bijwerkingen centrumlareb

Overview of reports received after substitution of levothyroxine due to Thyrax Duotab® out-of-stock

Introduction

In January 2016 the company Aspen Pharma Trading announced that there were production issues with Thyrax Duotab® (levothyroxine). Due to a change in production facility Aspen Pharma Trading was temporarily unable to produce Thyrax Duotab®. This led to an out-of-stock situation for Thyrax Duotab® 0.025mg in February 2016 and it was predicted that the 0.100mg and 0.150mg tablets would be out-of stock around June 2016. This out-of-stock situation would last during most of 2016 [1].

It was advised to start no new patients on Thyrax Duotab® and patients currently using Thyrax Duotab® should switch to a different product with levothyroxine when their own stock ran out [1]. Various products with levothyroxine are registered in the Netherlands, but none of these products is bio-equivalent to Thyrax Duotab® [2]. Therefore extra thyroid function tests were advised six weeks after the switch and if necessary the dose of levothyroxine should be adjusted accordingly [1]. Lareb is monitoring the adverse drug reactions reported after the switch from Thyrax Duotab® to other levothyroxine products and wants to provide the Medicines Evaluation Board (MEB) with a short periodic update on these reports.

Reports

From 1 February 2016 until 30 May 2016 the Netherlands Pharmacovigilance Centre Lareb received 75 reports concerning reactions associated with the substitution of Thyrax Duotab® into a different brand levothyroxine. These reports concerned 5 male and 70 female patients. Four reports were serious according to the CIOMS criteria, namely hospitalization for hypertension, hospitalization for a suspected pulmonary embolism, a suspected allergic reaction (serious other) and a miscarriage at 6 weeks (serious other). Table 1 shows an overview of the brands the patients received after substitution and the action taken for levothyroxine after the reactions occurred. The top 3 most reported reactions after switching from Thyrax Duotab® to other levothyroxine products were fatigue (n=26), headache or head discomfort (n=22) and palpitations (n=14).

Table 1. Overview of the 75 reports including the brands received after switching and the action taken for levothyroxine after the reactions occurred

Switched to brand	Number of reports	Action taken with drug after reactions occurred				
		Dose increased	Dose reduced	Dose not changed	Drug withdrawn	Unknown
Euthyrox®	38	1	13	10	8	6
Levothyroxine Teva	20	1	5	2	11	1
Thyrofix®	3	1	1	0	1	0
Brand unknown	14	1	7	3	2	1

Conclusion

It could be expected that the substitution of Thyrax® in a large group of patients led to some patient experiencing dysregulation of their thyroid levels. However, healthcare professionals and patients probably anticipated these effects and therefor a large peak in reporting levels was not seen. The reported ADRs follow the expected pattern of known levothyroxine-related reactions.

References

1. Aspen Pharma Trading. DHPC Thyrax Duotab out-of-stock in 2016. (version date: 12-1-2016) http://www.cbg-meb.nl/documenten/brieven/2016/01/12/dhpc-thyrax-duotab.
2. Span J., Kooijman M., Hunsel van F., Postma D. Alertheid geboden bij omzetten levothyroxine. Pharm weekbl 2016;(5):151-4.