

UNLICENSED MEDICINES

Information for adult patients and their carers

You will have been given this leaflet by your doctor or pharmacist because one of your prescribed medicines is not 'licensed' or is being used for a reason not covered by the licence.

Most medicines used in the UK have a licence that says exactly how the medicine should be used. However, this licence may not include use in a particular illness or condition.

This leaflet explains what we mean by the unlicensed use of a medicine, why medicines are licensed and why some useful medicines do not have licences.

Throughout this leaflet we refer to doctors as being the people who prescribe your medicine. It is important to remember that many healthcare professionals in the UK can prescribe medicines and might be responsible for your health care. This includes nurses, pharmacists, dentists and optometrists. They are sometimes collectively called 'prescribers'.

What is a licence?

A drug company must have a licence to promote a medicine.

The licence states:

- which illness(es) the medicine can be used for
- what doses (how much) can be used
- how the medicine should be given (e.g. by mouth, by injection)
- which group of patients it can be used for.

To get a licence, the drug company must prove that the medicine works and that it is safe to use, by testing it during clinical trials. Trials are almost always done with adults first.

A clinical trial is a test of the medicine. A clinical trial may be used to test how much of the medicine to give to a patient, if it works, or how safe it is. All clinical trials are carefully regulated in the UK.

What do we mean by unlicensed use?

Most licences for medicines are given after trials have shown they are effective and safe for use in adults.

After a medicine has been used for some time in adults, doctors – and other prescribers – will know more about how it works and its possible side-effects (effects that we don't want).

Once the medicine has been shown to work in adults, your doctor may want to use it to help other illnesses or conditions, or in other groups of patients, for example, elderly patients or children.

If a medicine is used in a way that is different from that described in its licence, this is called 'unlicensed' or 'off licence' use. This includes giving a medicine in a way that is different from that described in the licence.

Here are some examples of unlicensed uses:

- use of a licensed medicine for an age group that is not covered by its licence
- use of a licensed medicine for an illness that is not included in its licence
- use of a medicine that is only available from abroad and has to be imported (it may have a licence in other countries)
- use of a medicine that needs to be made specially because it cannot be obtained easily; for example, a patient may not be able to swallow a tablet or capsule (which is licensed) and needs a liquid (unlicensed) version of the medicine. Many medicines that are widely used are unlicensed. This gives doctors more choice about which medicine to use than if they could only use licensed medicines.

How do I know whether a medicine is unlicensed or being used off-label?

- Your doctor or pharmacist may tell you that the medicine is not licensed or the leaflet that comes with the medicine may not say anything about its use in your condition or your age group.
- This does not mean that it cannot be used safely for you – it means that the drug company does not have a licence for use of the medicine for your specific circumstances and so is not allowed to promote or give information about this use.
- If you want to know whether a medicine is unlicensed or off-label, ask your doctor, nurse or pharmacist.

How do I know that an unlicensed or off-label medicine is safe and will work?

Unlicensed or off-label medicines are only prescribed after careful consideration of other options available. Your doctor will have read information from medical publications supporting its use, and may have taken advice from other experts. An unlicensed or off-label medicine will only be used if it is the most appropriate medicine for you and your illness or condition.

Are there side-effects from using unlicensed medicines?

- Your doctor will tell you about any expected common side-effects that you may get.
- There may, sometimes, be other side-effects that are not known. If you notice anything unusual and are concerned, contact your doctor, nurse, pharmacist or the person who prescribed the medicine.
- You can also report any suspected side-effects to a UK safety scheme at: <http://www.mhra.gov.uk/yellowcard> .

What if I have more questions about my unlicensed or off-label medicines?

Talk it over with your doctor (or pharmacist) and tell them what you are worried about. They can tell you more about the information or advice that they have about the medicine. They can also tell you about any other treatments available and why they think this is the best one.

If you require information in an accessible format, such as large print or braille, or in a community language, please use the contact details on your patient information leaflet or letter, or talk to a member of staff.

Jeśli potrzebujesz informacji w specjalnym formacie, np. drukowanych dużą czcionką lub pisanych brajlem, czy też w języku, jakim posługuje się społeczność, skorzystaj z danych kontaktowych na ulotce informacyjnej lub w liście informacyjnym dla pacjenta, albo porozmawiaj z jednym z naszych pracowników.

如果您需要我们以其他可阅读格式为您提供信息，如，大字体、盲文版或其他族群语言版本，请按患者信息数据或信函上提供的方式联系我们，或者告知我们的工作人员。

ਜੇਕਰ ਤੁਸੀਂ ਜਾਣਕਾਰੀ ਨੂੰ ਵਿਕਸੇਵਰਤਣਯੋਗ ਪ੍ਰਾਰੂਪ ਵਿੱਚ, ਜਿਵੇਂ ਕਿ ਵੱਡੇ ਅੱਖਰ ਜਾਂ ਬ੍ਰੇਲ ਵਿੱਚ, ਜਾਂ ਵਿਕਸੇਸਮਾਜਕ ਬੋਲੀ ਵਿੱਚ ਚਾਹੁੰਦੇ ਹੋ ਤਾਂ ਵਿਰਧਾ ਕਰਕੇ ਮਰੀਜ਼ ਜਾਣਕਾਰੀ ਨਾਲ ਸਬੰਧਿਤ ਤੁਹਾਡੇ ਦਸਤੀ ਇਸ਼ਤਿਹਾਰ ਜਾਂ ਪੱਤਰ ਵਿੱਚ ਵਿੱਤੀ ਸੰਪਰਕ ਵੇਰਵਿਆਂ ਦੀ ਵਰਤੋਂ ਕਰ, ਜੋ ਜਾਂ ਅਮਲੇ ਦੇ ਵਿਕਸੇਸਮਾਜਕ ਨਾਲ ਗੱਲ ਕਰੇ।

إذا أنت ترغب في الحصول على المعلومات ب تنسيق يسهل الاطلاع عليه، على سبيل المثال طبعة أبيرة أو بطريقة بريل أو بلغة محليّة، يرجى استخدام تفاصيل الاتصال بالموضحة على نشرة معلومات المريض أو الخطاب موزع علينا، الخاص بك، أو تحدث إلى أحد

اگر آپ کو معلومات کی قابل سہولت اشد کمال جیسے واضح چھپائی یا بریل، یا کسی قومی زبان میں ضرورت ہیں تب براہ کرم آپ کے معلوماتی دستی اشد تیار یا خط براہ مریض میں دی گئی رابطہ کی تفصیلات کا استعمال کریں، یا عملہ کے کسی ایک فرد سے ب