



Medicines & Healthcare products  
Regulatory Agency



# Pharmacy vs Pharmacist supply – when is self-selection appropriate

Jan MacDonald



- Different legal categories
- Patient perspectives
- Current policy on sale & supply
- Pharmacy vs Pharmacist – examples
- Future

# UK Legal Categories

- Three legal categories
  - POM
  - P
  - GSL
- Four POM criteria
- One GSL criterion

# POM Criteria

## ***Regulation 62(3)***

A UK marketing authorisation must ... be available only on prescription if the licensing authority considers that the product—

- is likely to present a direct or indirect danger to human health, even when used correctly, if used without the supervision of a doctor or dentist;
- is frequently and to a very wide extent used incorrectly, and as a result is likely to present a direct or indirect danger to human health;
- contains substances, or preparations of substances, of which the activity requires, or the side effects require, further investigation; or
- is normally prescribed by a doctor or dentist for parenteral administration.

# GSL Criterion

## ***Regulation 62(5)***

A UK marketing authorisation may ... .. be available on general sale only if the licensing authority considers that the product can with reasonable safety be sold or supplied otherwise than by, or under the supervision of, a pharmacist.



# Listening to the Patient

- Patient & Public Engagement
- Confident with self-selection in a small number of areas
- Concerns
  - Is this the right medicine for me
  - What about interactions
  - Will I get side effects

# Pharmacist as Gatekeeper

- Pharmacy professionals can
  - Provide screening services
  - Consider wider range of treatment options
  - Be commissioned locally to provide services
  - Will have access to Summary Care Record
  - Undertake training in line with professional requirements





Oral emergency contraception

Secure | <https://www.rpharms.com/resources/quick-reference-guides/oral-emergency-contraceptives-as-pharmacy-medicines>

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Diagram on decision-making for the supply of oral emergency contraception as a pharmacy medicine

The copper intrauterine device is the most effective form of EC, if this is not a suitable option<sup>1</sup>, LC should be considered.

- CHILDREN COLLECTING MEDICINES FROM A PHARMACY
- PROTECTING CHILDREN AND YOUNG PEOPLE
- OBESITY AND WEIGHT MANAGEMENT
- SEXUAL HEALTH TOOLKIT

```

    graph TD
      Start([Last UPSE/72 hours ago]) -- YES --> C1(Contraindication(s) To UPA (see table 1))
      Start -- NO --> C2([Last UPSE/120 hours ago])
      C1 -- NO --> C3([BMI >24kg/m² or Weight > 70kg])
      C1 -- YES --> C4([LNG (See table 2 for additional points)])
      C3 -- YES --> C5([UPA Or LNG (See corresponding table for additional points) For LNG, see updated advice in table 3])
      C3 -- NO --> C6([UPA Or LNG (See corresponding table for additional points)])
      C4 --> C5
      C4 --> C6
      C2 -- YES --> Ref1([REFER])
      C2 -- NO --> C7(Contraindication(s) To UPA (see table 1))
      C7 -- YES --> Ref2([REFER])
      C7 -- NO --> C8([UPA (See table 1 for additional points)])
  
```

UPE = Unprotected sexual intercourse  
 UPA = Ulipristal acetate 30mg  
 LNG = Levonorgestrel 1.5mg  
 EC = Emergency contraception



