

## Major investigation into possible link between Pandemrix® and narcolepsy

Several countries have received reports on cases of narcolepsy (a rare disorder) in children as well as adults vaccinated with Pandemrix®. In Denmark, no reports of narcolepsy were received as a reaction to the H1N1 vaccine.

Although the cases of narcolepsy have been reported in temporal association with the use of Pandemrix®, it is still uncertain whether the vaccine contributed to the disorder.

The European Medicines Agency (EMA) has therefore started a review of the connection between narcolepsy and Pandemrix®.

The review is to establish whether there is a causal relationship between Pandemrix® and narcolepsy. As part

of the evaluation, the background rate for narcolepsy will be considered to assess if narcolepsy occurs more frequently in people who have been vaccinated with Pandemrix®. The investigation is joined by experts from a number of EU member states, the European Centre for Disease Prevention and Control (ECDC), international authorities as well as the World Health Organisation (WHO).

Since September 2009, at least 30.8 million Europeans have been vaccinated with Pandemrix®.

In Denmark, an estimated 340,000 people have been vaccinated from November 2009 to end-March 2010. About 100,000 of them have received a second dose.

Click this link to read the EMA press release:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/news\\_and\\_events/news/2010/08/newsdetail\\_001105.jsp&murl=menus/news\\_and\\_events/news\\_and\\_events.jsp&mid=WC0b01ac058004d5c1](http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2010/08/newsdetail_001105.jsp&murl=menus/news_and_events/news_and_events.jsp&mid=WC0b01ac058004d5c1)

Narcolepsy is a rare sleep disorder involving sudden sleep attacks. It is unknown what causes the disorder.

## Avandia® and risk of cardiovascular problems

In July, the Committee for Medicinal Products for Human Use (CHMP) under the European Medicines Agency (EMA) started reassessing the benefit-risk profile of rosiglitazone-containing medicines.

The review was initiated in response to two new studies which suggest that the risk of cardiovascular problems in patients using Avandia® is higher than assumed so far. The cardiovascular safety of Avandia® was questioned for the first time in 2007. Since then, the use of Avandia® has not been recommended, and Actos (pioglitazone, a substance belonging to the same drug class as

Avandia®) is 'recommended with precautions'. See: [Antidiabetics \(recommendations in Danish only\)](#)

Avandia® is used to a very limited degree in Denmark. According to a recent report from the Danish Medicines Agency, the number of patients in treatment with glitazones (the drug class to which Avandia® belongs) has decreased sharply since 2007 – which may be ascribed to a decrease in the number of new users emerging every year as well as discontinuation of treatment. Click this link to read the report: [Report: Polypharmacy in diabetes care](#)

Click this link to read the EMA press release:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/news\\_and\\_events/news/2010/07/news\\_detail\\_001062.jsp&murl=menus/news\\_and\\_events/news\\_and\\_events.jsp&mid=WC0b01ac058004d5c1&jsenabled=true](http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2010/07/news_detail_001062.jsp&murl=menus/news_and_events/news_and_events.jsp&mid=WC0b01ac058004d5c1&jsenabled=true)

Avandia® is used for treatment of type 2 diabetes.



# Danish Pharmacovigilance Update

## Medicines with special precautions for use

<a href="#">Isotretinoin-containing medicine</a>	<a href="#">Nplate®</a>
<a href="#">Aclasta®</a>	<a href="#">Qutenza®</a>
<a href="#">Benefix®</a>	<a href="#">Renvela®</a>
<a href="#">Cimzia®</a>	<a href="#">Retacrit®</a>
<a href="#">Daxas®</a>	<a href="#">Revlimid®</a>
<a href="#">Efient®</a>	<a href="#">Revolade®</a>
<a href="#">Exjade®</a>	<a href="#">Simponi®</a>
<a href="#">Gliolan®</a>	<a href="#">Soliris®</a>
<a href="#">Ilaris®</a>	<a href="#">Stelara®</a>
<a href="#">Increlex®</a>	<a href="#">Tasigna®</a>
<a href="#">Instanyl®</a>	<a href="#">Thalidomide Pharmion®</a>
<a href="#">Kaletra®</a>	<a href="#">Theelin®</a>
<a href="#">Lucentis®</a>	<a href="#">Tracleer®</a>
<a href="#">MabCampath®</a>	<a href="#">Tysabri®</a>
<a href="#">Macugen®</a>	<a href="#">Valdoxan®</a>
<a href="#">Mircera®</a>	<a href="#">Volibris®</a>
<a href="#">Mycamine®</a>	<a href="#">Zypadhera®</a>
<a href="#">Multaq®</a>	

