# Patient Information Leaflet

# Use of Unlicensed (Special) and Off-label Medicines

## What is this leaflet about?

You have been given this leaflet because a medicine you have been prescribed does not have a licence, known as a marketing authorisation, issued by the Medicine and Healthcare Products Regulatory Agency (MHRA). Or alternatively, you have been prescribed a medicine that is being used in a way that is different to that described in the licence i.e. off-label. **This leaflet is intended to reassure you that we have thought very carefully about the best medicine for you** and to help answer any questions that you may have. Please talk to your doctor or pharmacist if there is anything further that you would like to know.

Pharmaceutical companies must hold a marketing authorisation for each medicine that they sell in the United Kingdom. The MHRA issue these licences only after they have assessed information on the quality, safety and efficacy of the medicine.

## Why are some medicines not licensed or are used outside of their licence?

There are a number of reasons why the medicine may be used off-label or not be licensed, for example:

- The medicine may only be available from abroad and needs to be imported
- Limited data is available for treating certain conditions
- The medicine needs to be made specially
- The medicine has a licence but is administered in an unlicensed manner. For example, crushing tablets to allow for safe swallowing.

## Why have I been given a special or off-label medicine?

You have been prescribed a special or off-label medicine because no suitable licensed alternative is available to treat your condition. However, the person treating you will have thought very carefully about prescribing the most appropriate medicine for you and its use will be reviewed on a regular basis.

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## Should I be worried about taking special or off-label medicines?

The prescriber will have explained to you why they think that this medicine is the right one for you. If you are worried about taking this medicine, talk to your doctor or pharmacist about your concerns. They may be able to give you further information or help to put you in touch with a support group for your illness or condition.

If you do experience any unpleasant or unexpected effects whilst taking the medicine, you should report this to your doctor or pharmacist.

## What else do I need to know?

Sometimes it will take longer to order in special medicines. In which case, you will need to allow one or two weeks to obtain further supplies of your medicine. You should bear this in mind, if you need to get a repeat prescription from your doctor.

Occasionally special medicines have a short expiry date, please check before administering and ordering.

## Where can I get more information?

If you would like to discuss any information contained in this leaflet, please speak to a pharmacist or contact your GP. Alternatively, you can contact Patient Advice and Liaison Service (PALS) PALS on 08003896819 or Email PALS@Suffolk.nhs.uk.

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