



MHRA UK PUBLIC ASSESSMENT REPORT

Combined oral contraceptives (the Pill): when to start taking the Pill, and missed pill advice

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PLAIN-LANGUAGE SUMMARY

Background

The Medicines and Healthcare products Regulatory Agency (MHRA) is the government agency responsible for regulating the effectiveness and safety of medicines and medical devices in the UK. We continually review the safety of all medicines in the UK, and inform healthcare professionals and the public of the latest safety updates through several means, including public assessment reports.

The following report describes the rationale for changes to the product information^a for all combined oral contraceptive (COCs) drugs (also known colloquially as ‘the Pill’). The changes consist of updates to advice on when to start taking COCs, and actions to take if a pill has been missed. The aim is to ensure that this information is consistent between different brands of COCs, and that it is in line with national advice and clinical practice.

COCs belong to a group of medicines called hormonal contraceptives, which are one of the most effective methods of preventing pregnancy. COCs contain a combination of different versions of the hormones^b oestrogen and progestogen.

Most COCs are supplied as a pack of 21 tablets. One tablet is taken every day for 21 days, followed by seven pill-free days during which time a menstrual-like bleed occurs (similar to a period).

The product information for COCs contains, along with other information, advice on when a woman can start taking COCs, and what a woman should do if she misses taking her COC medicine for one or more days.

Currently there are some differences in this advice between the product information leaflets for different COCs, and between product information and national and international clinical guidelines on COC medicines. It is important that women prescribed COCs in the UK receive consistent advice from those providing contraceptives services, such as doctors and sexual health nurses, and from product information, and that this advice is evidence-based. Consistent information helps support safer and more effective use of COCs.

The MHRA and the Commission on Human Medicines (CHM)^c therefore reviewed the scientific evidence for World Health Organization ([WHO](#)) guidance on when to start COCs and actions to be taken when COCs are missed, and a search conducted for the latest evidence, in order to provide recommendations for consistent advice on these issues. This MHRA public assessment report summarises the evidence examined and the conclusions of the review.

^a The term ‘product information’ here refers to the patient information leaflet that accompanies every medicine in its box, and the ‘Summary of Product Characteristics’ which summarises information for health professionals, and is available on the [electronic medicines Compendium](#) website.

^b Chemicals released by certain cells in the body that have an effect on other cell types

^c An independent body which gives advice to UK government ministers on the safety, quality and efficacy of medicines

Conclusions

The review examined evidence from several sources, including WHO and the [Faculty of Sexual and Reproductive Healthcare](#). On the basis of the evidence and CHM advice, the MHRA recommends the following advice on when to start taking COCs (referred to as 'the Pill' in the text), and what actions to take when the Pill is missed, for COCs marketed in the UK.

When to start taking the Pill (combined oral contraceptive medicine)

- You can start the Pill at anytime in your menstrual cycle if you are sure you are not pregnant.
- If you start the Pill on the first day of your period you will be protected from pregnancy immediately.
- You can also start the Pill up to, and including, the fifth day of your period and you will be protected from pregnancy immediately.
- If you start the Pill at any other time in your menstrual cycle you will need to use additional contraception, such as condoms, for the first 7 days of pill taking.

What to do if you miss a COC pill

If you have missed one pill, anywhere in the pack:

- take the last pill you missed now even if it means taking two pills in one day
- continue taking the rest of the pack as usual
- no additional contraception is needed
- take your 7 day break as normal

If you have missed two or more pills (more than 48 hours late), anywhere in the pack:

- take the last pill you missed now even if it means taking two pills in one day
- leave any earlier missed pills
- continue taking the rest of the pack as usual and use an extra method of contraception for the next 7 days
- you may need emergency contraception – see below
- you may need to start the next pack of pills without a break – see below

Emergency contraception:

If you have had unprotected sex in the previous 7 days and you have missed two or more pills (more than 48 hours late) in the first week of a pack, you may need emergency contraception. Get advice from your contraception clinic, family doctor, or a pharmacist about this.

Starting the next pack after missing two or more pills (more than 48 hours late):

- If **seven or more pills are left in the pack** after the last missed pill, finish the pack and have the usual 7-day break before starting a new pack
- If **less than seven pills are left in the pack** after the missed pill, finish the pack and begin a new pack the next day (this means missing the usual 7-day break)

Further information on contraception and sexual health in the UK is available from the [Family Planning Association](#).

