



TWO TREATMENTS ONE TABLET

Your combination for success
in Mixed Dyslipidemia



2 TREATMENTS IN 1

STATIN

FENOFIBRATE

NOW IN ONE TABLET

For improved adherence and convenience of your patients

NAME OF THE MEDICINAL PRODUCT: CHOLIB TABLETS 145MG/20MG; QUALITATIVE AND QUANTITATIVE COMPOSITION: One film-coated tablet contains 145 mg of fenofibrate and 20 mg of simvastatin. **Therapeutic indications:** Cholib is indicated as adjunctive therapy to diet and exercise in high cardiovascular risk adult patients with mixed dyslipidaemia to reduce triglycerides and increase HDL-C levels when LDL-C levels are adequately controlled with the corresponding dose of simvastatin monotherapy. **Posology and method of administration:** Secondary causes of hyperlipidaemia, such as uncontrolled type 2 diabetes mellitus, hypothyroidism, nephrotic syndrome, dysproteinemia, obstructive liver disease, pharmacological treatment (like oral oestrogens), alcoholism should be adequately treated, before Cholib therapy is considered and patients should be placed on a standard cholesterol and triglycerides-lowering diet which should be continued during treatment. **Contraindications:** Hypersensitivity to the active substances, peanut, soya or to any of the; Known photoallergy or phototoxic reaction during treatment with fibrates or ketoprofen; Active liver disease or unexplained persistent elevations of serum transaminases; Known gallbladder disease; Chronic or acute pancreatitis with the exception of acute pancreatitis due to severe hypertriglyceridaemia; Moderate to severe renal insufficiency (estimated glomerular filtration rate < 60 mL/min/1.73 m²); Concomitant administration of fibrates, statins, danazol, ciclosporin or potent cytochrome P450 (CYP) 3A4 inhibitors; Concomitant administration of glecaprevir, pibrentasvir, elbasvir or grazoprevir; Paediatric population (age below 18 years); Pregnancy and breast-feeding; Personal history of myopathy and/or rhabdomyolysis with statins and/or fibrates or confirmed creatine phosphokinase elevation above 5 times the upper limit of normal (ULN) under previous statin treatment; Concomitant administration of amiodarone, verapamil, amlodipine or diltiazem; strong CYP3A4 inhibitors (e.g. itraconazole, ketoconazole, posaconazole, voriconazole, HIV protease inhibitors, boceprevir, telaprevir, erythromycin, clarithromycin, telithromycin and nefazodone), gemfibrozil, ciclosporin and danazol. **Special warnings and precautions for use:** Simvastatin 80 mg should be used only in patients who have been taking this dose for 12 months or more without evidence of muscle toxicity.; Simvastatin 80mg should not be started in new patients, including patients already taking lower doses of the drug.; It is recommended that liver function tests should be performed before the initiation of Cholib, and thereafter when clinically indicated. **Interaction with other medicinal products and other forms of interaction:** Do not exceed 10 mg simvastatin daily with verapamil, diltiazem and other fibrates (except fenofibrate).; Do not exceed 20 mg simvastatin daily with amiodarone, amlodipine and ranolazine.; Patients should be closely monitored when taking fusidic acid with simvastatin. Temporary suspension of simvastatin treatment may be considered.; Avoid grapefruit juice when taking simvastatin. **Undesirable effects:** The most commonly reported adverse drug reactions (ADRs) during Cholib therapy are increased blood creatinine, upper respiratory tract infection, increased platelet count, gastroenteritis and increased alanine aminotransferase.

For healthcare professional only. Full prescribing information available on request.

Abbott Laboratories Limited
20/F, AIA Tower, 183 Electric Road, North Point Tel: (852) 2566 8711 Fax: (852) 2219 7397

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