Department of Health

Protocol for Resupply of the Oral Contraceptive Pill

Tasmanian Pharmacist Initiative

Version 1.0
May 2024

Contents

1. Background

In September 2023 the Tasmanian Government announced the release and endorsement of the Tasmanian Pharmacy Scope of Practice Review.

The first stage in implementing the recommendations Tasmanian Pharmacy Scope of Practice Review saw the implementation of a pilot program that allowed pharmacists who have been endorsed authorised health professionals to assess patients and prescribe specific antibiotics for uncomplicated urinary tract infections consistent with an approved protocol.

The next stage in extending the scope of practice will allow Tasmanian pharmacists to extend prescriptions for the Oral Contraceptive Pill (OCP) for up to 12 months.

An interim change to the Poisons Regulations 2018 allows pharmacists to supply medications included in this protocol.

2. Purpose

This protocol has been developed to provide participating pharmacists with a clear framework to resupply the OCP. It is a regulatory requirement under the Tasmanian Poison Regulations 2018 that pharmacists follow this protocol under a structured prescribing arrangement. Participating pharmacists must only offer this structured prescribing service in a pharmacy premises that has been approved by the Department of Health. Pharmacy premises that have already been approved for the UTI pilot project are able to have their approval grandfathered for the OCP resupply initiative.

Participating pharmacists are also required to be currently AHPRA registered and have evidence of completion of a training course approved by the Department of Health. Currently there are approved training courses relating to contraception offered by the Australasian College of Pharmacy (Oral contraceptives: a comprehensive training course for pharmacists) and the Pharmaceutical Society of Australia (Contraception Essentials Explained).

3. Glossary

Authorised health professional: A health professional from a named profession in the Poisons Act 1971 authorised to possess, sell, supply and prescribe certain scheduled substances in certain circumstances – see below under legislative instrument for more details.

Structured prescribing arrangement: prescribing specific medications for a specified purpose in accordance with a protocol published by the Tasmanian Department of Health.

4. Interim Authorisation

Poisons Act 1971 S. R. 2024, No. 86 Poisons (Interim Authorisation) Order 2024

Poisons (Interim Authorisation) Order 2024. This order –

(a) declares pharmacists to be authorised health professionals for the purposes of the Poisons Act 1971; and
(b) declares the Department of Health to be the authorised body for pharmacists; and
(c) authorises pharmacists to possess, sell, supply and prescribe certain scheduled substances in certain circumstances
1. Authorisation in relation to pharmacists

A pharmacist, in the lawful practice of the pharmacist's profession, is authorised to possess, sell, supply or prescribe a scheduled substance, subject to the following conditions:

(a) that the possession, sale, supply or prescribing of the scheduled substance is in accordance with section 25C(2) of the Act·

(a) that the scheduled substance is only prescribed in accordance with -

(i) a treatment plan, in respect of a specific patient, that is produced by a medical practitioner; or

(ii) a protocol, in relation to the prescribing of that substance by a pharmacist, published by the department responsible for the administration of the Act.

5. Requirements of Pharmacists and Premises

The Department of Health must ensure that pharmacists and premises participating in the pilot are not currently subject to any practice or premises issues that may adversely impact the safety of people accessing the service.

If a pharmacist applicant is subject to any current Australian Health Practitioner Regulation Agency (AHPRA) and/or Pharmacy Board of Australia investigation, or registration restrictions, this may impact the pharmacist's ability to become endorsed and participate in the pilot until these issues have been detailed to the Department of Health by the applicant and resolved.

Similarly, if a premises is subject to investigations about the appropriateness under the Pharmacy Control Act or similar this may impact the ability for the premises to be approved for participation.

If a pharmacist who has been endorsed becomes subject to an investigation by AHPRA and/or Pharmacy Board of Australia, or their registration is restricted in any way during the endorsement period, the endorsed pharmacist must notify the project team at the Department of Health immediately and this may result in the revocation of an endorsement in the interests of protecting the public, the applicant and premises pharmacyscope@health.tas.gov.au.

