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Guidelines

Non-prescription dispensing of emergency oral contraceptives: Recommendations from the German Federal Chamber of Pharmacists [Bundesapothekerkammer]

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ABSTRACT*

Background: Emergency hormonal contraceptives (EHC) are contraceptives used to prevent unintended pregnancy following unprotected sexual intercourse (USI) or contraceptive failure. The EHCs available without a prescription include medicines containing levonorgestrel (LNG) in more than 80 countries and, recently, based on an EU-switch ellaOne®, which contains ulipristal acetate (UPA). EHCs work by stopping or delaying ovulation. Those containing LNG can be used up to 72 hours after USI or contraceptive failure, while UPA can be used up to 120 hours. In the context of the UPA implementation process, Germany switched LNG to non-prescription status as well.

Objectives: To develop recommendations, a protocol, and a continuing education program for pharmacists to assure quality when giving advice and dispensing EHCs in community pharmacies without a medical prescription.

Methods: The recommendations were developed by an iterative process of drafting, recognizing, and discussing comments and proposals for amendments as well a seeking agreement with a number of stakeholders such as the Federal Ministry of Health (BMG), Federal Institute for Drugs and Medical Devices (BfArM), Federal Chamber of Physicians (BÄK), Drug Commission of German Physicians (AkdÄ), professional organizations/associations of gynaecologists, pharmaceutical OTC-industry as well as government-controlled, private, and church-based organizations and centres providing advice on sex education and family planning.

Results: The recommendations were eventually endorsed by the BMG in consultation with the BfArM.

Conclusions: The recommendations were made public, published in the professional journal and used in an uncounted number of continuing education programs based on the curriculum and provided by the State Chambers of Pharmacists.

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INTRODUCTION

Emergency hormonal contraceptives (EHC) are contraceptives used to prevent unintended pregnancy following unprotected sexual intercourse (USI) or contraceptive failure. The emergency contraceptives available without a prescription include medicines containing levonorgestrel (LNG), such as Norlevo, Levonelle/Postinor, Levonoraristo, unofem HEXAL, PiDaNa and Levodonna, which have been authorised in the EU as well abroad (e.g., Plan B in the USA) through national procedures and a centrally-authorised medicine, ellaOne®, which contains ulipristal acetate (UPA) and was granted a marketing authorisation in the EU in 2009.

Emergency contraceptives work by stopping or delaying ovulation. Those containing LNG can be used up to 72 hours after USI or contraceptive failure, while UPA can be used up to 120 hours.

LNG-containing EHCs are available over-the-counter (OTC) in more than 80 European and non-European countries since more than 15 years. In November 2014, the European Medicines Agency (EMA) recommended switching the EHC drug UPA (ellaOne®) from prescription to non-prescription status. On 7 January 2015, the European Commission (EC) issued a legally binding decision valid, in principle, throughout the EU, which makes this EHC freely available as an OTC drug. In most EU countries, non-prescription EHC medicines are available in pharmacies behind the counter only, also called pharmacy-only drugs. In the Netherlands and Sweden, UPA is also sold outside pharmacies. In Luxembourg, for example, UPA is additionally distributed in family planning centres, whereas the UK also offers access through UK-based internet sites.[1]

LNG is also partly available or distributed outside pharmacies e.g., in The Netherlands, France, Portugal or Sweden. In Luxembourg and Romania, for example, UPA is additionally distributed in family planning centres, whereas the UK and France also offer access through government-based internet sites.[1]

Although the German Expert Advisory Committee on Prescription - only Drugs (Sachverstaendigenausschuss für Verschreibungspflicht) at the Federal Institute for Drugs and Medical Devices (BfArM, Bonn), recommended switching LNG to non-prescription status already back in 2003, the eventual responsible German Federal Ministry of Health (BMG) always refused to amend the Ordinance on Prescription-Only Medicinal Products accordingly. In the context of the UPA OTC-implementation process within the EU, Germany switched LNG to non-prescription status eventually. In Germany, both LNG and UPA are pharmacy-only drugs and must be dispensed behind the counter only.