1. INTRODUCTION

The Medicines and Healthcare products Regulatory Agency (MHRA) is the government agency responsible for regulating the effectiveness and safety of medicines and medical devices in the UK. We continually review the safety of all medicines in the UK, and inform healthcare professionals and the public of the latest safety updates through several means, including public assessment reports. The following report describes the rationale for changes to the product information for COCs marketed in the UK.

As with all medicines, the safety of combined oral contraceptives (COCs) is continually monitored. Safety warnings for COCs have been updated in line with expert advice (see our [webpage on hormonal contraceptives](#)), however, other product information for many of these medicines has not been substantially revised since they were first licensed. There have been differences between the product information for UK COC products and current clinical guidelines, particularly in relation to when to start taking COCs and actions to take if pills are missed. It is important that women prescribed COCs in the UK receive consistent, evidence-based advice from prescribing physicians and from product information, which will help support safer and more effective use of COCs.

In 2010, the MHRA, the Medicines for Women's Health Expert Advisory Group^a and the Commission on Human Medicines^b (CHM) reviewed advice on starting COCs, and actions to be taken when COCs are missed (the review included an assessment of guidance from the World Health Organization [WHO]). This MHRA public assessment report summarises the findings and conclusions from the review.

^a An advisory committee who advise the CHM on the safety of medicines related to women's reproductive health

^b An independent body which gives advice to UK government ministers on the safety, quality and efficacy of medicines

2. METHODS OF DATA COLLATION AND ASSESSMENT

2.1. Sources

The information reviewed by the MHRA included the following:

- Evidence-based recommendations published by WHO (2002, 2004 and 2008 editions^{1,2,3})^a
- A review of evidence by the UK Clinical Effectiveness Unit CEU of the [Faculty of Sexual and Reproductive Health Care](#) (formerly known as the Faculty of Family Planning and Reproductive Health Care; FFPRHC) of the Royal College of Obstetricians and Gynaecologists. The review was first published in July 2006 and updated in January 2007⁴.
- A Cochrane review published in April 2008⁵ on randomised controlled trials comparing the effectiveness of starting hormonal contraceptives immediately, with waiting until the start of the next menstrual cycle to begin taking hormonal contraceptives.
- A 2008 paper from the Society of Obstetrics and Gynaecology Canada (SOGC)^b which re-examined the evidence underpinning missed pill advice.

2.2. Assessing the evidence

A WHO Expert Working Group carried out a detailed assessment of the evidence, last revisited in 2008. This was taken as the basis of the evidence reviewed by the MHRA and presented in this paper. Some of the papers referenced by the WHO Expert Working Group, the [Faculty of Sexual and Reproductive Health Care](#), the Cochrane review or the Society of Obstetrics and Gynaecology Canada, which raised particular questions, are also discussed.

The evidence was assessed to answer two questions:

- **When during her menstrual cycle can a woman start COCs?**
- **What should a woman do if she misses taking her COC pills at any time?**

^a World Health Organization: Selected Practice Recommendations for Contraceptive Use [update] http://www.who.int/reproductive-health/publications/spr_2/index.html. 2004

^b SOGC Committee Opinion: Missed Hormonal Contraceptives: New Recommendations. JOCG 2008; 219, 1050-1062

3. DATA CONSIDERED

3.1. When can a woman start COCs?

3.1.1. WHO systematic review question:

How does starting COCs on different days of the menstrual cycle affect contraceptive effectiveness and compliance?

Main conclusions of the WHO Expert Working Group:

- Seven days of continuous COC use are deemed necessary to reliably prevent ovulation.
- Starting COCs in the first five days of the menstrual cycle is the most reliable method of preventing pregnancy with this treatment, as the risk of ovulation within the first 5 days of menstruation is acceptably low. Suppression of ovulation is considered to be less reliable when starting COCs after day 5 of the menstrual cycle.
- The need for additional contraceptive protection for women switching from another hormonal method^a will depend on the previous method used.
- There is some concern about the risk of pregnancy when removing an intrauterine device (IUD) within a cycle where there has already been intercourse. This concern led to the recommendation that, in such cases, the IUD should be left in place until the next menstrual period.

