

**Position statement on the prescribing of co-proxamol**

**NYCCG does not support the routine prescribing of co-proxamol for any indication in line with NHS England’s national guidance on medicines which should no longer be routinely prescribed.**

**Background**

Co-proxamol is used to treat mild to moderate pain and consists of a combination of two active ingredients, dextropropoxyphene (a weak opioid) and paracetamol.1 The paracetamol contained in each tablet is at a lower dose (325mg) than in standard OTC preparations (500mg) .1

Licensed co-proxamol was fully withdrawn from the market in December 2007 on the advice of the Committee on Safety of Medicines (CSM) amid serious safety concerns in January 2005. The Medicines and Healthcare Regulatory Agency (MHRA) provided a number of alternative pain management strategies for mild to moderate pain.1

Co-proxamol is now an unlicensed medicine obtained from specific suppliers and this incurs variable and significantly high costs. NYCCG spent exactly £13,556 between January to June 2021, which equates to £27k per annum. Vale of York spent £6,572 in the 12 months of July 2020 to June 2021.

**Key points**

• The lethal dose of co-proxamol is relatively low and can be potentiated by alcohol and other CNS depressants. Death from co-proxamol overdose can occur rapidly, even before hospital treatment can be received.1 The risk of dying after co-proxamol overdose is 2.3 times that for tricyclic antidepressants and 28.1 times that for paracetamol.1

• Co-proxamol is an unlicensed medicine so all prescribing responsibility rests solely with the prescriber.1 If the GP does decide to take on prescribing they should consider the GMC guidance around prescribing unlicensed medicines. <http://www.gmcuk.org/guidance/28349.asp>

• There is no robust clinical evidence that co-proxamol is more effective than full strength paracetamol in either acute1,2 or chronic use.1

• There is a risk of addiction and abuse associated with co-proxamol.1

• No patient group has been identified in which the risk vs. benefit ratio of using co-proxamol is positive.1

• Clinical data from America has shown that dextropropoxyphene can have serious effects on the electrical activity of the heart even at normal therapeutic doses.1

• Compound analgesic preparations that contain a simple analgesic (such as paracetamol) with an opioid component reduce the scope for effective titration of the individual components in the management of pain of varying intensity.3

**Recommendations1**

New patients:

• **No new patients should be started on co-proxamol**.3, 4

Existing patients:

1. Undertake a review of co-proxamol therapy as part of the chronic pain management review and consider changing them to alternative pain management strategies.1

* Consider a change from co-proxamol to full strength paracetamol where clinically appropriate.1
* If paracetamol on its own is ineffective, the addition of codeine1 might be beneficial.
* Utilise the support of relevant services to facilitate this change, such as local pain teams.

2. Co-proxamol should not be used for any acute pain indication or in patients under 18 years of age.1

3. Co-proxamol is contraindicated in certain groups of people and so should not be prescribed for:

* Patients who are alcohol-dependent or who are likely to consume alcohol whilst taking co-proxamol1
* Patients who are suicidal or have history of addiction1

In exceptional cases if continuing treatment:

Document clinical reason(s) for continuing to prescribe co-proxamol and efforts made to switch to suitable alternatives.

* Highlight co-proxamol’s potential for serious cardiac side-effects, even at therapeutic doses, and make patient aware of the symptoms and what to do if they experience any of them. Document this in the patient notes.
* If, in exceptional circumstances, there is a clinical need for co-proxamol to be prescribed in primary care, this should be undertaken in a cooperation arrangement with a multi-disciplinary team e.g local chronic pain team, and/or other healthcare professional and your local CCG Medicines Management Team. 4
* The prescriber should consider discussing the specific details of the case with their medical defence organisation to provide support and evidence of robust consideration of the case.

**Guidance for patients currently taking co-proxamol** 5

* The license for co-proxamol was withdrawn globally in 2005 due to concerns about the high incidence of suicide. From 1997 to 1999 in England and Wales, 18% of drug-related suicides involved co-proxamol; these constituted 5% of all suicides. The toxic effects of dextropropoxyphene (an ingredient in co-proxamol) on your breathing or heart function are usually the cause of death.
* Death from co-proxamol overdose can occur rapidly, even before hospital treatment can be received. The risk of dying after co-proxamol overdose is significantly higher than for paracetamol.
* The risk of overdose can extend to others in the household of the person for whom the drug is prescribed.
* There is significant difference in the cost to the NHS of co-proxamol compared to paracetamol and other pain killers. It can cost up to 50 times more than paracetamol.
* Your doctor will review your co-proxamol pain killers with you and try to change them to a safer alternative medicine. A patient information leaflet is available: <https://www.prescqipp.info/items-which-should-notroutinely-be-prescribed-patient-leaflets>

**References**

1. PrescQIPP NHS Bulletin Co-proxamol Bulletin B194 January 2018 2.0 <https://www.prescqipp.info/umbraco/surface/authorisedmediasurface/index?url=%2fmedia%2f1241%2fb194-co-proxamol-20.pdf>

2. Co-proxamol or paracetamol for acute pain? Drug and Therapeutics Bulletin, vol 36 No 10 October 1998.

<https://dtb.bmj.com/content/36/10/80> accessed 1st August 2016

3. Dextropropoxyphene: new studies confirm cardiac risks. Drug Safety Update 2011; 4 (6). <https://www.gov.uk/drugsafety-update/-dextro-propoxyphene-new-studies-confirm-cardiac-risks> accessed 16 August 2016

4. NHS England/ NHS Clinical Commissioners - Items which should not routinely be prescribed in primary care: A Consultation on guidance for CCGs

 <https://www.england.nhs.uk/wp-content/uploads/2017/07/Items-not-routinely-prescribed-in-primary-care.pdf>

5. PrescQIPP: Patient information – Changes to co-proxamol prescribing

<https://www.prescqipp.info/umbraco/surface/authorisedmediasurface/index?url=%2fmedia%2f1392%2fpatient-information-changes-to-co-proxamol-prescribing.pdf>