Unlicensed medicines

Why have I been given this leaflet?

You have been prescribed a medicine that is either not licensed in the UK or has been prescribed for a dose or illness that the medicine is not licensed for.

Whilst this leaflet does not provide specific information about the medicine you have been prescribed, it does try to explain why you have been prescribed an unlicensed medicine and try to alleviate any concerns.

What is an unlicensed medicine?

Each medicinal product manufactured by a pharmaceutical company requires its own unique product licence before it can be sold in the UK. The license is approved or denied by the MHRA (The Medicines and Healthcare products Regulatory Agency).

The product you have been prescribed may be unlicensed because:

- Illness treated has not been investigated thus not covered by the product licence;
- Dose or formulation of drug prescribed is not covered by the product licence.
- You may be outside the age bracket tested in clinical trials (most clinical trials are run recruiting patients aged between 18 & 65), therefore most medicines prescribed for children are unlicensed;
- The licensed product is unavailable and a suitable substitute has to be imported from outside of the UK;
- The pharmaceutical company have not sought a product licence due to a low market in the UK (rarity of condition treated or abundance of other licensed treatments).
Generally due to the lower demand the pharmacy would not stock the item and have to order it. Obtaining the item may take up to 10 working days as the item may be manufactured on order or has to be imported from outside the UK.

**More Information**

If you do not understand the information provided with your medicine, or would like an English translation, please phone the NBT Medicines Helpline. This advice line is for patients only and relates to information about medicines prescribed for you by the hospital.

NHS Constitution. Information on your rights and responsibilities. Available at [www.nhs.uk/aboutnhs/constitution](http://www.nhs.uk/aboutnhs/constitution)

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**How to contact us:**

NBT Medicines Helpline  
Monday to Friday  
9am to 4.30pm  
0117 414 2284

medicines-information@nbt.nhs.uk

www.nbt.nhs.uk

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If you or the individual you are caring for need support reading this leaflet please ask a member of staff for advice.

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