

Resource

## Co-Proxamol

The licence for co-proxamol was withdrawn in 2007, but for a small number of patients already taking the drug and who did not respond well to a suitable alternative, it continues to be prescribed on a named patient basis.

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### Update, March 2016:

Please note, the contract for the supply of Co-Proxamol on a named-patient, or unlicensed, basis is no longer being produced by Clinigen. Here are the names of the companies that we know are currently supplying this drug (as of March 2017):

Creo Pharma: 0844 879 3188

Ennogen: 01322 629220

### Update August 2009:

There has been some confusion recently surrounding the availability of co-proxamol, due to a recommendation from the EMEA (European Medicines Agency) to ban products containing Dextropropoxyphene. However, the MHRA (Medicines and Healthcare products Regulatory Agency) have already taken these steps in the UK when the license was revoked on Co-proxamol in December 2007. At this point, Co-proxamol became unlicensed and only available on a named patient basis. This has reportedly been very successful in reducing suicides, and the EMEA would like all European countries to follow suit. This will not affect the supply in the UK.

### Taken from NRAS magazine: Winter 2008

Following a decision by the Medicines Healthcare and Regulatory Authority (MHRA) the licence for co-proxamol was withdrawn from the market at the end of 2007. However, it is still available on a named patient basis to those who were unable to find a suitable alternative. From calls to our helpline, we know that some people had difficulty in obtaining supplies.

In order to clarify the situation in regard to the UK market, we recently met with Clinigen who have the licence to supply 'unlicensed' co-proxamol.

We can confirm that Co-proxamol will continue to be available on a named patient basis as an

unlicensed product. To clarify the situation, Clinigen have given us the following statement:

## STATEMENT FOR PATIENT ORGANISATIONS

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Co-proxamol (Distalgesic) available from Clinigen

Co-proxamol (Distalgesic), used for pain relief, is available from Clinigen on a 'named patient' or unlicensed basis. This follows restrictions placed on the supply of co-proxamol at the end of December 2007 by the Department of Health's regulatory body, the Medicines and Healthcare products Regulatory Agency (MHRA).

Clinigen is a specialist provider of unlicensed/specialist medicines, and it has the required licenses and processes approved by the MHRA to provide co-proxamol

(Distalgesic) to patients through local pharmacies.

If a doctor decides that there is no appropriate licensed pain relief medicine suitable for a patient, then he/she can issue a prescription for co-proxamol. A pharmacist can order co-proxamol directly from Clinigen and will explain to the patient that the medicine is being provided as an unlicensed product.

The MHRA is encouraging the controlled provision of co-proxamol to ensure that patients who need the medicine are provided with verified, quality product from an approved company.

The Medicines and Healthcare regulatory position on the withdrawal of co-proxamol

Taken from NRAS magazine: Autumn 2007

As reported in earlier editions of the newsletter, the committee on safety medicines advised, in 2005, that co-proxamol should be withdrawn from the market on the grounds that the benefits of taking co-proxamol are not considered to outweigh the risks.

The withdrawal has been gradual, and it will cease to be available on normal prescriptions at the end of 2007.

However, the MHRA has issued a statement saying:

We recognise, however, that there is a small group of patients who are likely to find it very difficult to change; when alternatives appear not to be effective or suitable. For these patients, continued provision of co-proxamol through normal prescribing may continue until the cancellation of the licences at the end of 2007. After this time there is a provision for the supply of unlicensed co-proxamol, on the responsibility of the prescriber. Patients wishing to go down this route should discuss this possibility with their doctor.

The withdrawal of co-proxamol has been raised in the House of Commons, by Anne Begg MP, who put forward the concerns of many patients and consultants who believe that co-proxamol is the most

effective treatment for some people with chronic pain; however, the MHRA statement above remains the latest guidance issued.

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