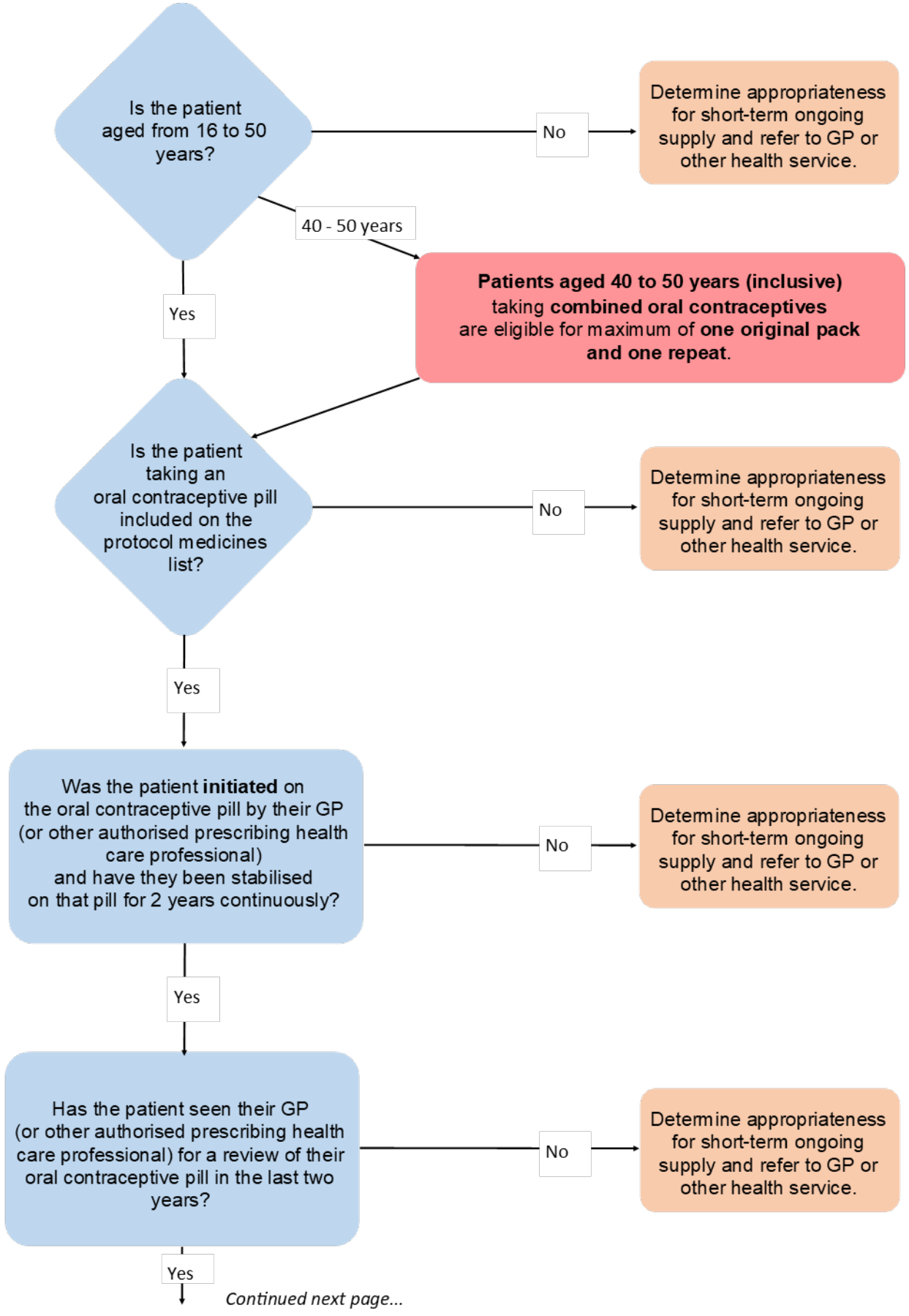
6. Assessment and Management Protocol

The following pages provide an assessment and management protocol for pharmacists for patients seeking a resupply of the oral contraceptive pill.

The protocol will not cover all possible clinical circumstances and pharmacists are required to exercise their professional judgement in adapting the treatment guideline to individual circumstances.

