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.

Notes

Contact details

If you would like any further information, please contact your Doctor or Pharmacist.

Alternatively, you can contact the Medicines Information Department on **01483 464120** or email **rsc-tr.medicinesinformation@nhs.net**

PALS and Advocacy contact details

Contact details of independent advocacy services can be provided by our Patient Advice and Liaison Service (PALS) who are located on the right hand side as you enter the main reception area. PALS are also your first point of contact for health related issues, questions or concerns surrounding RSCH patient services.

Telephone: 01483 402757

Email: rsc-tr.pals@nhs.net

Opening hours: 9.00am–3.00pm
Monday to Friday

If you would like information documents in large print, on tape or in another language or form please contact PALS.

Past review date: N/A
Future review date: January 2021
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PIN171220–1423

The Information Standard
Certified Member

NHS
Royal Surrey County Hospital
NHS Foundation Trust

Unlicensed Medicines

Pharmacy Department

The Unlicensed Medicine you have been given is:

Patient information leaflet

You have been prescribed a medicine in a way that is not covered by its UK marketing license. This is known as an unlicensed medicine. This information leaflet answers some of the more frequently asked questions about unlicensed medicines. If you would like to discuss this further, please speak to your doctor or pharmacist.

What is a medicine license?

In the UK, drug companies have to prove that their medicine is made to a high standard. Their medicine also has to undergo a system of checks to prove that it is safe and effective. Before approval, the drug is assessed in clinical trials, usually in adults aged 18-65.

Information from the trials is given to the Medicines and Healthcare Products Regulatory Agency (MHRA) who approves licenses for medicines.

What is meant by unlicensed or 'off-label use'?

These terms are used when a medicine is used in a way that is different to what is stated in the product license. This can be broadly divided into two groups:

'Unlicenced' medicines have no UK license at all. This can be for a range of reasons, including:

- they are licensed in other countries
- they are still in clinical trials but have been shown to be of benefit
- they are re-made so the medicine is easier for the patient to take, for example liquids made from tablets.
- they are rarely used and therefore it would be difficult to enlist enough participants onto a clinical trial to get a licence.

'Off-label' means that the medicine is licenced in the UK. It is, however, also used for illnesses, conditions, diagnostic tests or age groups not covered by the license.

What other terms mean unlicensed?

You may also hear the following terms used to describe different unlicensed medicines:

- 'special' (medicine made by a company for a specific patient)
- 'import' (an imported medicine that is usually licensed for use in the country it is manufactured in)
- 'off-licence' is another term meaning 'off-label'.

Why are children's medicines often unlicensed?

To get a medicine license, the drug company has to show the MHRA information from clinical trials. Usually these are only done in adults. To promote the use of a medicine in children, the drug company would have to do clinical trials involving children. This very rarely happens.

In some cases, doctors may choose a medicine which is unlicensed for a child. This may be because:

- there is not a licensed medicine for the condition
- the unlicensed medicine has advantages over a licensed one.

How will I know if my medicine is unlicensed?

Your doctor or pharmacist will tell you if the medicine you are prescribed is unlicensed.

Please be aware that the information leaflet which you are given with the medicine may not include use in your condition.

You should still read the leaflet as it will give general information which may be important.

Is this medicine safe?

Unlicensed medicines are only prescribed after the doctor has thought about the other licensed options.

How do I get further supplies?

If you need to continue with your medicine after leaving the hospital, your hospital doctor will continue to prescribe it. This will be dispensed by the outpatient pharmacy at the Royal Surrey County Hospital NHS Foundation Trust only.