Leicestershire Partnership NHS
NHS Trust

Unlicensed medicine or off-label use - what does it mean?



Patient information leaflet

Email: feedback@leicspart.nhs.uk
Website: www.leicspart.nhs.uk

Background

In order to protect the public, all medicines marketed in the UK must first obtain a product licence. A product licence is given when a medicine can be proven to be effective, acceptably safe and good quality. A product licence will stipulate the medical condition(s) the medicine may be used for, at what dose(s) and at what age(s).

What is off-label use?

This term is used when a medicine has a UK product licence but is being used in a way that is not stated in the product licence (for example the medicine is being used for a different medical condition, at different dose(s) or at different age(s)).

What is an unlicensed medicine?

It is simply a medicine that does not have a product licence in the UK (however, the product may have a licence in its country of origin). It therefore **may** not have the same level of guarantee of effectiveness, safety and quality compared to a medicine that has a product licence in the UK.



Is a medicine that is unlicensed or off-label safe?

The healthcare professional, in discussion with you, will carefully consider the risks and benefits to ensure that it is the best option for you. Over the decades, we have developed a wealth of knowledge about using medicines that are unlicensed and off-label. National experts have written text books which are regularly updated to guide healthcare professionals in making their decision. Furthermore, for unlicensed medicines, the pharmacy has a duty to ensure that it purchases a good quality product on your behalf.

Why is a medicine that is unlicensed or off-label used?

It is not always possible to meet your medical needs with a licensed medication and in accordance with its product licence. In these cases a healthcare professional, in discussion with you, may consider using an unlicensed medication or a medication off-label.

Where can I find out more?

You will be provided with a patient information leaflet which will tell you more about the medication, how to take it and its side effects. Talk to your doctor or pharmacist for more detailed information.

Can I renew my prescription with my GP?

Not all medicines that are unlicensed or used off-label can be obtained from your GP. The healthcare professional prescribing the medicines will tell you how to obtain a further supply.

If you need this information in another language or format please telephone 0116 295 0903 or email: Patient.Information@leicspart.nhs.uk

Arabic

إذا كنت في حاجة إلى قراءة هذه المعلومات بلغة أخرى أو بتنسيق مختلف، يرجى الاتصال بهاتف رقم 0116 295 0903 أو إرسال بريد إلكتروني إلى: Patient.Information@leicspart.nhs.uk

Bengali

যদি এই তথ্য অন্য কোন ভাষায় বা ফরমেটে আপনার দরকার হয় তাহলে দয়া করে 0116 295 0903 নম্বরে ফোন করুন বা Patient.Information@leicspart.nhs.uk ঠিকানায় ই-মেইল করুন।

Traditional Chinese

如果您需要將本資訊翻譯為其他語言或用其他格式顯示，請致電 0116 295 0903 或發電子郵件至：Patient.Information@leicspart.nhs.uk

Gujarati

જો તમારે આ માહિતી અન્ય ભાષા અથવા ફોર્મેટમાં જોઇતી હોય તો 0116 295 0903 પર ટેલિફોન કરો અથવા Patient.Information@leicspart.nhs.uk પર ઇમેઇલ કરો.

Hindi

अगर आप यह जानकारी किसी अन्य भाषा या प्रारूप में चाहते हैं तो कृपया 0116 295 0903 पर हमें फोन करें या Patient.Information@leicspart.nhs.uk पर हमें ईमेल करें

Polish

Jeżeli są Państwo zainteresowani otrzymaniem niniejszych informacji w innym języku lub formacie, prosimy skontaktować się z nami telefonicznie pod numerem 0116 295 0903 lub za pośrednictwem poczty elektronicznej na adres: Patient.Information@leicspart.nhs.uk

Punjabi

ਜੇ ਤੁਹਾਨੂੰ ਇਹ ਜਾਣਕਾਰੀ ਕਿਸੇ ਹੋਰ ਭਾਸ਼ਾ ਜਾਂ ਫਾਰਮੈਟ ਵਿਚ ਚਾਹੀਦੀ ਹੈ ਤਾਂ ਕਿਰਪਾ ਕਰਕੇ 0116 295 0903 ਤੇ ਟੈਲੀਫ਼ੋਨ ਕਰੋ ਜਾਂ ਇੱਥੇ ਈਮੇਲ ਕਰੋ: Patient.Information@leicspart.nhs.uk

Somali

Haddii aad rabto in aad warbixintan ku hesho luqad ama nuskhad kale fadlan soo wac lambarka 0116 295 0903 ama email u dir: Patient.Information@leicspart.nhs.uk

Urdu

اگرآپ کو یہ معلومات کسی اور زبان یا صورت میں درکار ہوں تو براہ کرم اس ٹیلی فون نمبر 0116 295 0903 یا ای میل پر رابطہ کریں Patient.Information@leicspart.nhs.uk

Date implemented: March 2015 Last reviewed: May 2015 Review date: May 2017
Leaflet No. 363 - Edition 2