In circumstances where a pharmacist determines that ongoing resupply is not suitable but a significant risk of unplanned pregnancy without ongoing supply is present, a short-term supply may be considered until an appointment is able to be secured with a GP or other health service.

7. Tasmanian Protocol for the Resupply of the Oral Contraceptive Pill (OCP)



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Has the patient been continuously taking the oral contraceptive pill?

No → Refer to General Practitioner or other health service.

See Page 9 - pill breaks.

Yes

Does the patient consent to private consult with pharmacist?*

No → Refer to General Practitioner or other health service.

** The patient must be physically present in the pharmacy.*

Yes

Assess patient needs to determine whether resupply is safe and appropriate:

- ☐ determine possibility of pregnancy or recent commencement of breastfeeding
- ☐ Offer contraceptive counselling to explore other options as appropriate, e.g. LARCs
- ☐ undertake reproductive health enquiry and advice, as needed (see page 9)
- ☐ Is STI screening referral indicated? (OCP may still be resupplied by the pharmacist)

Resupply is ***not*** considered safe or appropriate → Refer to General Practitioner or other health service.

Resupply ***is*** assessed as safe and appropriate.

Conduct clinical review:
(Review My Health Record, where available)

- ☐ Measure BP and determine BMI
- ☐ Smoking status: Smoker/ recent ex-smoker (last 12 months) including vaping
- ☐ Have new medications commenced
- ☐ Are they planning a pregnancy in the next 12 months

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Does the patient have any contraindications for supply (all OCPs)*:

- ☐ Ischemic heart disease, stroke/TIA
- ☐ Current or previous breast cancer or uninvestigated breast changes
- ☐ Current liver disease
- ☐ Unexplained/ un-investigated vaginal bleeding

Additional contraindications (for continuation of combined oral contraceptive only):

- ☐ Hypertensive: systolic 140mmHg or higher/ diastolic 90 mmHg or higher
- ☐ Any active cardiac disease (e.g. atrial fibrilation)
- ☐ BMI 35kg/m2 or more
- ☐ Migraine
- ☐ Smoking/ vaping in past 12 months and 35 yrs or older
- ☐ Current, previous or family history of DVT/PE, prolonged immobility (e.g. after major surgery)
- ☐ Blood clotting disorder
- ☐ Diabetes with microvascular complications

Please refer to Appendix 1 for full set of contraindications to resupply

Yes → Prompt referral to General Practitioner or other health service.

No - ongoing supply is deemed appropriate.

40 - 50 years

Issue a prescription* and repeats (max 12-month supply).

Patients MUST be provided with the option of having their prescription filled at the pharmacy of their choice.
**script must be compliant with reg 45 (Tas Poisons Regs 2018)*

Patients aged 40 to 50 years (inclusive) taking **combined oral contraceptives†** are eligible for **one original pack & one repeat**.
†12 months can be supplied for progestogen-only pills.

Dispensing (when same pharmacy as prescribing):
Dispensing process is to be performed separately from prescribing (for example: physically move from consult room into the dispensary)
Best practice advice: *wherever available, another pharmacy staff member should be involved in the dispensing process. A pharmacist (first-preference) or a dispense tech.*

Preventative Health advice:

- Cervical screening – routine testing is advised every 5 years from 25 years of age.
- Breast checks – encourage routine self-checks, mammography available over 40 Years, those with personal or family history should seek advice from GP regarding frequency and type of screening.
- Regular sexual health/ reproductive health checks are recommended including STI screening where appropriate.

Communicate agreed plan to resupply OCP:

- offer general advice about OCP as needed.
- provide copy of record of service to patient and patient's GP or other health practitioners.
- reminder that reviews by GP or other health provider recommended to occur at least every 2 years.

8. Documentation Requirements

The pharmacist must make a clinical record of the consultation that contains at a minimum:

- Sufficient information to identify and make contact with the patient
- The date of consultation
- Name of the pharmacist who undertook the consultation
- Documentation of consent given by the patient regarding:
  - Any costs
  - Pharmacist communication with other healthcare practitioners (e.g. patient's usual treating GP) and
  - Access to the patient's My Health Record for checking relevant medical history.
- Information relevant to the resupply of the OCP
- Clinical opinion reached by the pharmacist
- Actions taken by the pharmacist (including medication supplied or referrals made to a medical practitioner)
- Details of the resupply of the OCP
- Information or advice given to the patient

The pharmacist must provide a copy of the consultation summary to the patient.

