



澳門特別行政區政府  
Governo da Região Administrativa Especial de Macau  
衛生局  
Serviços de Saúde

No.1

參照編號 0638/DAF/10  
Nº ref.

日期: 18/06/2010  
Data/Date:

由

De/From: 部門/Dept.: 藥物事務廳 Department of Pharmaceutical Affairs  
簽署者/Ass./Signat.: 蔡炳祥廳長 Dr. Choi Peng Cheong – Department Chief  
傳真機/Fax: (853)-28524016  
致: 醫生、藥劑師及其他衛生專業人士  
Para/To: Physicians, pharmacists and other healthcare professionals  
主題: 關於左炔諾孕酮子宮內釋放系統(Levonorgestrel-Releasing Intrauterine System, Mirena®)安全性的最新資訊  
Ass./Subject: Latest safety update on Levonorgestrel-Releasing Intrauterine System(Mirena®)  
頁數: 1/2  
Nº folhas/N.pages:

隨件附上一則關於左炔諾孕酮子宮內釋放系統(Levonorgestrel-Releasing Intrauterine System, Mirena®)安全性的最新資訊, 請醫生、藥劑師及其他衛生專業人士參閱, 如台端懷疑由上述或其他藥物引致的任何不良反應, 請以下列任一方式向本廳通報:

- 網上通報 - [http://www.ssm.gov.mo/design/webservices/c\\_wservices\\_main.htm](http://www.ssm.gov.mo/design/webservices/c_wservices_main.htm)
- 郵寄 - 澳門士多烏拜斯大馬路 51號 華仁中心二樓
- 傳真 - 28524016

通報人士可親臨藥物事務廳索取或在[http://www.ssm.gov.mo/design/services/serpt\\_chn.pdf](http://www.ssm.gov.mo/design/services/serpt_chn.pdf)網址上下載通報表格。如有任何疑問, 請於辦公時間致電85983517或85983439與藥物監測暨管理處楊燕雯藥劑師或林俊耀藥劑師聯絡, 倘遇緊急的情況, 亦可於非辦公時間傳呼85008068。

謹祝 台安!

Attached herewith is the latest safety update on Levonorgestrel-Releasing Intrauterine System(Mirena®) for your reference. If physicians, pharmacists or other healthcare professionals suspect any kind of adverse reaction subsequent to the use of the above or any other medication, please report through any of the following methods:

- Online - [http://www.ssm.gov.mo/design/webservices/c\\_wservices\\_main.htm](http://www.ssm.gov.mo/design/webservices/c_wservices_main.htm)
- Mail to - 51 Avenida do Sidonio Pais, Edificio China Plaza, 2<sup>nd</sup> Floor, Macao S.A.R., China
- Fax to - 853-28524016

The report form can be collected in person at Department of Pharmaceutical Affairs or downloaded from the website designated as [http://www.ssm.gov.mo/design/services/serpt\\_chn.pdf](http://www.ssm.gov.mo/design/services/serpt_chn.pdf). Should you have any query, please contact Ms. Beatrice Young or Mr. Jeffrey Lam at 8598-3517 or 8598-3439 respectively from the Division of Pharmacovigilance and Pharmacoeconomics during office hours. In case of urgent situations during off hours, please page 85008068.

Thanking you in advance for your attention!

藥物事務廳廳長  
Chief, Department of Pharmaceutical Affairs

蔡炳祥  
Choi Peng Cheong



澳門特別行政區政府  
Governo da Região Administrativa Especial de Macau  
衛生局  
Serviços de Saúde

主題： 關於左炔諾孕酮子宮內釋放系統(Levonorgestrel-Releasing Intrauterine System, Mirena®)安全性的最新資訊

Subject : Latest safety update on Levonorgestrel-Releasing Intrauterine System(Mirena®)

拜耳公司(Bayer Inc.)與加拿大衛生部(Health Canada)通知衛生專業人士關於使用左炔諾孕酮子宮內釋放系統(Levonorgestrel-Releasing Intrauterine System, Mirena®)的婦女曾出現子宮穿孔的重要安全性資訊。與使用子宮內避孕裝置有關的子宮穿孔屬罕見及嚴重的不良事件，發生率介於1/1000至1/10000。爲了減低使用Mirena®後發生不良事件的風險，醫生和其他衛生專業人士必須：

- 確保本身熟悉和/或曾接受正確放置Mirena®系統的技術，以及詳細閱讀說明書中的放置指引。
- 如遇系統難以放置、病人感到痛楚或懷疑系統未正確放置的情況下，可考慮採用超聲波或X光映像。
- 於放置系統後4至12周，對病人作檢查，然後每年再作檢查，如有需要，可提高檢查的次數。
- 於放置系統前，告知病人子宮穿孔的風險，尤其在分娩後和哺乳期間所出現的風險，並教育病人可能出現的症狀，包括可能與出血有關的嚴重下腹疼痛。

藥物監測暨管理處

Bayer Inc., in collaboration with Health Canada, would like to remind health professionals of important safety information regarding reports of uterine perforation in women treated with Levonorgestrel-Releasing Intrauterine System(Mirena®). Uterine perforation is a rare, but serious complication associated with intrauterine contraceptive devices, and occurs at a rate between 1/1,000 and 1/10,000 insertions. In order to minimize the risk of complications associated with the use of Mirena®, physicians and other health professionals are encouraged to:

- Ensure they are familiar with and/or trained on the correct insertion technique for Mirena®, and carefully review the insertion instructions included in the labelling.
- Consider performing ultrasound or X-ray imaging in case of a difficult insertion, if patients complain of pain, or if there is suspicion that the system may not be correctly positioned.
- Follow up patients 4 to 12 weeks after insertion, and once a year thereafter of more frequently, as required.
- Inform patients before the procedure about the risk of uterine perforation, especially in the post-partum period and during lactation, and educate them on possible signs of this complication, including severe low abdominal pain, which may be associated with bleeding.

Division of Pharmacovigilance  
and Pharmacoeconomics(DFP)

參考資料/Reference and website :

[http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/\\_2010/mirena\\_hpc-cps-eng.php](http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/_2010/mirena_hpc-cps-eng.php)

[http://www.hc-sc.gc.ca/dhp-mps/alt\\_formats/pdf/medeff/advisories-avis/prof/2010/mirena\\_hpc-cps-eng.pdf](http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/medeff/advisories-avis/prof/2010/mirena_hpc-cps-eng.pdf)