Bundesamt für
Sicherheit im
Gesundheitswesen
BASG

Unternehmen/Frau/Herr
Organisationseinheit (optional)
(z. H.) Vorname Nachname
Straße
PLZ Ort

Datum: 22.04.2025
Kontakt: Ing. Veronika Heimlich BSc
E-Mail: pv-implementation@basg.gv.at
Unser Zeichen: PHV-104187516-A-250422

PHV-issue: Levonorgestrel IUS

Sehr geehrte Damen und Herren,

Nach der Fertigstellung des Verfahrens DE/H/xxxx/WS/1803/DE kam das CMDh zu dem Schluss, dass Ergebnisse aus dem Verfahren für alle Arzneimittel (IUS), die Levonorgestrel enthalten relevant sind.

Bei der Umsetzung in die Produktinformation der betroffenen Arzneispezialitäten beachten Sie auch die CMDh Minutes (Meeting vom 25-26 February 2025), Link unter:

www.basg.gv.at/fuer-unternehmen/pharmakovigilanz/mustertexte.

Die Zulassungsinhaber werden aufgefordert, eine Variation gemäß "Guidelines on the details of the various categories of variations, on the operation of the procedures laid down in Chapters II, IIa, III and IV of Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products and on the documentation to be submitted pursuant to those procedures." beim Institut LCM einzureichen.

Betroffene Arzneispezialitäten:

- xxx

Bei Unklarheiten bezüglich der Implementierung oder wenn die Änderungen bereits aufgenommen worden sind, kontaktieren Sie uns bitte per E-Mail (pv-implementation@basg.gv.at).

Beachten Sie auch die aktuellen sicherheitsrelevanten Änderungen der Produktinformation unter: www.basg.gv.at/fuer-unternehmen/pharmakovigilanz/mustertexte

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In der Begründung ist „**PHV-Issue: „Levonorgestrel IUS““** sowie die **Geschäftszahl (PHV-104187516-A-250422)** anzugeben.

Mit freundlichen Grüßen
Für das Bundesamt

Ing. Veronika Heimlich BSc

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Auszug aus den Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh) Minutes for the meeting on 25-26 February 2025

6.6.1. Levonorgestrel - DE/H/xxxx/WS/1803 / DE

The CMDh was informed about the outcome of a variation worksharing procedure for Levonorgestrel Intrauterine Systems (LNG-IUSs) (DE/H/xxxx/WS/1803) submitted according to a request from a PSUSA procedure (PSUSA/00010828/202305) concerning an update of the product information to highlight the role of ultrasound examination after LNG-IUS insertion, especially to assure correct location of the IUS and to prevent (partial) perforation.

PRAC advice was sought during the procedure to agree on the wording proposed to update sections 4.2 and 4.4 of the EU SmPC and to ensure a consistent safety assessment outcome for other LNG-IUS which were not involved in the worksharing variation. PRAC agreed the following wording to be included in sections 4.2 and 4.4 of the SmPC (new text in ***bold underlined italics***, deleted text ~~*strikethrough*~~):

Section 4.2:

Insertion

[…]

Important information to consider during or after insertion

In case of a difficult insertion and/ or exceptional pain or bleeding during or after insertion, the possibility of perforation should be considered and appropriate steps should be taken, such as physical examination and ultrasound.

After insertion, women should be re-examined after 4 to 6 weeks to check the threads and ensure that the device is in the correct position. Physical examination alone (including checking of threads) may not be sufficient to exclude partial perforation, ***and ultrasound may be considered (see section 4.4).***

Section 4.4

Medical examination/consultation

[…]

The women should be re-examined 4 to 12 weeks after insertion ~~and once a year thereafter or more frequently if clinically indicated~~. ***Vaginal ultrasound examination may be considered to ascertain the correct position of the system. In case <X> cannot be located in the uterine cavity, expulsion or complete perforation should be considered (see paragraph "perforation" below) and X-ray may be used. Thereafter, re-examination should be performed once a year or more frequently if clinically indicated.***

Perforation

Perforation or penetration of the uterine corpus or cervix by an intrauterine contraceptive may occur, most often during insertion, although it may not be detected until sometime later, and may decrease the effectiveness of <X>. ***In some cases, the device may migrate to the intra-abdominal area.*** *Such a system must be removed; surgery may be required.*

[…]

Re-examination after insertion should follow the guidance given above under the heading "Medical examination/consultation" ***including the consideration to use vaginal ultrasound examination to ascertain the correct position of the system 4 to 12 weeks thereafter,*** *which may be adapted as clinically indicated in women with risk factors for perforation.*

Lost threads

If the retrieval threads are not visible at the cervix on follow-up examinations, pregnancy must be excluded. The threads may have been drawn up into the uterus or cervical canal and may reappear during the next menstrual period. If pregnancy has been excluded, the threads may usually be located by gently probing with a suitable instrument. If they cannot be found, the possibility of expulsion or perforation should be considered. ***Vaginal u****~~U~~Ultrasound* ***examination*** *~~diagnosis~~ may be used to ascertain the correct position of the system. If ultrasound is not available or successful, X-ray may be used to locate Mirena.*

In addition, PRAC considered that the above agreed wording is also applicable to the other LNG-IUS products. Concerned MAHs are reminded to keep the product information of their products up to date with the current scientific knowledge and should consider submission of an appropriate variation (as detailed in Q/A 3.3 on variations, http://www.hma.eu/20.html).

Heimlich Veronika
am 22.4.2025

	Dieses Dokument wurde amtssigniert. Informationen zur Prüfung der elektronischen Signatur und des Ausdrucks finden Sie unter http://www.basg.gv.at/amtssignatur. Bundesamt für Sicherheit im Gesundheitswesen Traisengasse 5, 1200 Wien