Unlicensed medicines: a guide for patients

You may have been prescribed a medicine that is ‘unlicensed’. This leaflet will answer some of your questions. If you would like more information about your medicine, please speak to your doctor or pharmacist.

Why do medicines have a licence?
In the UK all medicines go through checks (such as clinical trials) to make sure that they are safe and effective. The Medicines and Healthcare products Regulatory Agency grants licences for medicines when they pass all the checks.

The licence (also known as 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 might 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 one – when a medicine is used for a condition not stated in its licence, it is called 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, why isn’t it licensed?
There are different reasons why a medicine you have been prescribed might 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 you?
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 might not include details of how the medicine might affect you.

Where can you 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 might have the same information in English, so please ask us if it 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 leaflets or search our website if you would like to read more.

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

What if you 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 other options and we can discuss these with you if you choose not to take this unlicensed medicine.

How do you get more of this unlicensed medicine?
If you need to continue with your medicine after leaving the hospital, the hospital doctor might ask your GP to prescribe it for you. Your GP will give you a prescription, which you will need to take to your community pharmacist to get your medicine. If your GP cannot do this for any reason, or if the pharmacist cannot 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 looking after you.

The unlicensed medicine you have been given today is .............................
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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 might refer you to a medicines information (MI) team member who can answer your questions in detail.

Please contact the Pharmacy medicines helpline, tel: 020 7188 8748, Monday to Friday, 9am-5pm, or email: mymedicines@gstt.nhs.uk.

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

Your comments and concerns
For advice, support or to raise a concern, contact our Patient Advice and Liaison Service (PALS), tel: 020 7188 8801, email: pals@gstt.nhs.uk. To make a complaint, contact the complaints department, tel: 020 7188 3514, email: 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, tel: 020 7188 8815, email: languagesupport@gstt.nhs.uk

NHS 111
This service offers medical help and advice from fully trained advisers supported by experienced nurses and paramedics. Available over the phone 24 hours a day, tel: 111, web: www.111.nhs.uk

NHS website
This website gives information and guidance on all aspects of health and healthcare, to help you take control of your health and wellbeing, web: 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, please get in touch, tel: 0800 731 0319, email: members@gstt.nhs.uk, web: www.guysandstthomas.nhs.uk/membership

Was this leaflet useful?
We want to make sure the information you receive is helpful to you. If you have any comments about this leaflet, we want to hear from you. Fill in our simple online form, web: www.guysandstthomas.nhs.uk/leaflets, or email: patientinformationteam@gstt.nhs.uk

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