The consultation summary is also to be shared with patient's usual treating medical practitioner or medical practice (the only exception to this is if the patient does not have a regular GP or does not consent to their information being shared).

9. Prescribing Considerations

Prescribing may only be undertaken by pharmacists who have received their endorsement as authorised health professionals.

Any prescription needs to comply with Regulation 45 of the Poisons Regulations 2018 which outlines the elements needed to produce a valid prescription in Tasmania. Electronic prescribing templates may be used provided they meet the requirements of Reg 45 and are signed in ink by the endorsed pharmacist. Pharmacists are to indicate the words "authorised health professional" after signature and name on the prescription. The original prescription is to accompany the repeats and the pharmacy is to establish a process to retain a copy of the original prescription on file.

10. Resources for Patients

- Tasmanian Department of Health – Contraception (fertility control)
  www.health.tas.gov.au/health-topics/sexual-and-reproductive-health/reproductive-health/contraception-fertility-control
- Family Planning Tasmania Website
  https://fpt.org.au/clinics/services/
- Health Direct – Contraception Options
  www.healthdirect.gov.au/contraception-options

11. Further Information

Assess Patient Needs

An assessment of the patient's needs must be undertaken to determine whether resupply of the OCP is safe and appropriate.

To determine whether resupply is safe and appropriate, pharmacists must understand the contraindications and precautions of the different OCPs. Pharmacists can find further information in the Therapeutic Guidelines and the current versions of the Royal College of Obstetricians and Gynaecologists Faculty of Sexual and Reproductive Healthcare (FSRH) documentation, including:

- UK Medical Eligibility Criteria for Contraceptive Use 2016 (UKMEC)

  (www.fsrh.org/documents/ukmec-2016)

- FSRH Clinical Guideline: Progestogen-only Pills (August 2022, Amended July 2023)
- FSRH Clinical Guideline: Combined Hormonal Contraception (January 2019, Amended July 2023)

  (www.fsrh.org/standards-and-guidance/documents/combined-hormonal-contraception)

Pill breaks

The pharmacist must ascertain whether use of the OCP has been continuous. If a pill break has occurred for:

- Less than 2 weeks: Resupply of the OCP may occur.
- More than 2 weeks, but less than 4 weeks: Resupply of 1 month of the OCP may occur with referral to their usual medical practitioner or other authorised prescribing healthcare practitioner.
- One month or more*: Do not resupply OCP. The patient should be referred to their usual medical practitioner or other authorised prescribing healthcare practitioner.

If a patient frequently takes pill breaks, pharmacists should exercise their professional judgement and consider referring the patient to explore alternative contraception options, e.g., long-acting reversible contraception (LARCs).

***Note:** The risk of venous thromboembolism (VTE) with the combined oral contraceptive pill (COCP) is highest in the first year of use, and particularly in the first 3-4 months after commencement. The level of risk returns, if the patient misses taking the COCP for 1 month or more.*

Sexual and Reproductive Health Counselling

Young people

- Patients under 16 years of age are to be confidentially referred to a general practitioner, family planning or sexual health clinic.

Consenting to medical treatment under 18 years of age:

- Consent to medical treatment of a patient younger than 18 years of age may be provided by either the:
  - parent or legal guardian
  - patient (must be assessed as having **capacity** to fully understand the treatment, risks, and wider consequences)
    Capacity: A child or young person's capacity can be observed and assessed by a pharmacist on a case-by-case basis. They may be considered to have capacity if they *have a sufficient understanding and intelligence enabling them to understand fully what is being proposed*.

Pharmacists are to consider whether there may be child protection concerns relating to a request for contraception and report to Child Protection accordingly by contacting the Strong Families, Safe Kids advice and referral line on **1800 000 123** or by visiting their website Strong Families, Safe Kids (https://strongfamiliessafekids.tas.gov.au).

Family planning

Determine if patient is planning pregnancy within the next 12 months, consider referral to GP or family planning for pre-natal planning and health checks.

