SERVIER INTERNATIONAL

May 2013

Direct Healthcare Professional Communication – Outcome of the Benefit-Risk Re-evaluation of Trimetazidine containing products.

Dear Healthcare Professional,

This letter is to inform you that the Product Information (SmPC) and patient leaflet of VASTAREL was revised in *Saudi Arabia* by SFDA on 21/03/1434 H.

Summary

This update follows the review of all available efficacy data by the CHMP (The European Medicines Agency's Committee for Medicinal Products for Human Use) which concluded that benefit/risk balance of VASTAREL only remains positive in a limited population of patients with stable angina pectoris who are inadequately controlled by or intolerant to first-line-anginal therapies as add-on therapy.

The safety review concluded that, although these symptoms are reversible after discontinuing VASTAREL, movement disorders, including Parkinsonism, cannot be excluded with VASTAREL. These should be investigated especially in elderly patients and patients with renal insufficiency in whom an increased exposure is expected.

Further Information

Therefore, in order to improve patient's management, the existing precautions and contraindications have been reinforced:

- VASTAREL is now contraindicated in patients with Parkinson's disease or parkinsonian symptoms. The onset of movement disorders such as Parkinsonian symptoms, restless leg syndrome, tremors, gait instability, should lead to the definitive discontinuation of VASTAREL. If Parkinsonian symptoms persist for more than 4 months after discontinuation, a neurologist's opinion should be sought.
- VASTAREL is contraindicated in patients with severe renal impairment. Caution should be exercised when prescribing VASTAREL to patients with a moderate renal impairment and elderly patients with age-related moderate renal insufficiency. Dosage reduction should be considered in these patients and dose titration exercised with caution.

The information in this letter has been agreed with the Saudi Food and Drug Authority (SFDA).

Call for reporting

As a reminder, there is a need to report any suspected adverse reactions in accordance with the national spontaneous reporting system:
http://www.sfda.gov.sa/en/drug/about/sector_departments/national_pharmacovigilance_center/Pages/reporting_forms.aspx
or by email: npc.drug@sfda.gov.sa
or by fax: +966 1 2057662

Communication information

For further inquiries concerning this information, please contact the Medical Information Department of SERVIER - Tel: 00966 2 6976997 and at *samy.sinnugrut@sametgrs.com*.

Yours sincerely,

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