

PJ PRACTICE CHECKLIST

OTC EMERGENCY CONTRACEPTION

Progestogen-only emergency hormonal contraception (EHC) is now available over the counter, with the licensing of Levonelle (levonorgestrel) as a P product. This card outlines key points that pharmacists must consider before supplying Levonelle, advice that should be given when a decision to supply has been taken, and general information about this new OTC treatment

1. HAS THERE BEEN UNPROTECTED SEX WITHIN THE PAST 72 HOURS? Levonorgestrel (as Levonelle) is licensed for use within 72 hours of unprotected sex. Efficacy is higher the earlier it is taken within this time period.

2. IS THE CLIENT PRESENT IN THE PHARMACY? Supply of EHC to third parties is not generally appropriate, but might be made in exceptional circumstances, eg, if the woman is housebound. In such cases, a telephone call to the woman could be helpful to check that treatment is appropriate and to provide advice.

3. ARE YOU SATISFIED THAT THE CLIENT IS AGED 16 OR OVER? The OTC product is only licensed for use in women aged 16 and over. If the client is believed to be under 16, advice can be offered on obtaining EHC on prescription, as the POM product (Levonelle-2) does not have this age restriction.

4. IS EHC NEEDED? The pharmacist may decide after talking with the client that EHC is unnecessary. However, if after discussion the woman is still concerned about pregnancy, supply should be considered.

5. COULD THE CLIENT BE PREGNANT ALREADY? EHC will not work

if a woman is already pregnant. To assess how likely it is that the client might already be pregnant, the following questions could be asked:

- Is your period late?
- Was your last period lighter or shorter than normal?
- Was your last period unusual in any

other way?

Since your last period, have you had unprotected sex at any time before this occasion?

If the client answers "yes" to any of these questions, referral should be considered.

6. IS THE CLIENT TAKING OTHER MEDICATION? Medicines or herbal remedies that

POINTS TO CONSIDER BEFORE SUPPLYING

1. Has there been unprotected sex within the past 72 hours?
2. Is the client present in the pharmacy?
3. Are you satisfied that the client is aged 16 or over?
4. Is emergency contraception needed?
5. Could the client be pregnant already?
6. Is the client taking other medication that might interact with levonorgestrel?
7. Does the client have any medical condition that might affect absorption of levonorgestrel?
8. Does the client have liver problems?
9. Has the client previously had an allergic reaction to levonorgestrel?

induce liver enzymes can reduce blood levels of levonorgestrel and in such cases the woman should be referred to her doctor for advice before taking EHC. This interaction involves barbiturates (including primidone), phenytoin, carbamazepine, St John's wort, rifampicin, rifabutin, ritonavir and griseofulvin.

Also, levonorgestrel may increase risk of ciclosporin toxicity; medical referral is advised for women taking this drug.

7. DOES THE CLIENT HAVE A CONDITION THAT MIGHT AFFECT LEVONORGESTREL ABSORPTION? Medical referral is needed for women with conditions associated with malabsorption, eg, Crohn's disease, severe diarrhoea.

8. DOES THE CLIENT HAVE LIVER PROBLEMS? Progestogen-only EHC is not recommended for women with severe hepatic dysfunction.

9. HAS THE CLIENT PREVIOUSLY HAD AN ALLERGIC REACTION TO LEVONORGESTREL? Allergy to levonorgestrel, which is rare, is a contraindication to treatment.



ADVICE THAT SHOULD BE GIVEN

HOW TO TAKE: Levonelle contains two tablets of levonorgestrel 750mcg. The first tablet should be taken as soon as possible (and no later than 72 hours) after unprotected sex. The second tablet should be taken 12 hours (no more than 16 hours) after the first.

SIDE EFFECTS: Around 25 per cent of women may feel sick and around 5 per cent may vomit. Irregular bleeding and spotting may occur until the next period.

VOMITING: If vomiting occurs within three hours of the first dose, a second tablet should be taken straight away and the woman needs to obtain a new pack of EHC and to take another tablet 12 hours later. If vomiting occurs within

three hours of taking the second tablet, another tablet should be taken. If the woman has vomited after taking progestogen-only EHC on a previous occasion, it might be worth considering prophylactic use of an OTC antiemetic.

CONTINUED CONTRACEPTION: Women should be told that EHC will not provide continued protection against pregnancy — other contraceptive measures are needed.

A woman seeking EHC because she has missed one or more oral contraceptive pills should be advised to discard the missed pills and the pill for the day of EHC treatment and then to continue taking her pills as normal. She should additionally use a barrier method of contraception for the next seven days.

BREASTFEEDING: Small amounts of levonorgestrel can appear in breast milk. To reduce the amount that the baby might ingest, the woman can be advised to take the levonorgestrel tablets immediately after feeding.

NEXT PERIOD: EHC will not bring on a period straight away but it can alter the timing of the next period. This may start early or late but is usually within three days of the expected time.

FOLLOW UP: Women should be advised to see their doctor or family planning clinic for a pregnancy test if their next period is more than five days late or is unusual in any way, or, for those on the pill, if there is no bleed in the pill-free interval.

WHO MIGHT REQUEST EHC?

Women at risk of pregnancy because of unprotected sex, contraceptive failure (eg, split condom) or missed pills.

WHEN DOES MISSING PILLS LEAD TO RISK OF PREGNANCY?

For combined pills, efficacy is compromised if two or more pills are missed from the first seven in a packet or four or more are missed mid-packet. If two or more pills are missed from the last seven in a packet, emergency contraception is not needed provided that the pill-free break is omitted.

For progestogen only pills, contraceptive efficacy is compromised if one or more pills are missed or taken more than three hours late.

HOW EFFECTIVE IS EHC?

Clinical trial data suggest that levonorgestrel EHC prevents 85 per cent of expected pregnancies. Efficacy declines with time (95 per cent if used within 24 hours of

unprotected sex, 85 per cent if used within 24-48 hours, and 58 per cent if used within 48-72 hours). The product is unlicensed for use after 72 hours.

HOW DOES IT WORK?

Depending on when it is given in the menstrual cycle, EHC is thought to work by preventing or delaying ovulation, preventing fertilisation or preventing implantation of a fertilised egg.

WHAT IF THE WOMAN IS ALREADY PREGNANT OR IF TREATMENT FAILS?

The questions asked before supply are intended to establish if the woman is likely to be pregnant. Pregnancy is a contraindication. However, if a woman does inadvertently take EHC when she is already pregnant, or if the treatment fails and pregnancy occurs, she can be reassured that EHC does not appear to pose any risk to the pregnancy or to have any adverse effects on the developing fetus.

WHAT RECORDS ARE NEEDED?

Record keeping for OTC emergency contraception is no different than for any other P medicine.

CAN IT BE USED MORE THAN ONCE IN A CYCLE?

It is safe to take more than one course of EHC in one menstrual cycle but this can disturb the cycle. EHC is not as effective as conventional methods of contraception and is not recommended for regular use.

CAN IT BE SUPPLIED FOR FUTURE USE?

Supply of the OTC product for use at a later date is not currently recommended. (Some doctors and family planning clinics might, however, prescribe EHC on this basis.)

WHAT IF IT IS MORE THAN 72 HOURS SINCE UNPROTECTED SEX?

A copper IUD can be fitted up to 120 hours (5 days) after unprotected sex for use as emergency contraception.

WHAT OTHER ALTERNATIVES ARE THERE?

An estrogen/progestogen combination, as in Schering PC4, can be used as emergency contraception (up to 72 hours after unprotected sex) and is available on prescription. However, clinical trial data suggest that this is less effective than progestogen-only emergency contraception and produces more vomiting.

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