On the background of a long-lasting discussion mainly with some professional associations of gynaecologists opposing the OTC-availability of EHCs especially LNG, the BMG asked the German Federal Chamber of Pharmacists (Bundesapothekerkammer, BAK) to develop recommendations, a protocol and a continuing education program for pharmacists to assure quality when giving advice and dispensing EHCs without a medical prescription on a National/Federal level. For all pharmacists in Germany, membership in their State Chamber of Pharmacists is mandatory. The 17 Chambers of Pharmacist in the 16 States of Germany are organized on the Federal level in the BAK.

The following recommendations, including online Appendices 1 – 4, are the result of an iterative process of drafting, recognizing and critical appraisal of comments and proposals for amendments as well a seeking agreement with a number of stakeholders such as BMG, BfArM, Federal Chamber of Physicians (BÄK), Drug Commission of German Physicians (AkdÄ), professional organizations/associations of gynaecologists, pharmaceutical OTC-industry as well as government-controlled, private, and church-based organizations and centres providing advice on sex education and family planning (for examples see Appendix 3). They have been finally endorsed by the BMG in consultation with the BfArM.

It has been shown that a written patient assessment checklist may improve the quantity and consistency of patient assessment.[2] If our structured approach will assure high quality advice provided by community pharmacies when handling requests for EHC remains to be elucidated.

DISCLAIMER

The following recommendations and documents on counselling/giving advice including online Appendices 1 - 4 and the curriculum by the German Federal Chamber of Pharmacists (Bundesapothekerkammer, BAK) and developed by the Drug Commission of German Pharmacists (AMK) reflect the state of current medical and pharmaceutical knowledge. They must be adapted in the event of new information becoming available and based on any additional provisions from the European Union (EU)3 or national legislator or regulators, respectively.

Express reference is made to the respective, applicable product information (Summary of Product Characteristics (SmPCs/SPCs) and package leaflets) for the levonorgestrel[4] and ulipristal acetate[5] containing non-prescription emergency hormonal contraceptives (EHC) products.

OUTLINE

I. Requirements for dispensing levonorgestrel (LNG) and ellaOne® (ulipristal acetate, UPA) for emergency contraception in self-medication

II. Directions for use and advice when dispensing emergency oral contraceptives (LNG, UPA)

IIa. General comments on advice and dispensing

IIb. Criteria for limits of self-medication and referral to a gynaecologist or a doctor at on-call medical services

IIc. Dispensing to minors

Appendix 1: Advice quality assurance: Checklist for dispensing emergency oral contraceptives ("morning-after pill") in self-medication

Appendix 2: Comparison of the emergency contraceptives LNG and UPA

Appendix 3: Sources of information on emergency contraception

Appendix 4: Emergency contraceptives ("morning-after pill") in self-medication Curriculum of the German Federal Chamber of Pharmacists

NON-PRESCRIPTION DISPENSING OF EMERGENCY CONTRACEPTIVES ("MORNING-AFTER PILL")

Recommendations from the German Federal Chamber of Pharmacists (Bundesapothekerkammer, BAK). English version as of 6 June 2016; translation of the official German version issued 7 October 2015.

I. Requirements for dispensing levonorgestrel (LNG) and ellaOne® (ulipristal acetate, UPA) for emergency contraception in self-medication

Advice to the woman:

It is recommended that the woman is advised, and one pack dispensed, personally.

As a general rule, no "advance" dispensing; if this is required in an individual case, the woman should be advised to see a gynaecologist.

See IIc. for dispensing to minors. Dispensing to girls under the age of 14 years is not recommended without the consent of a parent or legal guardian (refer to doctor). [Information sheet for the dispensing of medicinal products to children[6] and notes on § 17 of the Apothekenbetriebsordnung ([Ordinance on the

Operation of Pharmacies][8], dispensing to children and adolescents).

Time of unprotected sexual intercourse (USI):

Use the emergency contraception as soon as possible (preferably within 12 hours) after USI.

If USI was not more than 72 hours (3 days) previously: LNG or UPA.

If USI was more than 72 hours but not more than 120 hours (5 days) previously: UPA.

In general, do not dispense if the USI took place more than 120 hours previously; refer to gynaecologist.

Repeated use within the same menstrual cycle is not recommended. It should be avoided due to the undesirably high hormonal load for the patient and potential severe menstrual disorders.

Suspicion of an existing pregnancy:

Recommend/dispense a pregnancy test; refer to gynaecologist, if necessary.

If nausea/feeling sick or vomiting:

Risk of decreased efficacy of the oral emergency contraceptives LNG and UPA.

