



Inhoud

[Head article](#)

[New signals](#)

[Publications](#)

Lareb quarterly newsletter

In this fifth Lareb quarterly e-newsletter we present to you our new signals, abstracts of our publications and other relevant pharmacovigilance news from Lareb. We welcome feedback about this newsletter.

News

Pharmacovigilance books available

Lareb has some interesting pharmacovigilance books available for pharmacovigilance centres.

If you want to apply for one or more of these books, please send an email to ac.vangrootheest@lareb.nl with the title(s) you wish and information for what purpose you are going to use it. Please respond before the 30th of May 2011.

These books are second hand books, in good condition, but not always the latest edition.

The list of books that are available can be found [here](#)

Lareb annual report 2010

The year 2010 has been a busy year with some changes for Lareb as an organization. In 2010 the Minister of Health appointed Lareb, an independent organization with expertise in the field of adverse drug reactions, to monitor all vaccines in the National Immunization Program. Lareb was also appointed the task to host and further develop the Teratology Information Service. The entire annual report can be found [here](#)

Additional information with this annual report can be found on the Lareb website: www.lareb.nl

New Signals

This is the information about possible signals from the Netherlands Pharmacovigilance Centre Lareb for the 1st quarter of 2011.

Below you will find a short summary of the signals that Lareb has been working on in the previous period. You will be able to find the entire signals on our website www.lareb.nl, by clicking the link.

Oral terbinafine and hearing disorders

Lareb received 6 reports concerning hearing disorders with the use of terbinafine. In two cases a positive dechallenge has been reported, although in one of those cases, the patient recovered with sequelae. These cases suggest a signal of hearing disorders associated with the use of terbinafine. The entire signal can be found [here](#)

Fluoroquinolones and stomatitis, a possible group effect

The association between fluoroquinolones and stomatitis is supported by the disproportional number of reports both in the Lareb and WHO database and the mechanism of action of these antibiotics. Stomatitis is expected to be a group effect, which is supported by the reports in the Lareb and WHO database and by the fact that it is mentioned in the Dutch SmPC of moxifloxacin. The association with stomatitis is supported most strongly for norfloxacin and - in the Lareb database also for - levofloxacin, but can be expected to be valid for all fluoroquinolones. The entire signal can be found [here](#)

Metoject® and device-related problems

On the 17th of March 2010 the Dutch Health Care Inspectorate (IGZ) reported that for patients receiving methotrexate injections, the registered drug Metoject® should be used in stead of preparation of methotrexate injections in the pharmacy. Preparation of methotrexate injections in the pharmacy in similar strengths to the Metoject® injections would no longer be reimbursed. From March 17 2010 Lareb received 10 reports of device-related problems associated with Metoject®. The entire signal can be found [here](#)

Vitamin B12 and acneiform dermatitis

The association between vitamin B12 and acneiform dermatitis is described in the literature and further supported by the disproportional high percentage in both the Lareb and WHO database suggesting a causal relationship. The entire signal can be found [here](#)

Pandemic influenza vaccine (Pandemrix®) and injection site discolouration

Lareb received five reports of a skin discolouration confined to administration site associated with vaccination with Pandemrix®, not explained by a plausible mechanism, however, latencies are in five cases consistent with an acute event. The entire signal can be found [here](#)

An overview of reports on sitagliptin

Sitagliptin (Januvia®) was registered for the European market on March 21st 2007 with the Netherlands as rapporteur. The aim of this report was to give an overview of the ADRs associated with the use of sitagliptin using information from both the spontaneous reporting system as well as from the Lareb Intensive Monitoring system. The entire overview can be found [here](#)

Publications

An overview of our publications can be found [here](#)

If you have any remarks, comments or feedback about this newsletter, please let us know! You can send an email with your feedback to ac.vangrootheest@lareb.nl