

# Position statement on the prescribing of co-proxamol

# SW London CCGs\* do 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

\*\*Co-proxamol is used to treat mild to moderate pain and is a combination of two active ingredients: dextropropoxyphene (a weak opioid) and paracetamol.

## Rationale

- The licence for co-proxamol was withdrawn globally in 2005 due to concerns about the high incidence of suicide.<sup>1</sup> 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 on respiration or cardiac function are usually the cause of death.<sup>2</sup>
- The paracetamol content in each tablet is lower dose (325mg) than in standard OTC preparations (500mg). There is no robust evidence that co-proxamol is more effective than full strength paracetamol used alone in either acute or chronic use.<sup>3</sup>
- No patient group has been identified in which the risk: benefit ratio of using coproxamol is positive.<sup>3</sup>
- The advantages of using compound analgesic preparations have not been substantiated. The addition of a low dose of an opioid can result in opioid side-effects (e.g. constipation) and can complicate treatment of overdose without any additional pain relief. The elderly are particularly susceptible to the side effects of opioids.<sup>4</sup>
- There is a risk of addiction and abuse associated with co-proxamol.
- Clinical data from the USA has shown that dextropropoxyphene can have serious effects on the electrical activity of the heart even at normal therapeutic doses.<sup>5</sup> The lethal dose of co-proxamol is relatively low and can be potentiated by alcohol and other CNS depressants.<sup>5</sup>
- 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 of co-proxamol compared to paracetamol and other compound analgesics. As it is unlicensed the price is variable and can cost up to 50 times more than paracetamol.

#### References

- 1. MHRA Safety warnings, alerts and recalls for medicines: Co-proxamol. <u>https://www.gov.uk/drug-safety-update/co-proxamol-withdrawal-reminder-to-prescribers</u>
- Office for National Statistics. Statistical Bulletin, 29th August 2012. Deaths Related to Drug Poisoning in England and Wales, 2011. Accessed: 05/02/13. <u>http://www.ons.gov.uk/ons/dcp171778\_276681.pdf</u>
- The withdrawal of co-proxamol: alternative analgesics for mild to moderate pain. MeRec Bulletin; 2006; 16 (4) 5.
  (Dextro)propoxyphene: new studies confirm cardiac risks. Drug Safety Update 2011; 4 (6): H1
- http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON105759
- 5. Simkin, S., Hawton, K., Sutton, L., et al. Co-proxamol and suicide: preventing the continuing toll of overdose deaths. Quarterly Journal of Medicine 2005; 98: 159-170. <u>http://qimed.oxfordjournals.org/content/98/3/159.2.full</u>

Further information available from:

- NHS England. Items which should not routinely be prescribed in primary care: Guidance for CCGs. https://www.england.nhs.uk/publication/items-which-should-not-be-routinely-prescribed-in-primary-care-guidance-forccgs/. Updated November 2017.
- PrescQIPP Bulletin 42 Reviewing existing co-proxamol patients. <u>https://www.prescqipp.info/resources/send/90-co-proxamol/658-reviewingexistingco-proxamolpatientsbulletinv20</u>

<sup>\*</sup>SWL CCGs (NHS Croydon CCG, NHS Kingston CCG, NHS Merton CCG, NHS Richmond CCG, NHS Sutton CCG and NHS Wandsworth CCG) position statement on co-proxamol

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# Guidance for clinicians on reviews and prescribing alternative analgesia

### **Recommendations:**

- No new patients should be started on co-proxamol.
- Co-proxamol should not be used for any acute pain indication.
- Co-proxamol should not be used in patients under 18 years of age.
- Co-proxamol is contra-indicated in particular 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-proxamol.
  - Patients who are suicidal or have history of addiction.
- Carry out a review of patients still being prescribed co-proxamol with a view to changing to an alternative pain management regime.
- Inform the patient of the risks of serious cardiac side-effects with co-proxamol, even at therapeutic doses, and make the patient aware of the symptoms and what to do if they experience any of them.

### Therapeutic alternatives

Consider changing from co-proxamol to paracetamol 500mg tablets at a dose of 1g four times a day. If paracetamol on its own is ineffective, the addition of codeine phosphate might be beneficial. The codeine dosing as per the BNF recommends a dose of 30-60 mg every 4 hours when necessary, to a maximum of 240 mg daily for mild to moderate pain. This dose will need to be reduced in patients with hepatic or renal impairment. It also warns that codeine is too constipating for long-term use.

Alternatively, and if safe and appropriate, consider a switch from co-proxamol to co-codamol 8mg/500mg tablets. Bear in mind that the elderly are more susceptible to the side-effects of opioids.

### Guidance for patients currently taking co-proxamol, carers and guardians

- 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 on respiration or cardiac 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 of co-proxamol compared to paracetamol and other compound analgesics. As it is unlicensed, the price is variable and can cost up to 50 times more than paracetamol.
- Your doctor will review your pain killers and change them to a safer alternative medicine.

A patient information leaflet is available: <u>https://www.prescqipp.info/items-which-should-not-routinely-be-prescribed-patient-leaflets</u>

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