



## Pharmacy Department

# Unlicensed Medicines (Adults)

### Why have I been given this leaflet?

You will have been given this leaflet by your doctor, nurse or pharmacist because you have been prescribed a medicine that does not have a licence or is being used off-label.

Off-label use means that the medicine is not licensed for treatment of your condition, but the medicine will have a licence to treat another condition, and will have undergone clinical trials for this.

Your doctor will have thought carefully about which medicine is best for you in your situation and there is evidence to support the safe use of the medicine. The side effects are no greater than licensed alternatives.

### Why do medicines have a licence?

In the UK all medicines undergo a process of strict checks (such as clinical trials) to ensure the medicines are safe and effective. The Medicines and Healthcare products Regulatory Agency (MHRA) grants a Product Licence for a medicine when it passes such checks. The Product Licence for a medicine (also known as the “Marketing Authorisation”) will be specific for treating a particular condition or range of conditions.

### What is a clinical trial?

To be sure that a medicine works and is safe, it is first used in a small number of people in what is called a ‘clinical trial’. Information from clinical trials is given to the MHRA when the manufacturer asks for a ‘Product Licence’.

### When and why is an unlicensed medicine used?

Your doctor may have prescribed an unlicensed medicine for you if:

- There is evidence that this medicine would work for your condition, even though it is licensed for a different condition
- The medicine is not available in the UK and we have purchased it from another country (with equivalent UK standards of licensing)
- The medicine is normally available in one form, such as a tablet, but the doctor thinks a liquid form is required, which is made up as a “special” medicine, so is also unlicensed
- The medicine is used for a rare illness and has no licence at all.

**The Pharmacy Department will ensure that the medicine has been manufactured to a good standard and is of an acceptable quality.**

## **How will I know that my medicine is unlicensed?**

Your doctor will explain if a medicine is unlicensed, discuss side effects with you and have received your informed consent.

## **What if I do not want to take unlicensed medicines?**

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

## **Can I get more information about my unlicensed medicine?**

Your pharmacist may have a special information leaflet about your medicine or illness. Please ask. Often there are support groups for people with a particular illness or condition. Ask your doctor, nurse or pharmacist for information.

## **How do I obtain a further supply of an unlicensed medicine?**

If you require a further supply of an unlicensed medicine, please go back to your original prescriber to obtain a prescription. It is important that you do not let your supply run out and unlicensed medicines may be more difficult to obtain. Please allow at least seven days to obtain a further supply.

It is important that you take the medicine as directed on the label. Please keep all medicines out of the reach of children. If you have any side effects or concerns, please discuss with the doctor responsible for your care.

## **Contact Numbers:**

If you have any further questions about your medicine after you have left the hospital please:

**Telephone the hospital pharmacy: 01305 255294**, Monday to Friday 09:00am to 5:00pm  
**or Speak to your Community Pharmacist**

## **About this leaflet:**

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If you have feedback regarding the accuracy of the information contained in this leaflet, or if you would like a list of references used to develop this leaflet, please email [pals@dchft.nhs.uk](mailto:pals@dchft.nhs.uk)



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