## Medicines with special precautions for use

The list to the left contains the names of medicines that doctors must pay special attention to before prescribing them to patients.

For example:

- Prescription may require additional training for doctors.
- Patients must be given important information before use.

Click the name of a medicine to read its special precautions for use and see who is responsible for them. The names link to the summaries of product characteristics in Danish. English versions are available (for centrally authorised products only) at the website of the European Medicines Agency: [www.ema.europa.eu](http://www.ema.europa.eu) > [Find medicine](#) > [Human medicines](#)

The list is updated regularly.

Find out more about medicines with special precautions for use:

[Medicines linked to a risk management plan \(in Danish only\)](#)

## Medicines with stricter reporting requirements

Prescribers are reminded to report all suspected adverse reactions observed within the first two years following placement on the market.

Click on the list below to see what medicines are subject to stricter reporting requirements.

[List of medicines with stricter requirements for doctors, dentists and veterinarians to report side effects \(Excel file, only in Danish\)](#)

At the Danish website [www.medicin.dk](http://www.medicin.dk) you can also see if a medicine is subject to stricter reporting requirements. If this is the case, it will be stated under the description of adverse reactions.



## New children's book about medicine

**Can you make medicine from hippo fat? What is a vaccine, and how does it work? Why do we need antibiotics for a runny nose? These are but some of the questions addressed in a new Danish children's book.**

On 1 September, the Danish Medicines Agency published a factbook for children about medicine. Its Danish title 'Piller og Baciller' translates roughly as 'Pills and Germs' and aims to spur interest in medicine among children aged 6 to 11 years.

'Pills and Germs' touches on many topics: the use of medicine through history (from old Egypt's crocodile pooh and hippo fat to our days' use of syringes and pills), how vaccines work in the body, why antibiotics have no effect on viruses, how to invent new medicine, and what kind of weird "stuff" are viruses, bacteria, fungi and parasites (how they attack the body, and what we do to defend ourselves – with or without medicine) – all with illustrations to help guide the young audience.

The book has been translated from Swedish into Danish and was originally published by the Swedish Medical Products Agency. Idea and text have been provided by author and pharmacist Fredrik Brounéus, illustrations by brain scientist Nina Erixon-Lindroth.



The book, which is only available in Danish, can be bought at the website of the Danish Medicines Agency and costs DKK 97.50 including VAT. Click this link to buy the book: [Piller og Baciller – a children's book about medicine \(information is in Danish\)](#)





## React to serious and unexpected side effects – it improves patient safety

This is the appeal in a new campaign kicked off by the Danish Medicines Agency to capture hospital doctors across Denmark. The campaign aims to increase hospital doctors' awareness and knowledge about side effects – and their obligation to report them to the Danish Medicines Agency.

The Danish Medicines Agency runs this campaign because it estimates that whenever one side effect is reported by a hospital doctor, about 50 serious or unexpected side effects go unreported. The campaign has a positive outlook, so indicates a preliminary survey showing that 95 % of hospital doctors in Denmark find that the reporting of side effects is

an important element in improving patient safety.

The campaign will run until December 2010.

For more information about the campaign, please visit our website: *React when serious and unexpected side effects occur – it improves patient safety.*

*Click here for more detailed information, in Danish:*

You can report side effects at: *[www.dkma.dk](http://www.dkma.dk) > Pharmacovigilance > Report a side effect*

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