3.1.2. Other evidence considered:

One of the papers referenced by the WHO Working Group showed that an estimated 2% of women were in their fertile window (ie, the five days before ovulation plus the day of ovulation itself) by the fourth day of their menstrual cycle. On average at least 10% of women with regular menstrual cycles were in their fertile window on any given day of their cycle between days 6–21⁷. Of two papers referenced by the FFPRHC CEU⁴, one showed that ovulation did not occur when COCs were started on day 5 of the menstrual cycle⁸, and the other showed that the risk of ovulation was no greater with a day 7 start for COCs than with a day 1 start⁹.

The Cochrane reviewers concluded that, on the basis of five randomised controlled trials⁵, there was little evidence that immediately starting hormonal contraceptives at any point during the menstrual cycle was more effective in reducing unintended pregnancies or increasing treatment continuation than waiting until the start of the next menstrual cycle (ie, during menstruation) to begin taking COCs. The authors of one of the reviewed papers¹⁰ concluded that 'directly observed, immediate initiation of the pill improved short-term continuation' but this applied only to the second pack. By the third month of treatment, there was no difference in unintended pregnancies between women who had immediately started COCs at any point in their menstrual cycle and those who had a conventional start (the first day of menstrual bleeding).

^a Such as progestogen-only contraceptives

3.2. What should a woman do if she misses COCs?

3.2.1 WHO systematic review question

What is the effect on contraceptive effectiveness when COC pills are missed on different days of the cycle?

Main conclusions of the WHO Expert Working Group:

- Seven days of continuous COC use are deemed necessary to reliably prevent ovulation.
- It is important to take an active (hormonal) pill as soon as possible when pills have been missed.
- If pills are missed, the chance that pregnancy will occur depends not only on how many pills were missed, but also on when those pills were missed.
- Based on data regarding ovulation, the WHO Working Group determined that missing three or more 30–35 micrograms ethinylestradiol active pills (or two or more ≤ 20 micrograms ethinylestradiol pills) at any time during the 21-day treatment cycle warranted additional precautions.
- The risk of pregnancy is greatest when active pills are missed at the beginning or at the end of a pack; ie, when the hormone-free interval (during which a bleed should be experienced) is extended.

The evidence for 'missed pill' recommendations is primarily derived from studies of women using the 30–35 micrograms ethinylestradiol pills. Limited evidence on the lower-strength 20 micrograms ethinylestradiol pills suggested that there may be a higher risk of pregnancy when missing 20 micrograms ethinylestradiol pills than when missing 30–35 micrograms ethinylestradiol pills.

3.2.2. Other evidence considered:

The Society of Obstetrics and Gynaecology Canada found that:

There is evidence of residual ovarian activity with most COCs, particularly during the seven-day hormone-free interval and with very low-dose COCs. Studies exposing women to dosing errors in the first week of use have found some form of ovarian activity, and occasionally signs of ovulation. However, although reduced ovarian suppression may result in ovulation, other mechanisms of contraceptive action from COCs, such as thickened cervical mucus and endometrial atrophy, may help to offset the risk of unintended pregnancy.

Pharmacokinetic properties of contraceptive hormones will influence contraceptive efficacy when doses are missed, but evidence related to specific formulations is lacking. Moreover, there is evidence for large inter- and intra-individual variation in the metabolism of contraceptive hormones, suggesting that the effect of missed doses is likely to be highly variable among women.

In studies of adherence to COC regimens, 15–47% of users report missing one pill per cycle and 22% report missing two or more pills. Moreover, studies have shown that, although women know what to do when one pill is missed, fewer know what to do when two or more pills are missed in a row.

The Society defined a missed dose of COC as taking a pill (or starting a new pack) 24 hours or more after the scheduled time and concluded that:

- The hormone-free interval should not exceed 7 days
- Delaying the start of a COC by 24 hours or more, or missing one or more doses of COC during week 1 of the treatment cycle may increase the risk of unintended pregnancy
- Eliminating the hormone-free interval when one or more COCs are missed in weeks 2 or 3 of the treatment cycle will reduce the risk of unplanned pregnancy
- There is likely to be considerable inter-individual variation in metabolism of contraceptive hormones and thus variation among individual women in their susceptibility to contraceptive failure after missed COCs
- Emergency contraception may be required in certain circumstances.

