

PritorPlus[®]/Kinzalkomb[®] 40 mg/12.5 mg / 80 mg/12.5 mg / 80 mg/25 mg tablets

Refer to SmPC before prescribing

Composition: *Active ingredients:* 40 mg / 80 mg telmisartan and 12.5 / 25 mg hydrochlorothiazide. *Excipients:* lactose monohydrate, magnesium stearate, maize starch, meglumine, microcrystalline cellulose, povidone (K25), red or yellow ferric oxide (E172), sodium hydroxide, sodium starch glycollate (type A), sorbitol (E420).

Therapeutic indications: Treatment of essential hypertension in patients whose blood pressure is not adequately controlled on telmisartan alone or on PritorPlus[®]/Kinzalkomb[®] 80 mg/12.5 mg, or in patients previously stabilised on telmisartan and hydrochlorothiazide given separately.

Contraindications: Hypersensitivity to any of the active substances or excipients, second and third trimester of pregnancy, lactation, cholestasis and biliary obstructive disorders, severe hepatic impairment, severe renal impairment, refractory hypokalaemia, hypercalcaemia.

Warnings and Precautions: *not recommended:* first trimester of pregnancy, children below 18 years due to lack of data, primary aldosteronism; *use with caution:* hepatic impairment, renovascular hypertension, renal impairment and renal transplantation, hypovolaemia, other conditions with stimulation of the renin-angiotensin-aldosterone system, aortic or mitral stenosis or obstructive hypertrophic cardiomyopathy, metabolic and endocrine effects, electrolyte imbalance, hyperkalaemia, hereditary fructose intolerance. For further details please refer to SmPC.

Interactions: *concomitant use not recommended:* lithium, medicinal products that may increase potassium levels or induce hyperkalaemia. For further details please refer to SmPC.

Undesirable effects: The overall incidence of adverse events reported with PritorPlus[®]/Kinzalkomb[®] was comparable to those reported with telmisartan alone. *Common:* dizziness; *uncommon:* hypokalaemia, anxiety, syncope, arrhythmias, hypotension, diarrhoea, dry mouth, myalgia, erectile dysfunction, chest pain, blood uric acid increased; *rare:* angioedema. For further details please refer to SmPC. Adverse reactions known to occur with each individual component given singly may also occur during treatment with PritorPlus[®]/Kinzalkomb[®].

Medicinal product subject to medical prescription. Version: EU/6 **Date:** August, 2009

Marketing Authorisation holder: Bayer HealthCare AG, D-51368 Leverkusen, Germany