40 to 50 years of age inclusive

Following clinical consultation with local medical specialist colleagues and with reference to the UK Medical Eligibility Criteria, patients aged 40 to 50 years are at an increased risk of complications from the combined oral contraceptive pill (COC). Pharmacists are able to provide an extended supply of the COC to these patients (provided they do not have any risk factors) of one original pack and one repeat only. Pharmacists should encourage that these patients are regularly engaging with their GP to determine the most appropriate contraceptive ongoing.

Over 50 years of age

- The choice of contraceptive should be reconsidered at age 50, patients should be referred to their GP or other health service.

Sexual and domestic abuse

- Pharmacists must be aware of the possibility that a patient seeking contraception may be and/ or has been subjected to sexual violence or abuse, either within a relationship or outside of a relationship.
- If the pharmacist becomes aware of this during the consultation, they should provide referral to support options depending on the patient circumstances:
    - Contact should be made with the Family Violence Counselling and Support Service (Statewide) by calling **1800 608 122**. Referral options include to the local hospital, sexual health clinic and/or community-based sexual violence support services. Further information is available at the Safe at Home website at (www.safeathome.tas.gov.au/services/counselling)
- If required, emergency contraception may be supplied as per standard pharmacy care, or the person may be referred to an appropriate medical practitioner or health service for another method of emergency contraception e.g. insertion of a copper intrauterine device.

Contraceptive options and information for transgender and non-binary people

These services are inclusive of transgender, gender diverse, intersex or non-binary people assigned and/ or presumed female at birth.

Pharmacists should check that individuals assigned and / or presumed female at birth requesting contraceptive care have been engaging with specialist sexual health services or their GP to ensure they receive comprehensive and culturally safe sexual health care that is tailored to their individual needs.

Sexual health services and information for the lesbian, gay, bisexual, transgender, intersex, queer, and asexual/aromantic community, is available from the Department of Health (Tasmania) sexual and reproductive health (www.health.tas.gov.au/health-topics/sexual-and-reproductive-health).

Contraceptive and Sexual history

A brief sexual history should be considered to inform shared decision making/appropriateness of OCP resupply. The following issues may be considered but may not be relevant to all people: previous use and experiences with contraception, and risk factors for STIs (including STI history of current and/or recent partner if applicable).

Guidance and information on how to take a sexual history is available from Australian STI Management Guidelines (https://sti.guidelines.org.au/sexual-history)

Examination

The pharmacist should measure BP and calculate BMI to determine the person's suitability for continuing their OCP.

A single elevated BP reading is not enough to classify a patient as hypertensive (e.g. also take into consideration activity immediately prior to consultation) and a second BP reading should be taken at the end of the consultation. If BP remains elevated, the patient should be referred to a medical practitioner for further assessment and selection of an appropriate contraceptive method.

Patient History

Sufficient information must be obtained from the patient to assess the safety and appropriateness of any recommendations and medicines, including resupply of the OCP, for the patient. Review MHR where available and appropriate.

Consider:

- Age
- Pregnancy and breastfeeding status
- Underlying medical conditions, including new or recently diagnosed medical conditions, which may:
  - be a contraindication to hormonal contraception e.g. migraine with aura
  - impact on contraceptive effectiveness and choice
- Current medications, including check adherence and satisfaction with OCP
- Drug allergies/adverse effects, including any adverse effects of OCP
- Smoking status (there is an increased VTE risk in smokers over 35 years)
- BMI
- Last STI screen and Cervical Screening Test (CST)*
- Presence of genitourinary symptoms that may suggest STI:
  - Changes in vaginal or urethral discharge
  - Vulval, genital skin problems or symptoms
  - Lower abdominal pain
  - Dysuria
  - HPV vaccination status.

* All patients seeking contraception who have not had a CST in the previous 5 years should be advised to see a medical practitioner for a CST, and a referral provided if the patient consents. They are still eligible to receive a resupply of the Pill.

12. Confirm OCP Resupply/Contraception Plan is Appropriate

Pharmacists must consult the Therapeutic Guidelines, Australian Medicines Handbook and other relevant references to confirm the OCP is appropriate for the patient, including for:

- Contraindications and precautions
- Drug interactions
- Pregnancy and lactation.

