



Important information for healthcare professionals
Update to duration of use in Contraception and Idiopathic menorrhagia

Levonorgestrel - Mirena 52 mg intrauterine delivery system, PA1410/008/001

Dear Healthcare Professional,

Bayer Ltd would like to inform you that section 4.2 of the Mirena Summary of Product Characteristics (SmPC) has been updated with the following:

- *Contraception*: Mirena is now effective for 8 years.
- *Idiopathic menorrhagia*: Mirena should be removed or replaced in case symptoms return. If symptoms have not returned after 5 years of use, continued use of the system may be considered. Mirena should be removed or replaced after 8 years at the latest.
- *Protection from endometrial hyperplasia during oestrogen replacement therapy*: The system should be removed or replaced after 5 years. [The duration is unchanged.]
- The use of excessive force/sharp instruments during removal may cause breakage of the device. After removal of Mirena, the device should be examined to ensure that it is removed entirely.

Please refer to the SmPC for further details.

Please ensure that all relevant staff are made aware of the content of this letter and that the information is communicated to healthcare professionals (HCPs).

The communication of this information has been agreed with the Health Products Regulatory Authority (HPRA).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. HCPs are asked to report any suspected adverse reactions to HPRA Pharmacovigilance using the report form on the HPRA website, www.hpra.ie.

Adverse events should also be reported to Bayer Ltd. by telephone: 01 216 3300 or e-mail: adr-ireland@bayerhealthcare.com.

If you have any questions, please contact Bayer Ltd by telephone: 01 216 3300 or email: info.ireland@bayerhealthcare.com.

Yours faithfully,

Regards,

Dr. Tristan Cooper
Medical Director



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