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Nexplanon (etonogestrel): implants have been found rarely in the vasculature and lung. An update regarding possible risks and complications regarding insertion, localisation and removal.

Dear Healthcare professional,

Merck, Sharp and Dohme Limited, would like to inform you of the following:

Summary

There have been a small number of reports of Nexplanon implants being found in the vasculature (including the pulmonary artery) and chest wall. No definitive risk factors have been identified given the limited number of events; however, deep insertion, insertion in an inappropriate site, or being underweight could be potential risk factors. The detection and removal of implants that cannot be palpated is recommended as soon as medically appropriate.

Advice for healthcare professionals:

- Implants should only be inserted sub-dermally and by healthcare professionals who have been appropriately trained and accredited (see http://www.fsrh.org/pages/Letter_of_Competence_SDI.asp).
- Do not insert over the sulcus (groove) between the biceps and triceps.
- Take care to avoid blood vessels and nerve bundles e.g the ulnar nerve.
- Immediately after insertion, verify the presence of the implant by palpation.
- Any implant that cannot be palpated should be localised and removal considered as soon as medically appropriate.
- When implants cannot be located in the arm by palpation or imaging, chest imaging should be performed.
- Surgical or endovascular procedures may be required to remove an implant found in the chest.

Further information on the safety concern

Nexplanon (a radiopaque etonogestrel implant) is a one-rod, progestogen-only hormonal contraceptive that is administered sub-dermally (just under the skin). Safety and efficacy have been established in women between 18 and 40 years of age.

A cumulative search of the company global safety database from market introduction on 28 Aug 1998 to 1 April 2015 identified a small number of spontaneous post-marketing reports describing implants found within the

vasculature, lung or chest wall. The reporting rate of migration into the vasculature (including the pulmonary artery and lung) of the Nexplanon implant (which permits additional methods by which to detect it) is approximately 1.3 per million implants sold.

The instructions have been updated highlighting how to correctly insert the implant, including an amended diagram that shows the correct angle of insertion. The diagram also highlights that viewing the needle is necessary to avoid deep insertion. These updates are annexed to this letter.

Recommendations

Nexplanon should only be inserted and removed by healthcare professionals who have completed training on the use of the Nexplanon applicator and on the techniques for insertion and removal of the Nexplanon implant. A nurse trainer from the Nexplanon Training Support Programme (NTSP) can offer additional/refresher training on insertion and removal technique on request.

Training materials for the NTSP have been updated. There is a network of healthcare professionals who are 'expert removers', experienced in implant localisations and difficult removals and who are available for consultation. Additional information and more detailed instructions or training support for implant insertion and removal can be provided on request free of charge (telephone: 01992 467272).

Call for reporting

Please report suspected adverse events with the use of etonogestrel implant to the MHRA through the Yellow Card Scheme website: www.mhra.gov.uk/yellowcard.

Company contact point

If you have any questions or require additional information regarding the use of etonogestrel implant, please contact Merck Sharp & Dohme Limited, Hertford Road, Hoddesdon, Hertfordshire, EN11 9BU, United Kingdom. Telephone: 01992 467272

Annexes

- Attached relevant sections of the Product Information that have been revised (with changes made visible).
- Summary of product characteristic and patient information leaflet are available on the EMC website (<https://www.medicines.org.uk/emc/>).

Yours sincerely,



Dr Mark Toms
UK Medical Director