Bayer HealthCare

01 Feb 2015

Direct Healthcare Professional Communication on the association of Interferon Beta with the risk of thrombotic microangiopathy and nephrotic syndrome

Dear Healthcare Professional,

Bayer HealthCare Saudi Arabia in agreement with SFDA would like to inform you of important safety information regarding interferon beta products (Betaferon®) used in the treatment of multiple sclerosis.

Summary

- **Cases of thrombotic microangiopathy (TMA) including fatal cases have been reported during treatment of multiple sclerosis with interferon beta products. Most TMA cases presented as thrombotic thrombocytopenic purpura or haemolytic uraemic syndrome.**
- **Cases of nephrotic syndrome with different underlying nephropathies have also been reported.**
- **Both TMA and nephrotic syndrome may develop several weeks to several years after starting treatment with interferon beta.**
- **Be vigilant for the development of these conditions and manage them promptly if they occur, in line with the advice below.**

Advice regarding TMA:

- **Clinical features of TMA include thrombocytopenia, new onset hypertension, fever, central nervous system symptoms (e.g. confusion and paresis) and impaired renal function.**
- **If you observe clinical features of TMA, test blood platelet levels, serum lactate dehydrogenase levels and renal function. Also test for red blood cell fragments on a blood film.**
- **If TMA is diagnosed, prompt treatment (considering plasma exchange) is required and considers stopping treatment with interferon beta.**

Advice regarding nephrotic syndrome:

- **Monitor renal function periodically and be vigilant for early signs or symptoms of nephrotic syndrome such as oedema, proteinuria and impaired renal function especially in patients at high risk of renal disease.**
- **If nephrotic syndrome occurs, treat promptly and consider stopping treatment with interferon beta.**

Further information

This communication follows a review by European drug regulatory agencies after reports of TMA and nephrotic syndrome were received in association with use of interferon beta products for the treatment of multiple sclerosis. The review could not rule out a causal association between interferon beta products and nephrotic syndrome or between interferon beta products and TMA.

More information on the conditions:

TMA is a serious condition characterised by occlusive microvascular thrombosis and secondary haemolysis. Early clinical features include thrombocytopenia, new onset hypertension and impaired renal function. Laboratory findings suggestive of TMA include decreased platelet counts, increased serum lactate dehydrogenase (LDH) and schistocytes (erythrocyte fragmentation) on a blood film.
Nephrotic syndrome is a nonspecific kidney disorder characterised by proteinuria, impaired renal function and oedema.

The information in this letter has been approved by the Saudi Food and Drug Authority.

Call for reporting

As a reminder, there is a need to report any suspected adverse reactions to the National Pharmacovigilance and Drug Safety Center (NPC):

- Fax: +966-11-205-7662
- Call NPC at +966-11-2038222, Ext: 2317-2356-2353-2354-2334-2340.
- Toll free phone: 8002490000
- E-mail: npc.drug@sfda.gov.sa
- Website: www.sfda.gov.sa/npc

Or

Pharmacovigilance department in Bayer HeathCare

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Yours Sincerely,

f. 01/Feb/15

Abdullah Rajkhan

Pharmacovigilance Country Head, KSA and GCC