not recommended for use in children and adolescents (no available data). **CONTRAINDICATIONS:** Hypersensitivity to the active substances or to any of the excipients, or to other sulphonamide-derived substances. Second and third trimester of pregnancy. Severe renal impairment (CrCl < 30ml/min). Refractory hypokalaemia, hypercalcaemia. Severe hepatic impairment, biliary cirrhosis and cholestasis. Concomitant use with aliskiren-containing products in patients with diabetes mellitus or renal impairment(glomerular filtration rate (GFR) < 60 ml/min/1.73 m²). **SPECIAL WARNINGS AND PRECAUTIONS FOR USE:** Hypotension -volume -depleted patients, renal artery stenosis - renovascular hypertension, renal impairment and kidney transplantation,hepatic impairment, aortic and mitral valve stenosis, obstructive hypertrophic cardiomyopathy, primary aldosteronism, metabolic and endocrine effects, electrolyte imbalance, lithium, anti-doping test, choroidal effusion, acute myopia and secondary acute angle-closure glaucoma, photosensitivity reactions with thiazides diuretics.(See full SmPc) **PREGNANCY AND LACTATION:** The use of AIIRAs is not recommended during the first trimester of pregnancy. The use of AIIRAs is contraindicated during the second and third trimesters of pregnancy. CoAprovel is not recommended during breast-feeding; especially while nursing a newborn or preterm infant. (Not available data). **DRUG INTERACTIONS:** Other antihypertensive agents, Aliskiren-containing products or ACE-inhibitors, Lithium, medicinal products affecting potassium and/or affected by serum potassium disturbances, Non-steroidal anti-inflammatory drugs, Repaglinide: (See full SmPc). **EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:** When driving vehicles or operating machines, dizziness or weariness may occasionally occur during treatment of hypertension. **UNDESIRABLE EFFECTS:** Irbesartan/hydrochlorothiazide combination: *Common*: Increase in BUN, creatinine and creatine kinase, dizziness, nausea/vomiting, abnormal urination and fatigue. *Uncommon:* Decreases in serum potassium and sodium, syncope, hypotension, tachycardia, oedema, orthostatic dizziness, diarrhea, extremity swelling, flushing, jaundice, sexual dysfunction, libido change. *Not known:* headache, tinnitus, cough, dyspepsia, dysgeusia, impaired renal function, arthralgia, myalgia,hyperkalaemia, hypersensitivity reactions, hepatitis, and abnormal hepatic function. (See full SmPc). **OVERDOSAGE:** No specific information is available on the treatment of overdose with CoAprovel.Treatment should be symptomatic and supportive. Irbesartan is not removed by haemodialysis and degreeto which hydrochlorothiazide is removed by haemodialysis has not been established. The most likely manifestations of irbesartan overdose are expected to be hypotension and tachycardia; bradycardia might also occur. Overdose with hydrochlorothiazide is associated with electrolyte depletion (hypokalaemia, hypochloremia, hyponatraemia) and dehydration resulting from excessive diuresis. The most common and symptoms of overdose are nausea and somnolence. **SHELF LIFE:** 3 years. **SPECIAL PRECAUTIONS FOR STORAGE:** Do not store above 30°C, Store in the originalpackage in order to protect from moisture. **MARKETING AUTHORISATION HOLDER:** Sanofi Winthrop Industrie, 82 avenue Raspail, 94250 Gentilly, France. **DATE Of Text Revision Date:** January 2023.

To report an adverse event or if you have any medical enquiry, please call +964 751 740 2599 or email us at:
Levant.Pharmacovigilance@sanofi.com **for adverse events**
Levant.medinfo@sanofi.com **for medical enquiries**
Quality.Levant@sanofi.com **for product technical complaints**

Always refer to the full Summary of Product Characteristics (SmPC) before prescribing.

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