**Nicorandil: mucocutaneous ulceration (continued)**

- A very severe case report.

In 2012, a summary of an exemplary case report of adverse effects attributed to nicorandil was published in the newsletter of the Regional Pharmacovigilance Centre in Angers, France (1). Nicorandil has minor efficacy as a symptomatic treatment for angina pectoris. It is known to cause sometimes severe ulceration of the skin and mucosae (2).

An 87-year-old woman who had been taking nicorandil since 2003 developed severe aphthous stomatitis in mid-2009 (1). Nicorandil was discontinued in July 2009 and the lesions healed within a month. In August, nicorandil was reintroduced.

In December 2009, a sigmoidouterine fistula was diagnosed. In March 2011, a vesico-vaginal fistula was diagnosed. The stoma area became ulcerated in August 2011. Nicorandil was withdrawn in August 2011. By late September 2011, the ulceration around the stoma had improved and the pain had stopped. By November 2011, it has almost completely healed.

In view of nicorandil’s minor efficacy in angina, these adverse effects are unacceptable: patients would be better served if nicorandil were neither prescribed, used nor licensed.

**Venlafaxine: preeclampsia and eclampsia**

- Gestational hypertension.

In early 2012 the World Health Organization’s pharmacovigilance centre in Uppsala published an analysis of 31 cases of hypertensive disorders attributed to venlafaxine in pregnant women (1). They derived from the international Vigibase database. There were 4 cases of eclampsia, 21 of preeclampsia, 6 of gestational hypertension and 2 of the HELLP syndrome (severe preeclampsia, haemolysis, thrombocytopenia and liver damage). Only 3 of the women were under 29 years old. The daily doses of venlafaxine ranged from 9 to 300 mg and the treatment period ranged from 19 days to several years.

A cohort study of 5731 women showed that the risk of gestational hypertension was roughly twice as high among women taking a selective serotonin reuptake inhibitor antidepressant as in women not taking such drugs (odds ratio 1.9, 95% confidence interval (95% CI) 1.4 to 2.7) (1). The frequency of preeclampsia was 9% in women taking an SSRI and 2.4% in controls, and the risk was even higher with venlafaxine (relative risk 4.9, 95% CI: 2.7 to 8.8).

Blood pressure elevation is a well-known adverse effect of venlafaxine (2) and is one more reason to use antidepressants sparingly during pregnancy.