4. DISCUSSION

4.1. Starting COCs

The main issues assessed in the review were:

- When to start COCs
- The need for additional precautions or abstinence, depending on when COCs are started during the menstrual cycle.

Based on analysis of the scientific evidence, the WHO Expert Working Group concluded that COCs could be started on any day of the menstrual cycle. However, if COCs are started after the fifth day of the cycle or by amenorrhoeic women, additional precautions are required for the first seven days, since seven days' continuous treatment is required to prevent ovulation.

When to start COCs

Traditionally, women have been advised to start COCs in relation to their menstrual cycle. Initially, this was on day 1 (the first day of menstrual bleeding), in order to avoid using COCs during an undetected pregnancy. Development of quick, highly sensitive pregnancy tests, coupled with evidence of the lack of teratogenicity of COCs¹¹, has minimised this concern.

An advantage of starting COCs on the first day of the menstrual cycle is that there is no need for additional contraceptive precautions during the initiation of treatment. The disadvantage is that this advice may lead to delays in starting oral contraception, leaving women to use possibly less reliable methods of contraception in the interim. Indeed, in some developing countries, women have in the past been refused contraceptive services if they were not menstruating at the time of their visit. This approach also provides no useful guidance for women with amenorrhoea.

Analysis of studies comparing the immediate initiation of treatment, irrespective of the menstrual cycle, with conventional advice (to start COCs on the basis of the menstrual cycle, usually on the first day of menstruation or within the first five to seven days of menstruation) does not show any difference in the two approaches with regard to effectiveness, continuation and acceptability. However, it is suggested that further comparative trials are required as only two trials compared immediate and conventional initiation of COCs. The review did not find evidence to support concerns about the possible adverse effect of delaying starting COCs.

The need for additional precautions

There is evidence suggesting that it is possible for women to enter their fertile window before day 5 of their menstrual cycle. Other studies have not confirmed this; one study shows, for example, that the risk of ovulation when COCs were started on day 7 was no greater than when they were started on day 1⁹. However the authors suggested that a larger study was required before changing clinical practice in relation to the use of back-up contraception when starting COCs. On the basis of a range of studies of this sort, the WHO Expert Working Group recommended that no

additional precautions were necessary if COCs were started on days 1–5 of the menstrual cycle.

The CHM supported the advice that COCs could be started on any day of the menstrual cycle (with additional contraceptive precautions if COCs were started outside days 1–5 of the cycle, where day 1 is the first day of menstrual bleeding).

4.2. Missed COC pill advice

There are relatively few studies that have investigated the effect of missing one or more COC pills at different stages in the treatment cycle. Assessments have been based on indirect measures such as ovarian ultrasound and hormonal evidence of ovulation. These studies have shown suppressed folliculogenesis when up to four consecutive pills were missed, at least up to the middle of the cycle.

Based on analysis of these studies, the WHO Expert Working Group concluded that, for COCs containing 30-35 micrograms ethinylestradiol, additional precautions when pills are missed are not required unless at least three pills are missed. Potentially, this could represent a pill-free interval just short of 72 hours.

The WHO Expert Working Group also concluded that the risk of contraceptive failure depends not only on the number of pills that are missed but on the time in the cycle that this occurs. The WHO therefore advises that:

- if three or more 30-35 micrograms ethinylestradiol pills are missed or delayed in the first week of the cycle and unprotected sex has taken place, emergency contraception might need to be considered
- if three or more 30-35 micrograms ethinylestradiol pills are missed in the third week of the cycle, a new pack should be started as soon as the active pills are finished.

Since most of the evidence considered by the Expert Working Group related to COCs containing 30–35 micrograms ethinylestradiol, the group recommended a more precautionary approach for COCs containing ≤ 20 micrograms ethinylestradiol. This approach included advice that:

- if two or more ≤ 20 micrograms ethinylestradiol pills are missed in week 1 of the COC treatment cycle, and unprotected sex has also taken place in week 1, emergency contraception may need to be considered
- if two or more ≤ 20 micrograms ethinylestradiol pills are missed in week 3 of the cycle, a new pack should be started as soon as the active pills are finished

The CHM acknowledged that the advice from WHO was supported by the scientific evidence but highlighted the merits of a pragmatic approach, based on a single set of missed pill advice applicable to all COCs, which would provide clear and consistent guidance for both health professionals and COC users alike, minimising the risk of confusion. For this reason the CHM recommended a single set of missed pill advice, based on the WHO advice for low-dose pills.

