

Unlicensed Medicines: A Guide for Patients

Pharmacy

Introduction

You have been given this leaflet by your doctor or pharmacist because you have been prescribed a medicine that is unlicensed. To help you understand what this means, this leaflet answers some of the most frequently asked questions. We want to reassure you that we have thought very carefully about the best medicine for you and to answer any questions you may have. If you would like to talk to anyone further about your medicine, please speak to your doctor or pharmacist.

Why do medicines have a licence?

The agency that regulates the use of medicines in the UK is called the Medicines and Healthcare Products Regulatory Agency (MHRA). The MHRA ensures that a medicine meets the minimum standard for quality and safety before it grants marketing authorisation. It also ensures that the medicine is effective for the particular illness that it is being licensed for.

What is an unlicensed medicine?

A medicine that has not been granted marketing authorisation in the UK is referred to as an unlicensed medicine.

What is an “off-label” Use of a Medicine?

At the time of marketing authorisation, medicines will be granted a license to treat specific illnesses. This is also the case for specific patient groups, for example, a lot of medicines are only tested in adults and so will not have a specific license for use in children.

If the medicine is being used to treat an illness or group of patients' that it is not licensed for, then it is referred to as either unlicensed use or “off-label” use.

The patient information leaflet that comes with your medicine will specify all the illnesses and groups of patients that the medicine has been licensed for.

When and why is an unlicensed medicine or off-label medicine used?

Medicines which are not licensed are not necessarily unsafe, and can be prescribed if a health professional feels the medicine will be of benefit to you without causing you harm.

When an unlicensed medicine is imported, where possible it will normally be bought from a country with which the UK has a mutual agreement on standards of licensing.

The prevention of infection is a major priority in all healthcare and everyone has a part to play.

- **Please decontaminate your hands frequently for 20 seconds using soap and water or alcohol gel if available**
- **If you have symptoms of diarrhoea and/or vomiting, cough or other respiratory symptoms, a temperature or any loss of taste or smell please do not visit the hospital or any other care facility and seek advice from 111**
- **Keep the environment clean and tidy**
- **Let's work together to keep infections out of our hospitals and care homes.**

There will be times when your doctor will advise you to take an unlicensed medicine or use a medicine off-label. There may be a number of reasons for this such as:

- Your doctor thinks that a particular medicine would work well for your condition even though it is licensed for a different condition. It may be that an alternative licensed medicine does not meet your individual needs
- Current practice supports the unlicensed use of a medicine. This means there is sufficient evidence (such as from clinical trials) or clinical experience, that shows the medicine is effective and safe to treat a specific illness or group of patients', for example, children
- The medicine is made in one form, such as a tablet, and your doctor may recommend that a liquid preparation will suit your needs better. If this liquid has to be made as a "special" medicine it will be considered unlicensed.

We use specific reference sources to assist doctors in deciding on the use of unlicensed medicines or off-label uses. Your doctor will consider all the medical evidence available before prescribing an unlicensed medicine.

If this medicine works for me, why is it not licensed?

There may be a number of reasons why the medicine you are prescribed is not licensed. The medicine may be unlicensed because there is not enough commercial interest in marketing the treatment to make it financially worthwhile for the manufacturers to apply for a license, or because it is awaiting approval for a license.

What monitoring will I receive?

As with licensed medicines, your doctor will closely monitor you for any side effects and check that the medicine is working for you. All medicines can have side effects, and it is important to discuss any side effects or concerns you have with your doctor.

What information will I be given?

In prescribing an unlicensed medicine or off-label use of a medicine, your doctor is choosing a particular line of treatment which will have involved careful consideration of the evidence. The doctor will explain the reasons for using an unlicensed medicine and discuss the potential benefits of treatment and possible side effects, so that you can make an informed choice about the treatment. It is your right to decline the treatment, in which case your doctor or pharmacist will discuss the alternative treatments available.

Where current practice supports the use of a medicine off-label, it is not always necessary for the prescriber to draw your attention to the license when discussing treatment options.

How should I take my medicine & where can I get further Information?

It is important to take the medicine as directed on the label, if you are at all unclear it is important to check with your doctor or pharmacist.

