



The British Pain Society

Use of medicines outside of their UK marketing authorisation in pain management and palliative medicine – information for patients

This is a consensus document prepared on behalf of the British Pain Society in consultation with the Association for Palliative Medicine of Great Britain and Ireland.

September 2012

To be reviewed in 2017

Published by:

The British Pain Society

3rd floor

Churchill House

35 Red Lion Square

London WC1R 4SG

Website: www.britishpainsociety.org

ISBN: 978-0-9561386-3-7

© The British Pain Society 2012

This leaflet explains how some medicines are used differently to how they were originally developed and approved. Sometimes there are clinical situations when the use of medicines outside the terms of their licence ('off-label') or the use of unlicensed medicines may be judged to provide you with the best or most suitable treatment.

An example of this is your medicine

Which is being given to you for

How are medicines licensed for use?

In the UK, a medicine must have a licence, also called a marketing authorisation (MA), before it can be used to treat patients. The licence outlines what conditions the medicine is to be used for, what the doses should be and any precautions for its use. The licence is also confirmation that the medicine has been tested for safety and is of an appropriate quality. However, the licence does not prevent a doctor from prescribing the medicine for other uses as long as the doctor is satisfied that it is effective and safe in those circumstances.

Why may I be prescribed an off-label or unlicensed medicine?

Sometimes evidence shows that a medicine can also be used in circumstances outside of its original licence.

Who can prescribe off-label or unlicensed medicines?

Doctors can prescribe both off-label and unlicensed medicines. In certain circumstances they can also be prescribed by some nurses and pharmacists who have had specific training. Pharmacists can dispense them and nurses can give them to patients.

What differences might I notice if I am prescribed or supplied with an off-label or unlicensed medicine?

In certain settings, because off-label or unlicensed medicines are so often prescribed, it may not be always highlighted to you. However, at other times, your doctor or pharmacist will point out that you are being given an off-label or unlicensed medicine, explain why it is the preferred treatment and discuss its safety and effectiveness with you. If you are given any further written information, please read it carefully.

You may notice that a manufacturer's information leaflet supplied with the medicine is not specific to you. For example, you may notice that it does not include information about the condition for which you are being treated, or about the use of the medicine in children, or it may state a dose that is different from that which the doctor has prescribed.

A common example of this is the use of certain antidepressant medicines to treat pain. These have a licence for the treatment of depression but not pain and so the information leaflet enclosed with the medicine does not refer to pain.

What should I do if I have any concerns about the off-label or unlicensed medicine I have been given?

Whether within licence or not, whoever prescribes you the medicine should also provide you with a clear explanation of the medicine, including how to take it, the expected benefits and possible side effects.

If you experience a side effect from any medicine, you should first tell your doctor or other member of the health-care team. You are also encouraged to report any side effects using the Yellow Card Scheme – go to www.mhra.gov.uk to find out more.

What do I do if I want more information?

Please talk to your doctor or pharmacist. They are knowledgeable and experienced with medicines and will be pleased to answer your questions. In particular, get in touch with them if you have any worries or concerns about any medicine, are not sure about any information or directions you have been given, or just want more information.

Your prescriber's contact details are:

.....

.....

Members of the working group

Chairs

Dr William Campbell, *Consultant in Pain Medicine, Anaesthesia & Intensive Care and member of the British Pain Society*

Dr Andrew Wilcock, *Macmillan Reader in Palliative Medicine and Medical Oncology and member of the Association for Palliative Medicine of Great Britain and Ireland*

Members

Prof. Sam Ahmedzai, *Professor of Palliative Medicine and member of the British Pain Society and the Association for Palliative Medicine of Great Britain and Ireland*

Dr Nick Allcock, *Associate Professor of Nursing and member of the British Pain Society*

Dr John Goddard, *Consultant in Pain Medicine & Paediatric Anaesthesia and member of the British Pain Society*

Dr Roger Knaggs, *Associate Professor in Clinical Pharmacy Practice and member of the British Pain Society*

Dr Mick Serpell, *Consultant & Senior Lecturer Pain Medicine & Anaesthesia and member of the British Pain Society*

Nia Taylor, *Patient representative*



THE BRITISH PAIN SOCIETY

Churchill House - 35 Red Lion Square
London WC1R 4SG UK

www.britishpainsociety.org
info@britishpainsociety.org

*A company registered in England and Wales and limited by guarantee.
Registered No. 5021381. Registered Charity No. 1103260.
A charity registered in Scotland No. SC039583*