5. RECOMMENDED NEW ADVICE

On the basis of the evidence described in this report and advice from the CHM, MHRA recommends the following advice for inclusion in product information for all COCs marketed in the UK.

5.1 Information for COC users (for inclusion in the Patient Information Leaflets)

Starting the Pill

- You can start the pill anytime in your menstrual cycle if you are sure you are not pregnant.
- If you start the pill on the first day of your period you will be protected from pregnancy immediately.
- You can also start the pill up to, and including, the fifth day of your period and you will be protected from pregnancy immediately.
- If you start the pill at any other time in your menstrual cycle you will need to use additional contraception, such as condoms, for the first seven days of pill taking.

If you forget to take a pill or start a pack late

Missing pills or starting the pack late may make your pill less effective. The chance of pregnancy after missing pills depends on **when** pills are missed and **how many** pills are missed. A pill is late when you have forgotten to take it at the usual time. A pill has been missed when it is more than 24 hours since the time you should have taken it.

If you miss one pill anywhere in your pack or start the new pack one day late, you will still have contraceptive cover. However, missing **two or more pills** or starting the pack **two or more days late** (more than 48 hours late) may affect your contraceptive cover. As soon as you realise you have missed any pills, take the last pill you missed immediately. In particular, during the seven day pill free break your ovaries are not getting any effects from the pill. If you make this pill free break longer by forgetting two or more pills, your ovaries might release an egg and there is a real risk of becoming pregnant.

Follow the advice below. If you are not sure what to do, continue to take your pill and use additional contraception, such as condoms, and seek advice as soon as possible.

If you have missed **one pill**, anywhere in the pack:

- take the last pill you missed now even if it means taking two pills in one day
- continue taking the rest of the pack as usual

- no additional contraception needed
- take your 7 day break as normal

If you have missed **two or more pills (more than 48 hours late)**, anywhere in the pack:

- take the last pill you missed now even if it means taking two pills in one day
- leave any earlier missed pills
- continue taking the rest of the pack as usual and use an extra method of contraception for the next seven days
- you may need emergency contraception – see below
- you may need to start the next pack of pills without a break – see below

Emergency contraception

If you have had unprotected sex in the previous seven days and you have missed two or more pills (more than 48 hours late) **in the first week of a pack**, you may need emergency contraception. Get advice from your contraception clinic, family doctor, or a pharmacist about this.

Starting the next pack after missing two or more pills (more than 48 hours late)

If **seven or more** pills are left in the pack after the last missed pill:

- finish the pack
- have the usual seven-day break

If **less than seven** pills are left in the pack after the missed pill:

- finish the pack and begin new one the next day (this means missing out the break)

5.2 Information for health professionals (for inclusion in the Summaries of Product Characteristics):

Pill initiation:

Provided that it is reasonably certain that a woman is not pregnant:

- COCs can be started at any time within 5 days of the start of menstrual bleeding without additional contraceptive precautions;

- COCs can be started at any other time in the cycle, or by women who are not menstruating, with additional contraceptive precautions for the first 7 days;
- a switch can be made from other methods of contraception, whether hormonal or not, at any time in the cycle. Additional contraceptive precautions are required for the first 7 days if changing from a non-hormonal method outside the first 5 days of the menstrual cycle.

Missed pills:

- if one pill is missed during weeks 1, 2 or 3, or if a pack is started 1 day late, the pill should be taken as soon as possible and no additional contraceptive precautions need be taken.
- if more than one pill is missed during weeks 1, 2 or 3, or if a pack is started more than 1 day late, a pill should be taken immediately, daily pills should be continued and additional contraceptive precautions should be taken for the next 7 days;
 - if the pills are missed in the first week and unprotected sex has taken place, the woman should discuss with a healthcare professional the use of emergency contraception;
 - if the pills are missed in the third week, the current course of pills should be completed and the next pack should be started immediately.