If the medicine you are given is unlicensed then the leaflet may not relate to your condition. You can get more information from your doctor or pharmacist. The Trust may also have a special information leaflet specific to your condition and medicine.

Where can I renew my prescription?

Your consultant will usually carry on prescribing your treatment for a period of time after you are discharged from hospital. The consultant may then liaise with your family doctor (GP) and community pharmacist to organise further supplies. If your GP or pharmacist is unable to do this then the hospital will continue to supply the unlicensed medicine.

What if I do not want to take this medicine?

If you have any concerns about your medicine or treatment, please speak to your doctor or pharmacist. We want to help you to make the right choice and it is important that we understand what your concerns are. There may be alternative options and we can discuss these with you if you choose not to take this unlicensed medicine.

Why are so many children's medicines unlicensed?

A lot of medicines are only tested with adult volunteers. Therefore, they will not have a licence for use in children. Our hospitals have processes in place to review medicines and decide on what is best to treat children and young people. Your doctor or pharmacist will be able to tell you if the medicine prescribed for your child is one commonly used for children.

Contact us

For more information about any of the issues raised in this leaflet, please talk to the staff caring for you. They may refer you to the Medicines Information (MI) department who may be able to answer your questions.

Your comments and concerns

For advice, support or to raise a concern, contact our Patient Advice and Liaison Service (PALS).

Telephone: 01902 307999 Ext: 5368 / 5362

email: rwh-tr.pals@nhs.net

To make a complaint, contact the complaints department.

Telephone: 01902 695332

email: rwh-tr.complaints@nhs.net

Language and accessible support services

If you need an interpreter or information about your care in a different language or format, please get in touch with the Patient Information Centre:

Telephone: 01902 307999 Ext: 5368 / 5362

email: rwh-tr.pals@nhs.net

NHS 111

Offers medical help and advice from fully trained advisers supported by experienced nurses and paramedics. Available over the phone 24 hours a day.

Telephone: 111

NHS Choices

Provides online information and guidance on all aspects of health and healthcare, to help you make choices about your health. website: www.nhs.uk

English

If you need information in another way like easy read or a different language please let us know.

If you need an interpreter or assistance please let us know.

Lithuanian

Jeigu norėtumėte, kad informacija jums būtų pateikta kitu būdu, pavyzdžiui, supaprastinta forma ar kita kalba, prašome mums apie tai pranešti.

Jeigu jums reikia vertėjo ar kitos pagalbos, prašome mums apie tai pranešti.

Polish

Jeżeli chcieliby Państwo otrzymać te informacje w innej postaci, na przykład w wersji łatwej do czytania lub w innym języku, prosimy powiedzieć nam o tym.

Prosimy poinformować nas również, jeżeli potrzebowaliby Państwo usługi tłumaczenia ustnego lub innej pomocy.

Punjabi

ਜੇ ਤੁਹਾਨੂੰ ਇਹ ਜਾਣਕਾਰੀ ਕਿਸੇ ਹੋਰ ਰੂਪ ਵਿਚ, ਜਿਵੇਂ ਪੜ੍ਹਨ ਵਿਚ ਆਸਾਨ ਰੂਪ ਜਾਂ ਕਿਸੇ ਦੂਜੀ ਭਾਸ਼ਾ ਵਿਚ, ਚਾਹੀਦੀ ਹੈ ਤਾਂ ਕਿਰਪਾ ਕਰਕੇ ਸਾਨੂੰ ਦੱਸੋ।

ਜੇ ਤੁਹਾਨੂੰ ਦੁਭਾਸ਼ੀਏ ਦੀ ਜਾਂ ਸਹਾਇਤਾ ਦੀ ਲੋੜ ਹੈ ਤਾਂ ਕਿਰਪਾ ਕਰਕੇ ਸਾਨੂੰ ਦੱਸੋ।

Romanian

Dacă aveți nevoie de informații în alt format, ca de exemplu caractere ușor de citit sau altă limbă, vă rugăm să ne informați.

Dacă aveți nevoie de un interpret sau de asistență, vă rugăm să ne informați.

Traditional Chinese

如果您需要以其他方式了解信息，如易读或其他语种，请告诉我们。

如果您需要口译人员或帮助，请告诉我们。