

Pritor®/Kinzalmono® 20 mg / 40 mg / 80 mg tablets

Refer to SmPC before prescribing

Composition: *Active ingredient:* 20 mg / 40 mg / 80 mg telmisartan. *Excipients¹:* Povidone (K25), meglumine, sodium hydroxide, sorbitol (E420), magnesium stearate.

Therapeutic indications: Treatment of essential hypertension.

Contraindications: Hypersensitivity to the active substance or to any of the excipients, second and third trimester of pregnancy, lactation, biliary obstructive disorders, severe hepatic impairment.

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, hyperkalaemia, hereditary fructose intolerance. For further details please refer to SmPC.

Interactions: *concomitant use not recommended:* potassium sparing diuretics or potassium supplements, lithium. For further details please refer to SmPC.

Undesirable effects: The overall incidence of adverse events reported with telmisartan was usually comparable to placebo. *Uncommon:* hyperkalaemia, syncope, vertigo, hypotension, diarrhoea, dry mouth, myalgia, renal impairment including acute renal failure, chest pain; *rare:* angioedema; *not known:* sepsis including fatal outcome. For further details please refer to SmPC.

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

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