

## Co- Proxamol (paracetamol 325mg and dextropropoxyphene 32.5mg) Tablets Area Prescribing Committee Position Statement

*The prescribing of co-proxamol tablets is not supported by Barnsley Area Prescribing Committee (APC). Co-proxamol has a grey non formulary classification.*

*In line with NHS England guidance:*

- No new patients should be initiated on co-proxamol.*
- Patients currently prescribed co-proxamol should have their prescription reviewed and co-proxamol should be deprescribed in all patients.*

Co-proxamol tablets are included in the NHS England guidance '**Items which should not routinely be prescribed in Primary Care**' with no exceptions.<sup>1</sup>

**The use of co-proxamol is associated with significant safety concerns.**<sup>1,2</sup>

In Barnsley, primary care expenditure on co-proxamol tablets between March 2021 and February 2022 was approximately £55K.

The Medicines Management Team can support primary care prescribers in reviewing patients and deprescribing co-proxamol tablets.

### Background<sup>1</sup>

**Co-proxamol** was a pain-killer which was previously licensed in the UK until being fully withdrawn from the market in 2007 due to **safety concerns**.<sup>3</sup> All use in the UK is now on an **unlicensed** basis. Since 1985 advice aimed at the reduction of **co-proxamol toxicity and fatal overdose** has been provided, but this was not effective and subsequently resulted in withdrawal of co-proxamol by the **MHRA**. Since the withdrawal, further safety concerns have been raised which have resulted in co-proxamol being withdrawn in other countries.

### Rationale for switching from co-proxamol to an alternative pain medicine<sup>2</sup>

- There is **no robust clinical evidence** that co-proxamol is more effective than full strength paracetamol in either acute or chronic use.
- There is a **risk of addiction and abuse** associated with co-proxamol.
- No patient group has been identified in which the risk: benefit ratio of using co-proxamol is positive.
- 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>4</sup>
- 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. The risk of dying after co-proxamol overdose is 2.3 times that for tricyclic antidepressants and 28.1 times that for paracetamol.
- The risk of overdose can extend to others in the household of the person for whom the drug is prescribed.
- Co-proxamol is an **unlicensed medicine** so all prescribing responsibility rests solely with the prescriber. If the GP does decide to take on prescribing he/she should consider the GMC guidance around prescribing unlicensed medicines, <https://www.gmc-uk.org/guidance/28349.asp>

## Deprescribing<sup>2</sup>

- Discuss **alternative analgesic options** for mild-moderate pain with the patient and come to a joint decision about which option is best to relieve the patient's pain.
- Consider a **switch** from co-proxamol to **paracetamol 500mg tablets** at a dose of 1g four times a day. Care should be taken when deciding on a dose of oral paracetamol for patients weighing less than 50kg. A maximum total daily dose of 2-3g may be warranted, particularly in the frail elderly population.<sup>5</sup>
- If paracetamol on its own is ineffective, the addition of **codeine phosphate** at a '**when required**' dose might be beneficial.
- For codeine phosphate, the BNF recommends a dose of 30-60 mg every four hours when necessary, to a maximum of 240mg 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 frail elderly are more susceptible to the side-effects of opioids.
- If the patient has been taking co-proxamol on a regular basis for a long period of time, the patient may experience opioid withdrawal symptoms if switched to paracetamol. Consider prescribing codeine phosphate in addition to paracetamol in these patients. The dose of codeine phosphate can then be reduced slowly to avoid opioid withdrawal symptoms. Barnsley Recovery Steps (01226 779066) can support clinicians and patients when reducing opioids.
- Alternatively consider **non-drug treatments**.
- It is important to ensure that a patient has a **wider pain management strategy** in place that is not solely reliant on medication.
- A **patient information leaflet** explaining the changes to co-proxamol prescribing is available: <https://www.prescgipp.info/resources/category/414-items-which-should-not-routinely-be-prescribed-in-primary-care-patient-leaflets>
- **If a patient is unable to stop co-proxamol, refer them to a specialist for a review of their pain management and support to switch to suitable alternatives.**

## Costs

Co-proxamol price comparison with other analgesics for mild to moderate pain (Drug Tariff April 2022)

| Product                          | Cost per 100 tablets   |
|----------------------------------|--|
| Co-proxamol 32.5mg/325mg tablets | As co-proxamol is an unlicensed medicine, it has to be obtained from specific suppliers and prices vary considerably. It also incurs out-of-pocket expenses.<br><br>In Barnsley the average cost of 100 co-proxamol tablets between March 2021 and February 2022 was £245. |
| Paracetamol 500mg tablets        | £2.41  |
| Codeine phosphate 30mg tablets   | £3.54  |
| Co-codamol 8mg/500mg tablets     | £3.70  |

## References

1. NHS England guidance 'Items which should not routinely be prescribed in Primary Care: Guidance for CCGs'. Version 2, June 2019. Available at: <https://www.england.nhs.uk/publication/items-which-should-not-be-routinely-prescribed-in-primary-care-guidance-for-ccgs> Accessed <20.04.2022>
2. PrescQIPP CIC Drugs to Review for Optimised Prescribing – Co-proxamol. January 2018. Available at: <https://www.prescgipp.info/media/1241/b194-co-proxamol-20.pdf> Accessed <27.04.22>
3. MHRA Drug Safety Update 2014. Available at: <https://www.gov.uk/drug-safety-update/co-proxamol-withdrawal-reminder-to-prescribers> Accessed <27.04.22>
4. MHRA Drug Safety Update 2014. Available at: <https://www.gov.uk/drug-safety-update/-dextro-propoxyphene-new-studies-confirm-cardiac-risks> Accessed <27.04.22>
5. Barnsley Guidance for Oral Paracetamol Dosing. January 2022. Available at: <http://best.barnsleyccg.nhs.uk/clinical-support/medicines/prescribing-guidelines/Oral%20Paracetamol%20Dosing.pdf> Accessed <27.04.22>