6. REFERENCES

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7. GLOSSARY

Amenorrhoea

Absence of **menstruation**

Case-control study

A **clinical study** that compares one group of individuals who have a disease or condition (cases) with another group of individuals who are free from that particular disease (controls)

Cervical mucus (also known as cervical fluid)

A fluid secreted by **glands** in and around the **cervix**, which changes in consistency through a woman's menstrual cycle. It is thickened by hormonal contraceptives, which prevents sperm from entering the **uterus**

Cervix

The narrow opening to the **uterus** (from the vagina) in a woman's body

Clinical study

A research study that tests the effectiveness and safety of medicines in humans

Cohort

A group of people who share a common characteristic or experience (such as a disease or medical condition) within a defined time

Combined oral contraceptives (COCs; also known as 'the Pill')

Medicines containing oestrogen and a progestogen, which are used to prevent pregnancy. COCs come in the form of a pill and are taken once a day

[Commission on Human Medicines](#)

(CHM): An independent committee comprised of health professionals and scientists who give advice to UK government Ministers on the safety, efficacy and quality of medicines

Committee on Safety of Medicines

A former medicines advisory committee for the government, from which the **CHM** was formed in 2005.

Compliance

How well a patient follows a prescribed treatment regimen

Contraceptive

A device or drug that prevents pregnancy

Emergency contraception

A **contraceptive** drug or device which must be taken or used within a specified time after having sex in order to prevent pregnancy

Endometrial atrophy

A diminished **endometrium**

Endometrium

A membrane which lines the **uterus** and thickens over the monthly menstrual cycle in preparation for pregnancy. If pregnancy does not occur, the endometrium is shed: this is the bleeding that occurs during a menstrual period.

Ethinylestradiol

A synthetic form of **oestrogen** commonly used in oral hormonal **contraceptive** medicines

Fertile window

A term for the period of time during the menstrual cycle when a woman is most likely to get pregnant (usually ranging from 5 days before **ovulation** until 1–2 days afterwards)

Follicle

A structure which develops in an **ovary** and contains an egg that may be released during **ovulation**

Folliculogenesis

The stimulation of **follicle** development in the **ovary**

Gland

An organ in a body which produces substances such as **hormones** for use elsewhere in the body

Gynaecologist

A physician who specialises in health care for women

Hormone

A substance produced by one part of the body that travels to another part of the body and causes a **physiological** effect

Hypothalamic-pituitary-ovarian axis

Refers to the effects of areas of the brain (hypothalamus and pituitary gland) and the ovary, which release **hormones** that act in cooperation to regulate the **menstrual cycle**

Intrauterine device (IUD) (also known as an intrauterine contraceptive device [IUCD])

A form of **contraceptive** device which is surgically implanted by a physician into a woman's **uterus** and physically prevents pregnancy

Levonorgestrel

A synthetic **progestogen** used in some hormonal **contraceptives** (including **emergency contraceptive pills**)

Menstrual cycle

A monthly cycle of changes in a woman's **ovaries** and **endometrium** that prepares the body for pregnancy.

Menstruation (also known as a 'period')

The monthly shedding of the **endometrium** (as blood) when pregnancy does not occur

Obstetrician

A physician who specialises in health care for women during pregnancy and childbirth

Oestrogen

A **hormone** that controls female sexual development. Natural and manufactured types of oestrogen are included in many hormonal contraceptive medicines

Ovarian

Of, or relating to, the **ovary**

Ovary

A gland located next to the uterus in the female body which produce eggs and female hormones

Ovulation

The release of an egg from the **ovary**

Physiological

Normal body function (not related to disease)

Placebo

Inactive dummy treatment given in a **clinical trial** to a particular patient group so their responses can be compared with the group receiving the test medicine

Post partum

The period of a few days immediately after birth

Progestogen

A **hormone** that controls female sexual development. Natural and manufactured types of progestogen are included in many hormonal contraceptive medicines

Randomised controlled trial

A **clinical trial** in which the study participants are randomly assigned to receive a test medicine, or a **placebo** or comparator medicine

Teratogenicity

The capability of a substance to cause malformations of the fetus (developing baby) in the **uterus**

Uterus

A hollow muscular organ in the female pelvic cavity in which a fertilized egg is deposited and a fetus develops

[World Health Organization](#)

An United Nations public health agency which coordinates international health activities and helps governments improve health services