To reduce/prevent nausea/vomiting, having something to eat before taking the tablet is recommended.

In persistent vomiting: refer to gynaecologist or other physician.

Breastfeeding:

After UPA: 1-week break from breastfeeding.

After LNG: 8-hour break from breastfeeding.

Potentially relevant interactions:

The effectiveness of LNG and UPA can be reduced by CYP3A4 inducers, e.g.: St John's wort/hypericin, phenytoin, phenobarbital, carbamazepine, oxcarbazepine, primidone, ritonavir, efavirenz, nevirapine, rifampicin, rifabutine. If necessary, recommend consulting a gynaecologist on the possible insertion of a copper intrauterine device (IUD).

Note: Additional information, above all on side effects and interactions, can be found in the respective valid product information sheets (Summaries of Product Characteristics (SmPCs) and package leaflets)[3-5], which are expressly referred to.

II. Directions for use and advice when dispensing emergency oral contraceptives (LNG, UPA)

IIa. General comments on advice/counselling and dispensing

- Active substances and proprietary medicinal products for emergency oral contraception

In Germany, proprietary medicinal products with the active substance levonorgestrel or ulipristal acetate are available as emergency contraception without medical prescription:

Proprietary medicinal products with the active substance levonorgestrel (LNG): Levonoraristo® 1.5 mg tablet, PiDaNa® 1.5 mg tablet, Postinor® 1500 µg tablet and unofem HEXAL® 1.5 mg tablet. There are valid German authorisations for other medicinal products.

Proprietary medicinal products with the active substance ulipristal acetate (UPA): ellaOne® 30 mg tablet.

- Information on the properties, effects and importance of taking emergency oral contraceptives early ("morning-after pill")

The "morning-after pill" postpones ovulation. It is therefore only effective if it is taken in good time before ovulation. If ovulation has already taken place, a pregnancy can occur despite the medicinal product being taken. Ovulation occurs on average around 14 days before the start of the next period, subject to individual deviations and cannot be precisely predicted. Sperm can survive, and are therefore capable of fertilisation, for up to 5 days.

Levonorgestrel (LNG) is a synthetic progestogen (progestin) and is taken as emergency contraception in a single dose of 1.5 mg as soon as possible after unprotected sexual intercourse or contraceptive failure; preferably within 12 hours and not more than 72 hours (3 days) later. The contraceptive effect is mainly the result of the inhibition of the menstrual cycle-dependent increase in luteinizing hormone (LH) and, therefore, LNG is not effective if ovulation has already occurred. It does not prevent the implantation of a fertilised ovum.

In the event of an existing (unknown) pregnancy, a single dose of 1.5 mg LNG is not of concern.

Ulipristal acetate (UPA), a selective progesterone receptor modulator, must also be taken as soon as possible, within at most 120 hours (5 days) after unprotected sexual intercourse or contraceptive failure, in a single oral dose of 30 mg. UPA delays or prevents ovulation even when the LH level has already increased. The effect is primarily based on ovulation inhibition, but other mechanisms of action and effects on the endometrium as well as implantation of the fertilised ovum have also been discussed.

UPA should not be taken if an existing pregnancy is suspected.

Taking an emergency contraceptive does not always guarantee the prevention of a pregnancy, particularly in cases where there are uncertainties regarding the last period (menstruation) or the time of the unprotected sexual intercourse.

- There is evidence that emergency oral contraceptives are less effective in patients with a higher bodyweight or body mass index (BMI).

These data are, however, limited and not conclusive. Therefore, emergency contraceptives are still recommended for all women irrespective of their bodyweight or BMI (see also Appendix 2).[3-5,7,11,12]

