

Danish Pharmacovigilance Update

Danish Pharmacovigilance Update is an electronic newsletter for doctors intended to ensure easy access to current, updated knowledge about medicines and adverse reactions. It provides quick updates on current medicine safety issues with a practical focus for doctors.

By putting focus on special problems and applicable recommendations, we seek to support medical subscription to reduce the risk of adverse reactions.

The newsletter (in Danish) is sent out to email subscribers on the last Thursday of every month (excluding July) and is available from the website of the DKMA: [Danish Pharmacovigilance Update](#).

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Visual adverse reactions added to the product information for corticosteroid medicine

In January 2017, the European Pharmacovigilance Risk Assessment Committee, PRAC, decided to add the adverse reaction of blurred vision to the product information for all corticosteroid medicines authorised in the EU. The decision applies also to locally-acting medicines such as nasal spray and cream.

In addition to blurred vision, a warning about visual disturbances has also been added.

Background leading to PRAC's conclusion

PRAC's conclusion is based on a Danish-led monitoring procedure for the corticosteroid budesonide, which reviewed the evidence in the periodic safety update report (PSUR) from the pharmaceutical company. The following was noted:

- Blurred vision is described as a common adverse reaction in the summary of product characteristics of budesonide capsules (Entocort), but not for other budesonide medicines. On a global scale, 126 cases have been reported of blurred vision as a suspected adverse reaction to the most commonly used budesonide medicine for inhalation. Since it is assumed that the effect occurs through systemic uptake of budesonide, and since other budesonide formulations are also absorbed systemically, the adverse reaction is relevant for all formulations and must be included in their product information.

- Central serous chorioretinopathy (CSCR) is characterised by a circumscribed retinal detachment caused by the accumulation of fluid. This disorder has long been linked to stress and the use of systemic corticosteroids. The disorder has now also been described after local administration of corticosteroids via inhaled and intranasal, epidural, intra-articular, topical dermal and periorcular routes. It is therefore considered likely that topical forms of budesonide could also increase the risk of CSCR. In case of eye problems, it is therefore important to direct patients' and doctors' attention to the possibility that topical corticosteroid is a possible contributor to disease onset and/or worsening.

A warning is therefore placed in the summary of product characteristics. It advises doctors to refer patients to an ophthalmologist if signs of visual disturbances, possibly caused by CSCR, occur.

Based on the published literature, PRAC assessed that the updates should apply to the whole class of corticosteroids and that these medicines' product information should be changed to reflect these additional warnings and adverse drug reactions accordingly.

Doctors should be aware of the following:

If a patient experiences blurred vision or other visual disturbances, referral to an ophthalmologist should always be considered. Visual disturbances could be symptoms of glaucoma, cataract or CSCR. Glaucoma and cataract are already known adverse reactions of all formulations of corticosteroids, and they appear from the product information.

Links

[Danish Pharmacovigilance Update, August 2014](#)

[PRAC's decision and updates to the summaries of product characteristics authorised in the EU](#)

Finasteride (1 mg) for treatment of hair loss may cause psychiatric adverse reactions

The DKMA, has been contacted by several citizens who have experienced psychiatric adverse reactions in connection with a longer course of treatment with finasteride (1 mg) for hair loss.

Warning about possible psychiatric adverse reactions is added to the product information for finasteride (1 mg)

The issue was discussed at the last meeting in the European Pharmacovigilance Risk Assessment Committee, PRAC, which resolved to place a warning in the product information. The warning will describe that there have been reports of depression, mood changes and suicidal thoughts in treatment with finasteride for hair loss.

Patients should be advised to pay attention to the development of psychiatric symptoms. Patients who experience psychiatric symptoms should stop treatment and contact their doctor.

Indication

Finasteride is authorised both for the treatment of benign prostatic hyperplasia (5 mg) and for the treatment of men with hair loss (1 mg).

As part of routine surveillance of medicines in the EU, the Pharmacovigilance Risk Assessment Committee, PRAC, assesses signals of possible adverse reactions every month to determine whether further measures are needed to improve medicines safety.

The list of signals leading the PRAC to recommend further measures is published on the website of the European Medicines Agency, EMA, every month.

The most important safety signals discussed on the PRAC meeting on 3-6 April 2017 concern the following products:

- **Albiglutide** – acute kidney injury
- **Leflunomide; teriflunomide** – falsely decreased ionised calcium levels

See EU's list of recommendations on safety signals: [PRAC recommendations on signals adopted 3-6 April 2017](#) as well as the [Danish translations of the product information](#).

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ADR signals

An ADR signal is a new observation that raises suspicion of a potential association between a medicine and an adverse reaction or a new aspect of a known adverse reaction, e.g. that the adverse reaction is more common than described previously.

ADR signals can come from a multitude of sources, including ADR reports, clinical studies or scientific literature.

The DKMA uses Danish ADR reports to detect possible new ADR signals. Signals about new possible adverse reactions are forwarded in the EU system to the European Pharmacovigilance Risk Assessment Committee, PRAC. The PRAC assesses if there is sufficient documentation to establish causality and, for example, if changes to the medicine's product information are warranted.