LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

NO. 5 • VOLUME 7 • MAY 2016

DANISH PHARMACOVIGILANCE UPDATE

Contents

News from the EU

Risk of migration of etonogestrel implants (Implanon/ Implanon NXT/Nexplanon)

The product information of Implanon/Implanon NXT/Nexplanon has been updated with important information about the localisation of migrated implants as well as correct insertion:

Localisation of migrated implants:

- If the implant cannot be palpated, it should be localised. Once the non-palpable implant has been localised, removal is recommended as soon as medically appropriate.
- Migration of the implant usually involves minor movement relative to the original position, which could lead to the implant not being palpable at the location in which it was placed. Imaging procedures may be required for localisation of implants that have been deeply inserted or have migrated and therefore are not palpable.
- Suitable methods for localisation include two-dimensional X-ray and CT scanning, ultrasound scanning with a high-frequency linear array transducer (10 MHz or greater) or magnetic resonance imaging (MRI).
- There have been rare reports of implants located within the blood vessels of the arm and the pulmonary artery. Some of these cases reported chest pain and/or dyspnoea; others were reported as asymptomatic.
- If the implant cannot be localised in the arm, it should be considered to examine the chest using the mentioned methods of localisation. If the implant is located in the chest, surgical or endovascular procedures may be needed, in which case a specialist in the field should be consulted.

Insertion of implants

- The basis for successful use and subsequent removal of the implant is a correct subdermal insertion of the implant in accordance with the instructions.
- It is strongly recommended that the implant be inserted and removed only by healthcare professionals who have completed training for the use of the applicator and techniques for insertion and removal of the implant. Supervision is recommended as appropriate during insertion and removal of the implant.
- The implant should be inserted subdermally just under the skin at the inner side of the upper arm, avoiding the sulcus between the biceps and triceps muscles where the large blood vessels and nerves lie in the neurovascular bundle deeper in the subcutaneous tissue.
- An implant inserted more deeply than subdermally (deep insertion) may not be palpable, and the localisation and/or removal can be difficult.

The manufacturer will send out letters to relevant doctors with the above information. In addition, a new training programme is being developed to minimise the risk associated with insertion and to advise doctors and patients about what to do in case of vascular migration of the implant.

No instances of vascular migration have been reported in Denmark.

Indication for Implanon® /Implanon® NXT/Nexplanon
Implanon® /Implanon® NXT/Nexplanon are etonogestrel-containing implants for subdermal insertion approved as contraception. They contain barium sulphate which makes it possible to locate the implant using X-rays or CT scanning.

EU's list of recommendations on safety signals

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 signal discussed at the PRAC meeting in April 2016 concerns the following medicinal product:

- **Olanzapine** – Drug reaction with eosinophilia and systemic symptoms (DRESS)

See EU's list of recommendations on safety signals: *PRAC recommendations on signals April 2016* as well as the *Danish translations of the product information*.

Danish Pharmacovigilance Update is published by the Danish Medicines Agency
www.dkma.dk
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ISSN 1904-2086