## ORLISTAT 60MG P MEDICINE

### Quick reference guide

#### RELATED RESOURCES

##### SUPPORT RESOURCE

Cholesterol testing

📅 22 December 2010



##### SUPPORT RESOURCE

Diagnostic testing and screening services

📅 21 May 2010



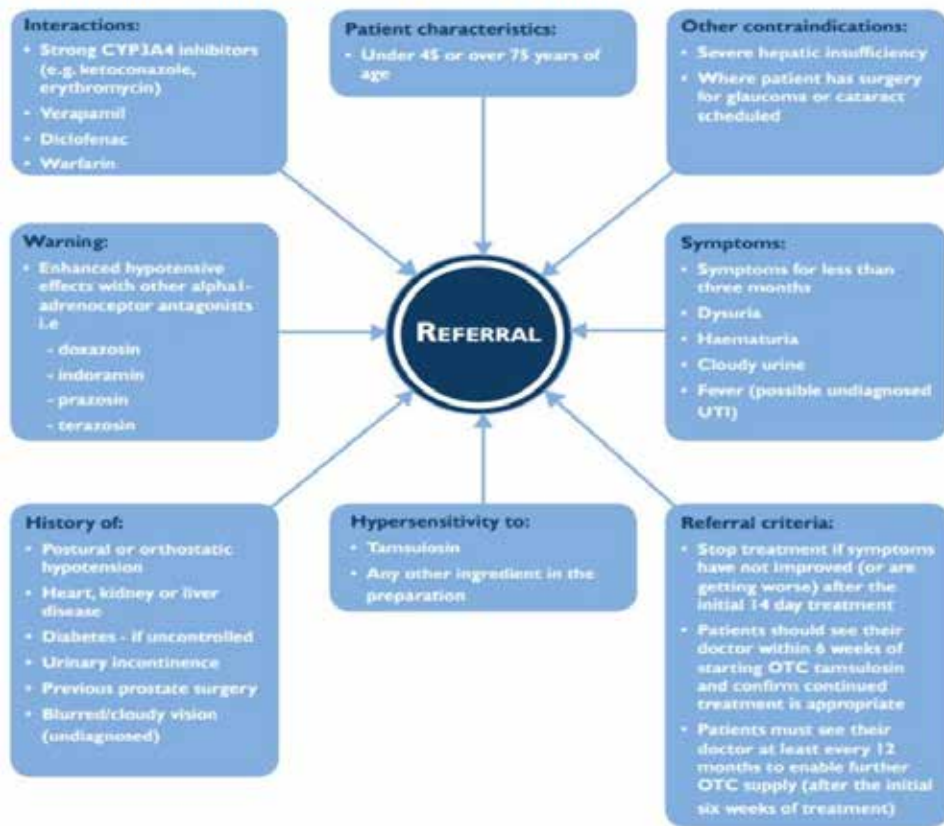
##### SUPPORT RESOURCE

Obesity and weight management

📅 05 July 2010



## Contraindications (and other referral criteria)



## SUPPLY OF ANTI-MALARIALS AS PHARMACY MEDICINES

### Quick reference guide

Maloff Protect 250mg/100mg film-coated tablets (atovaquone with proguanil hydrochloride) was launched as a Pharmacy (P) medicine in June 2017. It is indicated for the prevention of *Plasmodium falciparum* (*P. falciparum*) malaria in adults aged 18 years and over, weighing more than 40kg who are travelling to areas where malaria is widespread. It is especially recommended for prevention of *P. falciparum* malaria where the pathogen may be resistant to other anti-malarials.

Maloff Protect is one of four anti-malarial products currently available as P medicines for supply from pharmacies in the UK. Avloclor, Paludrine and Paludrine/Avloclor Anti-Malarial Travel pack are now rarely used due to the development of resistance.

- **Maloff Protect** (atovaquone 250mg with proguanil hydrochloride 100mg)
- **Avloclor** (chloroquine 250mg)
- **Paludrine** (proguanil hydrochloride 100mg)
- **Paludrine/Avloclor Anti-Malarial Travel Pack** (proguanil hydrochloride 100mg/chloroquine 250mg)

#### Who needs to read this?

Pharmacists and pharmacy staff who may be involved in providing travel advice to patients including the supply of anti-malarials.

