

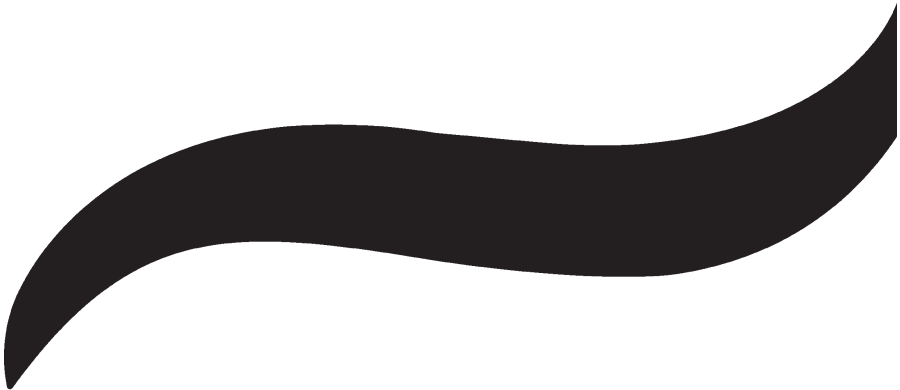


Unlicensed Medicines

Information for patients, relatives and carers

Introduction

You have been given this leaflet because a medicine you have been prescribed is not licensed in the UK. We hope it will answer any questions you might have.



What are licensed medicines?

We need to make sure that medicines given to people in the UK are safe. There are strict rules that all medicines in the UK have to follow. These are set by the Medicines and Healthcare Products Regulatory Authority (MHRA). The company that makes the medicine must show it works and is safe for people to take. When the company can do this they are given what's called a marketing authorisation or product licence. This means the medicine can be legitimately used to treat a medical condition.

What are unlicensed medicines?

You might be given a medicine that is not licensed in the UK yet. This is because the person prescribing it believes it will work well for your condition or illness and that it will have more benefits than risks. The medicine might not have a license because:

- ❖ it does not have UK marketing authorisation. For example, you might need it in a formulation that it's not licensed for. It could be that someone needs the medicine as a liquid because they can't swallow tablets very well, but only the tablets are licensed. In that case, we may use an unlicensed liquid medicine.
- ❖ no companies sell the medicine in the UK, or it is not classed as a medicine
- ❖ it is still going through clinical trials

Why would I be prescribed an unlicensed medicine?

The person prescribing you the medicine will usually try to use a licensed medicine first. Sometimes though, they might think that an unlicensed medicine is needed to give you the best possible treatment.

How do I know an unlicensed medicine is safe?

You will only be given an unlicensed medicine after the person prescribing it has carefully thought about all the other options. They will make sure there is good evidence from medical research to show that the medicine can help you. They might also speak to other experts and get their advice. You will only be prescribed the unlicensed medicine if they think it's the best choice for you and your illness or condition.

All medicines can have side effects. In the UK, companies who make medicines must include a leaflet to tell you what the medicine does and what side effects there might be. If you are given an unlicensed medicine you may find that the leaflet isn't written in English. Or, it might not match your illness or condition. If this happens, your medical team will give you another leaflet or information sheet.

There might be side effects that no-one knows about yet. If you notice anything strange or you're worried about something you should tell your doctor, nurse, pharmacist or the person who prescribed it to you. You can also report any side effects to the UK safety scheme: <http://www.mhra.gov.uk/yellowcard>

Can I refuse to take an unlicensed medicine?

You will have been given an unlicensed medicine because the person prescribing it believes it's the best treatment for you. They've looked carefully at the medical evidence before deciding this. If you're not happy about it you should speak to your doctor, nurse or pharmacist to see what other options there might be for you. You might need to sign a consent form before you can start taking some unlicensed medicines. Even if you do sign the form, you can change your mind later.

How do I find out more about my unlicensed medicine?

If you have any questions or you're worried, then please say to the person prescribing the medicine. 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 for you.

If the leaflet that comes with your medicine does not have information about your condition, please ask your prescriber or pharmacist. If the information is in another language, they will try and get an English translation for you. If there isn't a leaflet about your condition your prescriber or pharmacist may put some information together for you. You could also ask them for support groups and websites where you can learn more about your illness or condition.

Confidentiality and the use of patient information

NHS Lanarkshire take care to ensure your personal information is only accessible to authorised people. Our staff have a legal and contractual duty to keep personal health information secure, and confidential. In order to find out more about current data protection legislation and how we process your information, please visit the Data Protection Notice on our website at www.nhslanarkshire.scot.nhs.uk or ask a member of staff for a copy of our Data Protection Notice.

If you want an existing patient leaflet translated please email patientinformation@lanarkshire.scot.nhs.uk

If you want anything else translated e.g. a patient letter or patient record please email translationservices@lanarkshire.scot.nhs.uk



www.careopinion.org.uk

Pub. date:	April 2025
Review date:	April 2027
Issue No:	01
Department:	Pharmacy Services
Clinical Lead:	