Olmesartan Medoxomil: Drug Safety Communication - Label Changes To Include Intestinal Problems (Sprue-Like Enteropathy)

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FDA提醒降血壓藥Olmesartan Medoxomil可能造成腸病變(sprue-like enteropathy)。其症狀包含嚴重慢性腹瀉伴隨體重減輕。FDA已經核准將此訊息加註於該藥品的仿單。其他ARB類藥物未發現有同樣副作用。

FDA將持續評估Olmesartan的品項，並隨時更新訊息。

建議

若使用Olmesartan的病人有慢性腹瀉伴隨體重減輕時，即使此症狀需經年累月才會變嚴重，醫療人員應聯繫病人；有此症狀的病人也應主動告訴醫療人員。

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AUDIENCE: Health Professional, Cardiology, Patient

ISSUE: FDA is warning that the blood pressure drug Olmesartan Medoxomil (marketed as Benicar, Benicar HCT, Azor, Tribenzor, and generics) can cause intestinal problems known as sprue-like enteropathy. Symptoms of sprue-like enteropathy include severe, chronic diarrhea with substantial weight loss. FDA has approved changes to the labels of these drugs to include this concern. Sprue-like enteropathy has not been detected with ARB drugs other than olmesartan.

FDA will continue to evaluate the safety of olmesartan-containing products and will communicate again if additional information becomes available.

BACKGROUND: Olmesartan medoxomil is an angiotensin II receptor blocker (ARB) approved for the treatment of high blood pressure, alone or with other antihypertensive agents, and is one of eight marketed ARB drugs.

RECOMMENDATION: Health care professionals should tell patients to contact them if they develop severe, chronic diarrhea with substantial weight loss while taking an olmesartan-containing product, even if it takes months to years for symptoms to develop. Patients should contact their health care professional right away if they take an olmesartan-containing product and experience severe diarrhea, diarrhea that does not go away, or significant weight loss.