**Boceprevir: serious haematological disorders**

- Monitoring blood cell counts is essential.

In November 2013, the French Health Products Agency analysed the pharmacovigilance data collected as part of the national monitoring of boceprevir and telaprevir, used in combination with either peginterferon alfa or ribavirin to treat hepatitis C (1,2).

Data acquired during the first year of monitoring of boceprevir included nearly 150 reports of serious adverse effects and about 100 reports of non-serious adverse effects. The most frequent were blood cell line disorders: anaemia, neutropenia or thrombocytopenia, as well as 2 cases of agranulocytosis and 3 cases of pancytopenia (1). Infections, including 4 cases of septic shock (3 of which were fatal), and a brain haemorrhage in a patient with thrombocytopenia were also identified. The other adverse effects were: asthenia, gastrointestinal disorders (nausea, vomiting, diarrhoea), psychological disorders, dysgeusia, and skin disorders including 2 cases of DRESS (drug reaction with eosinophilia and systemic symptoms). Fourteen deaths were reported during the first year of monitoring: due to cardiac arrest, septic complications or brain haemorrhage. Adverse effects reported during the second year of monitoring were generally similar.

The first year of monitoring of telaprevir provided little new information (1). Serious adverse effects mainly included skin disorders, blood cell line disorders (anaemia, neutropenia and thrombocytopenia), gastrointestinal disorders including cases of pancreatitis (one patient died of necrotising pancreatitis) and haematobiliary disorders, renal failure and hyperuricaemia.

In practice, the haematological adverse effects of the antiviral drugs used to treat hepatitis C expose patients to the risk of serious complications, especially with boceprevir, hence the importance of monitoring patients’ blood cell counts and considering other treatment options if they drop too low. It is also important to bear in mind the serious cutaneous adverse effects of telaprevir.

**Colchicine: more deaths**

- Advanced age and renal failure are risk factors.

Colchicine is a cytotoxic drug used for symptom relief of gout attacks. It acts by attenuating the inflammatory response. Diarrhoea is a known adverse effect and the first symptom of colchicine overdose (1).

In 2014 the French Health Products Agency provided access to pharmacovigilance data on colchicine collected between January 2012 and May 2013 (2). 213 cases were analysed.

18 deaths occurred during this 17-month period, of which 14 were considered to be linked to colchicine. Advanced age and chronic renal failure were the main risk factors.

25 of the patients were receiving another drug known to interact with colchicine, mainly by inhibiting cytochrome P450 isoenzyme 3A4 or P-glycoprotein. Two patients who died were also receiving a macrolide.

Diarrhoea was reported in 88 cases, 6 of which were fatal. Severe diarrhoea occurred within 5 days after the beginning of colchicine treatment in about half these cases. Colchicine was withdrawn on the first day of severe diarrhoea in less than half the cases.

Colchicine has a narrow therapeutic index and potentially life-threatening adverse effects.