- Emergency contraceptives are not abortifacients i.e., an existing pregnancy cannot be terminated by taking LNG at a single oral dose of 1.5 mg or UPA in a single oral dose of 30 mg.
- LNG and UPA do not protect against sexually transmitted diseases (e.g., gonorrhoea, syphilis, chlamydia, HPV, hepatitis, HIV). If the woman expresses such concerns, she should immediately seek medical advice.
- Emergency contraceptives should only be taken in the event of unprotected sexual intercourse, i.e.:
  - without contraception
  - after incorrect use or failure of a condom
  - after a combined hormonal contraceptive dose has been forgotten:
    - more than 12 hours previously: generally emergency contraception. A combined hormonal contraceptive ("pill") dose must be made up for later, even if two hormone-containing drugs must then be taken. Supplementary use of barrier methods (e.g., condoms) is necessary until the end of the menstrual cycle (until the next period/menstruation).
    - Note: If the dose was forgotten less than 12 hours previously, emergency contraception is not required. The dose of the "pill" should be taken immediately and the drug continued.
  - After a forgotten "minipill" (progestogen-only drug) dose: With regard to the "minipill", taking the dose on schedule at 24-hour intervals is vital for the contraceptive effect. Depending on the drug (see SPC), the contraceptive effect may be lost even if the dose is taken 3 to 12 hours late. In the event of unprotected sexual intercourse, emergency contraception. The "minipill" dose should be made up for and the drug continued, even if two hormone-containing drugs must then be taken. Supplementary use of barrier methods (e.g., condoms) is necessary until the next period.
  - If vaginal ring (e.g., Nuvaring®, Circlet®) failure is suspected: contraception is no longer guaranteed if:
    - the ring was outside the vagina for more than 3 hours
    - the break period has been exceeded by more than 7 days or
    - the vaginal ring has not been changed for more than 4 weeks.

    After unprotected sexual intercourse refer to emergency contraception. Use of barrier methods (e.g., condoms) is necessary until the next period.
  - If the failure of a transdermal patch (e.g., Evra®) is suspected:
    - If the contraceptive patch has been incorrectly attached for more than 24 hours, contraception is no longer guaranteed. After unprotected sexual intercourse, emergency contraception. Use of barrier methods (e.g., condoms) is necessary until the next period.
    - Note: If the contraceptive patch has been incorrectly attached for less than 24 hours, the patch must be re-attached in the same place or immediately replaced by a new patch. No emergency contraceptive is necessary.
  - In the event of incorrect use or failure of another contraceptive method, e.g.:
    - Temperature method/measurement of basal body temperature
- If the menstrual period is delayed by more than 7 days, a gynaecologist should be consulted.
- Emergency oral contraceptives should only be dispensed if the woman is not pregnant. Signs of a possible existing pregnancy are:
  - delayed period
  - abnormal period strength (lighter)
  - abnormal period duration (shorter)

  If one of these signs is present, then the woman should be advised to consult a gynaecologist or a pregnancy test carried out. If this is positive, refer to gynaecologist.
- Common and significant side effects

  LNG and UPA are comparatively well tolerated. However, they should only be used for emergency contraception (cf. authorisation!). (Very) common side effects are headache, nausea, dizziness, stomach and abdominal pain, dysmenorrhoea (with pain and prolonged cramps accompanying menstruation), vomiting, fatigue, tenderness in the breasts.

  There is currently no firm evidence of an increased thrombosis risk from the one-time use of LNG as an emergency contraceptive. Individual cases of thromboses have been described for LNG, most of which occurred in association with the regular administration of the "pill". An elevated thrombosis risk from LNG cannot, however, be ruled out if there are additional risk factors (existing factor V Leiden mutation, thrombosis in their personal or family medical history, smoking).
- Decreased efficacy due to vomiting – conduct in the event of vomiting

If the woman vomits within 3 hours of taking the dose, another LNG or UPA tablet must be taken immediately. In the event of persistent vomiting, a doctor or gynaecologist should be consulted. If nausea with a severe feeling of sickness occurs or there are other signs of acute vomiting, this should be taken into consideration accordingly.

To reduce/prevent nausea/vomiting, having something to eat before taking the tablet is recommended (bread and butter or something similar).

- There is no contraceptive protection for the rest of the menstrual cycle

  Hormonal contraception should be continued as normal following emergency contraception with LNG or UPA. A supplementary (!) use of barrier methods (e.g., condoms) is required until the end of the menstrual cycle (up to the next period), as the efficacy of hormonal contraceptives is no longer guaranteed.

- Action in the event of the next menstruation being delayed

  The next period occurs as expected for the majority of users after taking LNG or UPA. However, it can start up to 7 days earlier or later; in individual cases it has been delayed by more than 20 days. If the period is delayed by more than 7 days after the expected date, the woman should take a pregnancy test and consult a gynaecologist.

