



***Direct Healthcare Professional Communication on the association of the risk of serious hypersensitivity reactions, including Stevens-Johnson Syndrome and acute anaphylactic reaction/shock, with Adenuric (febuxostat)***

18<sup>th</sup> May 2012

Dear Healthcare Professional,

This letter is sent in agreement with the European Medicine Agency (EMA) and Irish Medicines Board (IMB) after a review of safety data collected during post-marketing surveillance.

**Summary**

- Serious hypersensitivity reactions, including Stevens-Johnson Syndrome and acute anaphylactic/shock reactions have been reported with Adenuric (febuxostat). In most cases, these reactions occurred during the first month of therapy with Adenuric (febuxostat).
- Some, but not all, of the patients experiencing hypersensitivity reactions were reported to have a prior history of hypersensitivity to allopurinol and /or renal disease.
- Patients should be advised of signs and symptoms of severe hypersensitivity.
- Treatment should be immediately stopped if signs or symptoms of serious hypersensitivity reactions occur, since early withdrawal is associated with a better prognosis.
- If a patient has developed hypersensitivity reactions associated with the use of Adenuric (febuxostat), including Stevens-Johnson Syndrome and acute anaphylactic reaction/shock, Adenuric (febuxostat) must not be re-started in this patient at any time.

**Further information on the safety concern**

Adenuric (febuxostat) is indicated in adults for the treatment of chronic hyperuricaemia in conditions where urate deposition has already occurred (including a history or presence of tophus and/or gouty arthritis).

Rare serious hypersensitivity reactions to Adenuric (febuxostat), some of which were associated with systemic symptoms, have been reported in the post-marketing period.

Hypersensitivity reactions to Adenuric (febuxostat) can be associated with skin reactions characterised by infiltrated maculopapular eruption, generalised or exfoliative rashes, but also skin lesions, facial oedema, fever, haematologic abnormalities such as thrombocytopenia and single or multiple organ involvement (liver and kidney including tubulointerstitial nephritis). Stevens-Johnson Syndrome is characterised by progressive skin rashes associated with blisters or mucosal lesions and eye irritation.

The assessment of post-marketing safety data resulted in an update of the product information for Adenuric (febuxostat) with information on serious allergy/hypersensitivity reactions. (Please refer to the SmPC in the Annex).

### **Reporting Requirements**

Please remember that any suspected adverse reaction following the use of Adenuric (febuxostat) should be reported to the IMB online at [www.imb.ie](http://www.imb.ie) or by using a freepost yellow card.

Reports may also be notified to:

A.Menarini Pharmaceuticals Ireland Ltd.,  
Pharmacovigilance Department  
Castlecourt  
Monkstown Farm  
Monkstown  
Glenageary  
Co. Dublin

Tel. 01 284 6744

Fax 01 284 6769

Email: [ireland@menarini.ie](mailto:ireland@menarini.ie)

### **Communication information**

Should you have any questions or require further information regarding Adenuric (febuxostat), please contact A. Menarini's Medical Information Department using the details above.

Yours faithfully,

*Angela Gillian*

Angela Gillian PhD  
Medical Manager

### **Annex**

Summary of Product Characteristics, updated on 24 Jan 2012