#### What this guidance will tell you?

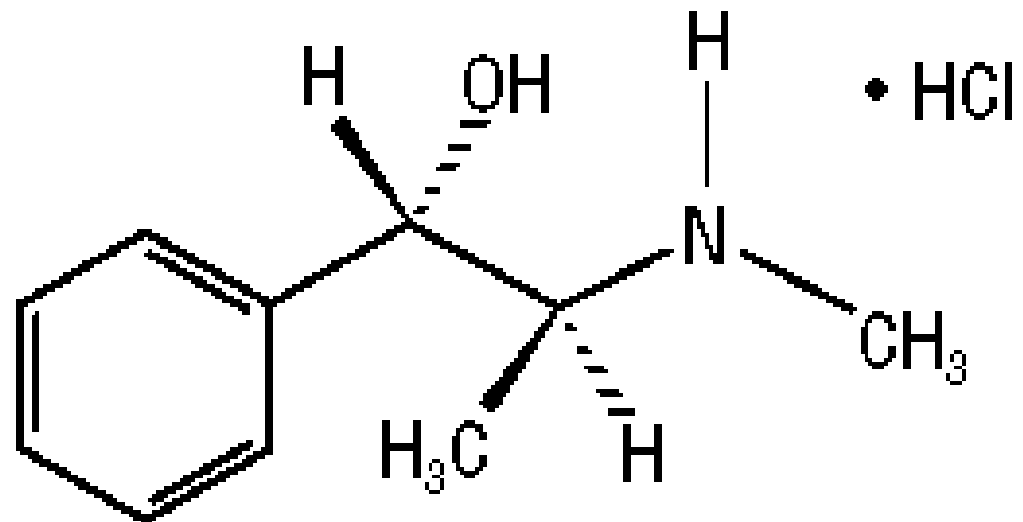
This guidance provides information on what pharmacists need to consider before supplying anti-malarials as P medicines to patients, information on the condition, the product supplied, other treatment options, malaria prevention measures, signs and symptoms of malaria infection and action required if suspected infection, and signposting to resources for both the pharmacist and their patients.

#### What this guidance will not tell you?

This guidance does not cover the treatment options for infection with malaria, only prevention. Pharmacists should refer anyone they consider may be infected with malaria to seek immediate medical assistance.

The guidance only covers those anti-malarials that are currently available as P medicines. For information on other anti-malarials that are available see the [British National Formulary \(BNF\)](#) and [Summaries of Product Characteristics \(SPC\)](#) for individual products.





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# Drug Safety Update

From: [Medicines and Healthcare products Regulatory Agency](#)

## **Miconazole (Daktarin): over-the-counter oral gel contraindicated in patients taking warfarin**

Patients taking warfarin should not use over-the-counter miconazole oral gel (Daktarin).

Cardiovascular disease and lipidology and 5 others Published: 26 September 2017

# Drug Safety Update

From: [Medicines and Healthcare products Regulatory Agency](#)

## **Oral diclofenac no longer available without prescription**

Oral diclofenac is associated with a small increased risk of cardiovascular side effects and is therefore no longer available over the counter.

Pain management and palliation and 1 others Published: 22 January 2015

**SELF CARE WEEK**

**NHS**

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**13-19 November 2017**

**[www.nhs.uk/selfcare](http://www.nhs.uk/selfcare)**



## The self-care continuum

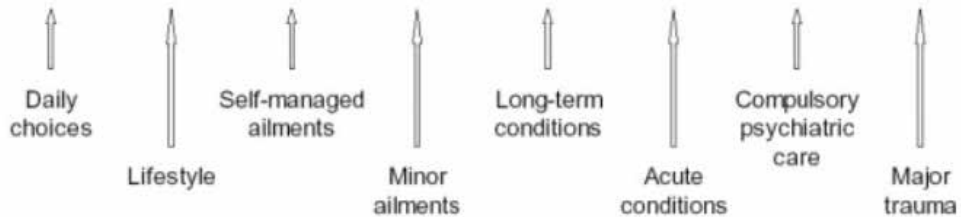
**Pure self care**

Responsible  
individual

**Pure medical care**

Professional  
responsibility

**The self-care continuum**



Healthy living

Minor ailments

Long-term conditions

In-hospital care



Guidance

## Patient group directions: who can use them

Updated 10 April 2017

### Contents

[Who can supply or administer under a PGD](#)[Legal requirements](#)[Medicines you can supply under a PGD](#)[Further guidance](#)[Arrangements for independent healthcare providers in Scotland](#)[More information](#)

Patient group directions (PGDs) are written instructions to help you supply or administer medicines to patients, usually in planned circumstances. They take a significant amount of time and resource to develop and implement.

You can only supply and or administer medicines under PGDs if there is an advantage for the patient without compromising their safety.

PGDs should be put together by a multi-disciplinary group including a doctor, a pharmacist and a representative of any professional group expected to supply the medicines under the PGD. It's good practice to involve local drug and therapeutics committees, area prescribing committees and similar advisory bodies.

The expiry date for a PGD needs to be decided on a case-by-case basis in the interest of patient safety. The expiry date should not be more than 3 years from the date the PGD was authorised.

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This free service is funded by NHS England

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### Items which should not be routinely prescribed in primary care: A Consultation on guidance for CCGs