Unlicensed medicines: A guide for patients

You may have been prescribed a medicine that is “unlicensed”. To help you understand what this means, we have given you this leaflet which answers some of the most frequently asked questions. 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?
In the UK all medicines undergo a process of checks (such as clinical trials) to ensure that they are safe and effective. The Medicines and Healthcare Products Regulatory Agency grants licences for medicines when they pass such checks in this country.

The licence (also known as the “Marketing Authorisation”) for a medicine will be specific for treating a particular condition or range of conditions.

When and why is an “unlicensed” medicine used?
Your doctor may have prescribed an unlicensed medicine for you if:

- they believe that this medicine would work well for your condition even though it is licensed for a different condition – when a medicine is used for a condition not stated in its licence, it is said to be “unlicensed”

- the medicine is not available in the UK and we have to get it from another country which has similar high standards of licensing as the UK

- the medicine is normally available in one form, such as a tablet, and your doctor thinks that a liquid form is better for you – this will have to be made up as a “special” medicine, so it will be “unlicensed”

- they have chosen to use a product that is safe but may not be classified as a medicine and so would not have been through the medicine licensing process.

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.
If this medicine works for me, why isn’t it licensed?
There are various reasons why the medicine you have been prescribed may not be licensed at this time. It could be because the number of patients with the same condition is too small for full clinical trials to be conducted. It is also possible that the licensing process is underway for this medicine, but this takes some time to complete.

What does this mean for me?
Your doctor will consider the medical evidence available when prescribing an unlicensed medicine. All medicines can have side effects. In the UK, all manufacturers have to include an information leaflet about their licensed medicine. If the medicine you are taking is not licensed for your particular condition, the information leaflet may not include details of how the medicine may affect you.

Where can I find out more?
If the leaflet that comes with your medicine does not relate to your condition, please ask your doctor or pharmacist for more information. If the medicine comes from another country and the packaging is not in English, we may have information that is translated into English, so please ask us if this has not been included with your medicine. We also have leaflets on a range of conditions and medicines – please ask us for one of our patient information leaflets if you would like to read more.

There are many support groups that can provide information to patients, and there may be one for your particular condition. Please tell your doctor or pharmacist if you would like more information and they will be able to direct you to the right place.

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.

How do I obtain more of this unlicensed medicine?
If you need to continue with your medicine after leaving the hospital, the hospital doctor may ask your GP to prescribe it for you. Your GP will then give you a prescription, which you will need to take to your community pharmacist in order to get your medicine. If your GP is unable to do this for any reason, or if the pharmacist is unable to get hold of the unlicensed medicine, the hospital will continue to supply it for you.

It is important that you always take the medicine as directed on the label. If you have any side effects or concerns, you should discuss them with the doctor responsible for your care.

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Date: ____________________
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 a Medicines Information (MI) team member who is better able to answer your questions.

Please contact the Pharmacy Medicines Helpline on 020 7188 8748 (Monday to Friday, 9am to 5pm).

For more information leaflets on conditions, procedures, treatments and services offered at our hospitals, please visit www.guysandstthomas.nhs.uk/leaflets

Pharmacy Medicines Helpline
If you have any questions or concerns about your medicines, please speak to the staff caring for you or call our helpline.
  t: 020 7188 8748 9am to 5pm, Monday to Friday

Your comments and concerns
For advice, support or to raise a concern, contact our Patient Advice and Liaison Service (PALS). To make a complaint, contact the complaints department.
  t: 020 7188 8801 (PALS)  e: pals@gstt.nhs.uk
  t: 020 7188 3514 (complaints)  e: complaints2@gstt.nhs.uk

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:
  t: 020 7188 8815  e: languagesupport@gstt.nhs.uk

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.
  t: 111

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

Get involved and have your say: become a member of the Trust
Members of Guy's and St Thomas' NHS Foundation Trust contribute to the organisation on a voluntary basis. We count on them for feedback, local knowledge and support. Membership is free and it is up to you how much you get involved. To find out more, and to become a member:
  t: 0800 731 0319  e: members@gstt.nhs.uk  w: www.guysandstthomas.nhs.uk/membership