Excluding Pregnancy

If the patient is still taking the OCP and there are no symptoms or signs of pregnancy, they can be reasonably assumed not to be pregnant. However, if there is any doubt regarding whether the patient may be pregnant, the patient should be advised to take a pregnancy test and provided this is negative, they may then return to the pharmacy for the resupply of their OCP.

13. List of Medicines

Under the initiative, Tasmanian pharmacies are only authorised to resupply two types of oral hormonal contraceptive pills: the combined oral contraceptive pill (COCP) and the progestogen only pill (POP or mini pill), specifically those that are listed in the table below.

Note: COCPs with a high estrogen dose (50 micrograms of ethinylestradiol or equivalent) are not routinely recommended for contraception because of the unacceptable risk of VTE and have been excluded from this initiative.

Combined oral contraceptive pills (COCP

Monophasic oral formulations: low-dose estrogen

Estrogen dose (micrograms)	Progestogen dose (micrograms)	Brand name examples
ethinylestradiol 20*	levonorgestrel 100	Femme-Tab ED 20/100, Lenest 20 ED, Loette, Microgynon 20 ED, Micronelle 20 ED
ethinylestradiol 20*	drospirenone 3000	Yaz
estradiol 1500	nomegestrol 2500	Zoely

Monophasic oral formulations: standard-dose estrogen

Estrogen dose (micrograms)	Progestogen dose (micrograms)	Brand name examples
ethinylestradiol 30*	levonorgestrel 150	Eleanor 150/30 ED, Evelyn 150/30 ED, Femme-Tab ED 30/150, Lenest 30 ED, Levlen ED, Microgynon 30 ED, Micronelle 30 ED, Monofeme, Nordette, Seasonique
ethinylestradiol 30*	desogestrel 150	Madeline, Marvelon
ethinylestradiol 30*	dienogest 2000	Valette
ethinylestradiol 30*	drospirenone 3000	Petibelle, Yasmin
ethinylestradiol 30*	gestodene 75	Minulet
ethinylestradiol 35	cyproterone 2000	Diane-35 ED, Estelle-35 ED, Juliet-35 ED, Brenda-35 ED
ethinylestradiol 35	norethisterone 500	Brevinor, Norimin
ethinylestradiol 35	norethisterone 1000	Brevinor-1, Norimin-1, Pirmella

Triphasic: low or standard dose estrogen

Estrogen dose (micrograms)	Brand name examples
Phase 1 (6 pills): ethinylestradiol 30 + levonorgestrel 50	Logynon ED, Trifeme, Triphasil, Triquilar ED
Phase 2 (5 pills): ethinylestradiol 40 + levonorgestrel 75	
Phase 3 (10 pills): ethinylestradiol 30 + levonorgestrel 125	

Quadriphasic: low or standard dose estrogen

Estrogen dose (micrograms)	Brand name examples
Phase 1 (2 pills): estradiol valerate 3000 alone	Qlaira
Phase 2 (5 pills): estradiol valerate 2000 + dienogest 2000	
Phase 3 (17 pills): estradiol valerate 2000 + dienogest 3000	
Phase 4 (2 pills): estradiol valerate 1000 alone	

* NB: first-line choice of COCP is a monophasic formulation containing ethinylestradiol (20 or 30 micrograms) and levonorgestrel (Therapeutic Guidelines)

Progestogen only pills (POP) oral contraception

Progestogen dose (micrograms)	Brand name examples
Levonorgestrel 30 micrograms	Microlut
Norethisterone 350 micrograms	Noriday
Drospirenone 4 milligrams	Slinda

14. Communicate Agreed Plan for OCP Resupply

Offering comprehensive counselling that covers adverse effects, instructions for use and patient expectations where this is required assists to promote effective and ongoing contraceptive use.

Comprehensive advice and counselling (including supporting written information when required) as per the Therapeutic Guidelines, Australian Medicines Handbook, UKMEC 2016, and other relevant references, should be provided to the patient regarding:

- Individual product and medicine use,
- Managing missed pills and emergency contraception options available if required
- How to manage adverse effects
- When to seek further care and/or treatment:
  - The signs of VTE and what to do if it is suspected
  - The importance of reporting new or worsening mood-related symptoms to the pharmacist and usual medical practitioner.