- The confidentiality of the advice must be ensured in accordance with Section 4, Clause 2a, Sentence 3 of the Ordinance of the Operation of Pharmacies (ApBetrO): “The sales area must be furnished in such a manner that the confidentiality of consultations, especially in the locations where pharmaceuticals are dispensed to customers, is preserved, so that it can be largely prevented that other customers overhear a consultation”.[8]

- Assumption of costs by the Statutory Health Insurance funds (SHI; gesetzliche Krankenversicherung, GKV)

  Even after the removal of the morning-after pill’s prescription-only status, the costs are still assumed in the same way by the SHI companies for insured women under the age of 20, under the principle of benefits in kind. The requirement for this is the existence of a medical prescription.

  Information materials and other advisory services

- Instruct the woman that the information on correct use contained in the package leaflet and other written information provided (for sources available in Germany see Appendix 3) must be followed.

- If the woman has any further questions, any uncertainties regarding the self-diagnosis or the appropriateness of self-treatment or any questions that go beyond drug dispensing (for example, on copper intrauterine devices, contraception, sexuality or sexually transmitted diseases), the woman should consult a doctor or gynaecologist.

- Information on the possibility of anonymous and free consultation on pregnancy and contraception issues at a recognised family planning information centre (database on the Federal Centre for Health Education – BZgA [Bundeszentrale für gesundheitliche Aufklärung] – website among others – www.familienplanung.de/beratung/beratungsstellensuche) and, if applicable, issuing of the information materials from the BZgA that are available for order there (see Appendix 3).

IIb. Criteria for limits of self-medication and referral to a gynaecologist or a doctor at on-call services

- If the time of the unprotected sexual intercourse or contraception failure was more than 120 hours (5 days) earlier.

- If the use of an emergency oral contraceptive is not possible (e.g., clinically significant interactions, known intolerance(s)).

- If an existing pregnancy is suspected. Signs include a delayed period, unusual period strength or unusual period length, as well as a positive pregnancy test.

The following situations are not per se reasons for not dispensing an emergency oral contraceptive; a subsequent visit to the doctor or a gynaecologist is, however, recommended:

- Acute health problems or chronic diseases that can be associated with the risk of reduced emergency oral contraceptive safety or efficacy of the emergency oral contraceptive, e.g.: history of persistent vomiting, malabsorption syndrome (e.g., Crohn’s disease), severe liver disease, previous inflammation of the Fallopian tubes, abdominal or ectopic pregnancy in their medical history.

- In the event of signs suggesting a risk of sexually transmitted disease following unprotected sexual intercourse or contraceptive failure.

- If there is forensically relevant evidence (e.g., suspicion of use of force). Information on the use of additional advisory services, such as the Hilfetelefon Gewalt gegen Frauen [Violence Against Women Helpline] (Tel.: 08000 116 016 or online at https://www.hilfetelefon.de) or rape crisis centres (www.frauen-gegen-gewalt.de) and medical care.

- If there are any further questions, any uncertainties regarding the self-diagnosis or the appropriateness of self-treatment or any questions that go beyond drug dispensing (for example, on copper intrauterine devices,

contraception, sexuality or sexually transmitted diseases).

IIc. Dispensing to minors

Special duty of care obligations must be observed if minors request a non-prescription drug. However, there are no specific medicinal product law provisions and the product information for LNG- and UPA-containing emergency contraceptives do not give any age limits ("... for all women of child-bearing age").

The German Federal Chamber of Pharmacists (Bundesapothekerkammer, BAK) has published an information sheet on "Dispensing medicinal products to children in pharmacies" as a guideline regarding providing information to, and advising, patients when dispensing medicinal products (first and repeat prescriptions as well as self-medication).[6]

The criteria specified in this information sheet, together with healthcare knowledge and personal contact in the pharmacy can help the pharmacist to make a responsible decision on dispensing in individual cases. Additional recommendations and tools can also be found in the comment on the Section 17 of the Ordinance for the Operation of Pharmacies (ApBetrO[8]; Commentary section 3.20. Dispensing to children and adolescents[9]).

If a minor asks for an emergency contraceptive (age as stated by the woman herself), it is recommended that a written record (date, time, content of the advice, dispensed/not dispensed) is kept (cf. checklist/pharmacy records).

In addition, a (subsequent) visit to a physician should always be recommended to minors in particular.

Emergency contraceptives should not be dispensed to girls under the age of 14 years without the consent of a parent or legal guardian (refer to doctor).

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