HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Implanon NXT - Risk of device migration in vasculature and lung

Implanon NXT 68mg is a radiopaque, non-biodegradable progestogen only flexible implant for subdermal use (containing the active substance etonogestrel), which is authorised in Ireland since 2010 for contraception. It is strongly recommended that Implanon NXT should only be inserted and removed by healthcare professionals (HCPs) who have completed training in the use of the applicator and techniques for insertion and removal, and, where appropriate, that supervision be requested prior to inserting or removing the implant.

There have been reports of migration of the implant within the arm from the insertion site, which may be related to deep insertion or external forces (e.g. manipulation or contact sports). There have also been rare post-marketing reports of etonogestrel implants (non-radiopaque and radiopaque) located within the vessels of the arm and the pulmonary artery, which may be related to deep insertions or intravascular insertions. Following a review of relevant data from global sources, the product information (Summary of Product Characteristics (SmPC) and Package Leaflet (PL)) for Implanon NXT has been updated to highlight this risk and to inform healthcare providers and patients about the potential consequences and possible actions to take should intravascular migration occur, as well as providing updated instructions for insertion in order to further minimise this risk.

Advice to Healthcare Professionals

- An implant should only be inserted subdermally and by a healthcare professional that has been appropriately trained.
- Insertion, localisation and removal should closely adhere to the detailed guidance and recommendations described in the SmPC.
- Immediately after insertion, the presence of the implant should be verified by palpation.
- The patient should be advised that if the implant cannot be palpated immediately after insertion, or at any time, she should be advised to return to the healthcare professional who inserted the implant immediately.
- If the implant cannot be found in the arm after comprehensive localisation attempts, consideration should be given to applying imaging techniques to the chest.
- In cases where the implant has migrated to the pulmonary artery, endovascular or surgical procedures may be needed for removal.
- As part of the risk minimisation activities to support safe and effective use of Implanon NXT, the Marketing Authorisation Holder (MAH) has updated their Clinical Training Programme providing a framework to offer practical and consistent guidance and training on Implanon NXT insertion, localisation and removal to all interested healthcare professionals. The MAH has also been requested to bring this information to the attention of healthcare professionals who have already participated in training programmes.
- A Direct Healthcare Professional Communication (DHPC) was circulated by the MAH to relevant healthcare professionals in May 2016 to highlight these updates.

Key Message

- There have been rare reports of Implanon NXT implants reaching the lung via the pulmonary artery.
- An implant that cannot be palpated at its insertion site in the arm should be located as soon as possible and removed at the earliest opportunity.
- The product information (SmPC and PL) for Implanon NXT has been updated to reflect this information and a DHPC was circulated to healthcare professionals in May 2016.
- The MAH is currently updating their Clinical Training Programme for healthcare professionals. Healthcare professionals who have previously been trained will have the option to re-train.

Further details on Implanon NXT are available at www.hpra.ie

This section has been supplied by the HPRA for use in MIMS Ireland. However, the HPRA is independent and impartial to any other information contained in this directory.