General Advice

Patient resources

Where appropriate, individuals may be provided with additional resources to support sexual health. It is the pharmacist's responsibility to ensure the suitability and accuracy of any resources provided, and to ensure compliance with all copyright conditions.

Factsheets and other information suitable for patients on the OCP and sexual health include:

- Department of Health (Tasmania) sexual and reproductive health website provides a wide range of information and resources on sexual health:
  - www.health.tas.gov.au/health-topics/sexual-and-reproductive-health
- Family Planning Tasmania offers a wide range of sexual and reproductive health services:
  - https://fpt.org.au/

15. Follow Up

Pharmacists should advise the patient that they can seek a resupply of their OCP at the pharmacy of their choice when they next need a replacement pack (approximately four months later depending on OCP pack size).

It is recommended that:

- The patient's BP should be monitored at 12 monthly intervals, and
- Patients should be reviewed by their GP at least every 2 years.

Appendix 1 - Contraindications to resupply

The *Therapeutic Guidelines - Contraception* indicates a range of contraindications and precautions for combined hormonal contraception and progestogen-only oral contraception. These are based on the UK Medical Eligibility Criteria (UKMEC) and include conditions in Table 3 and 4 (not an exhaustive list).

For a full list of UKMEC 3 and UKMEC 4 classified conditions, see:

- UKMEC April 2016 (Amended September 2019) - Faculty of Sexual and Reproductive Healthcare
- UKMEC April 2016 Summary Sheet (Amended September 2019) - Faculty of Sexual and Reproductive Healthcare

Combined Oral Contraceptive Pill (COCP)

Table 1: Contraindications to resupply of the COCP

UKMEC Category 3 and 4 contraindications, and other conditions that require immediate referral.
• Current or previous history of breast cancer (including carriers of known gene mutations associated with breast cancer) • Migraine with/without aura • Current or past history of ischaemic heart disease, stroke or transient ischaemic attack • Aged 35 years or older and current smoker or recently quit smoking (including vaping*) in the last 12 months • Hypertension (systolic blood pressure 140 mmHg or higher, or diastolic blood pressure 90 mmHg or higher), including adequately controlled hypertension • Hypertension, with vascular disease • Complicated valvular or congenital heart disease • Cardiomyopathy with impaired cardiac function • Atrial fibrillation • Current or past history of VTE or a first-degree relative with a VTE (provoked or unprovoked) under the age of 45 years • Positive antiphospholipid antibodies • Known thrombogenic mutations, e.g. factor V Leiden, prothrombin mutation, Protein S, Protein C, antithrombin deficiencies • Prolonged immobilisation • Severe (decompensated) cirrhosis • Hepatocellular adenoma or malignant liver tumour • Body mass index (BMI) 35 kg/m2 or more • Diabetes with nephropathy, retinopathy, neuropathy or other vascular disease • Gall bladder disease (medically treated or current) • Undiagnosed mass/breast symptoms (only if the condition is pre-existing and the COCP is initiated) • Multiple risk factors for cardiovascular disease (such as smoking, diabetes, hypertension, obesity, and dyslipidaemias) • Past COC related cholestasis • Organ transplant - Complicated: graft failure (acute or chronic), rejection, cardiac allograft vasculopathy • Acute viral hepatitis, or flare (only if the condition is pre-existing and the COC is initiated)

**As per Australian consensus guidelines*

Breastfeeding and postpartum risks have been excluded from Table 1 due to the requirement for a 2-year history of continuous OCP use to be eligible for this service.

Progestogen Only Oral Contraceptive Pill (POP)

Table 2: Contraindications to resupply of the POP

UKMEC Category 3 and 4 contraindications, and other conditions that require immediate referral.
• Current or previous history of breast cancer • Unexplained vaginal bleeding (suspicious for a serious condition) before investigation for the cause • Severe (decompensated) cirrhosis • Hepatocellular adenoma or malignant liver tumour • Ischaemic heart disease, stroke or transient ischaemic attack (TIA) that develops during use

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