PAN MERSEY APC

PAN MERSEY AREA PRESCRIBING COMMITTEE
PRESCRIBING POLICY STATEMENT
APC BOARD DATE: 31 OCT 2018

NHS
Pan Mersey
Area Prescribing Committee

CO-PROXAMOL tablets

BLACK

The Pan Mersey Area Prescribing Committee does not recommend the prescribing of CO-PROXAMOL tablets.

The NHS England document 'Items which should not routinely be prescribed in primary care: Guidance for CCGs' contains the following advice.[1]

Recommendation	• Advise CCGs that prescribers in primary care should not initiate co-proxamol for any new patient. • Advise CCGs to support prescribers in deprescribing co-proxamol in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.
Annual Spend (National)	£9,002,824 (NHS Digital)
Background and Rationale	Co-proxamol was a pain-killer which was previously licensed in the UK until being fully withdrawn from the market in 2007 due to safety concerns. 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 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 Since the withdrawal, further safety concerns have been raised which have resulted in co-proxamol being withdrawn in other countries. Due to the significant safety concerns, the joint clinical working group considered co-proxamol suitable for inclusion in this guidance.
Further Resources and Guidance for CCGs	MHRA Drug Safety Update: November 2007, January 2011 PrescQIPP CIC Drugs to Review for Optimised Prescribing – Co-proxamol Patient information leaflets: https://www.prescqipp.info/items-which-should-not-routinely-be-prescribed-patient-leaflets

Note: Patients who are not eligible for treatment under this statement may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy. In this situation, follow locally defined processes.

CO-PROXAMOL tablets

DE-PRESCRIBING SUPPORT INFORMATION

- Prescribers may wish to use the NHS England Patient Information Leaflet available at patient-information-changes-to-co-proxamol-prescribing to support their discussions with patients.
- Co-proxamol is an unlicensed analgesic, containing paracetamol 325mg and dextroproxyphene 32.5mg.
- It was withdrawn from the UK market on the advice of the Committee on Safety of Medicines amid serious safety concerns in January 2005.[2]
- In 2009, the European Medicines Agency's Committee for Medicinal Products for Human Use concluded that the benefits of dextropropoxyphene do not outweigh its risks and recommended that all marketing authorisations should be withdrawn throughout the European Union.[2]
- New clinical data in 2011 from the USA showed that dextropropoxyphene can have serious effects on the electrical activity of the heart (resulting in prolongation of the P-R and Q-T intervals, and widened QRS complexes), even at normal therapeutic doses. Products containing dextropropoxyphene were withdrawn from the US Market and the Federal Drug Administration advised healthcare professionals to stop prescribing dextropropoxyphene.[2]
- There is no robust evidence that co-proxamol is more effective than full strength paracetamol used alone in either acute or chronic use.[2]
- There is a risk of addiction and abuse associated with co-proxamol.[2]
- The paracetamol contained in each co-proxamol tablet is at a lower dose (325mg) than in standard paracetamol preparations (500mg).
- 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 greater than for tricyclic antidepressants and 28.1 times greater than for paracetamol.[2]
- The lethal dose of co-proxamol is relatively low and can be potentiated by alcohol and other central nerve depressants.[2]
- The cost of prescribing co-proxamol as an unlicensed 'special' is significantly higher than the licensed cost-effective alternatives. The average cost per item in Pan Mersey is £132.61

DISCONTINUATION AND SWITCHING INFORMATION

- Patients should be reviewed. Their pain and its management should be assessed and if medication is still required they should be switched to an alternative.[2]
- The risk of addiction, withdrawal and abuse should be assessed. Further advice is available from CCG Medicines Management Teams.
- Alternatives include co-codamol and co-dydramol or paracetamol plus codeine phosphate when required.
- Detailed information on reviewing existing co-proxamol patients is available in the PresQIPP co-proxamol bulletin (subscription required) or from CCG Medicines Management teams.

REFERENCES

1. NHS Clinical Commissioners. Items which should not routinely be prescribed in primary care: Guidance for CCGs. NHS England Gateway Publication 07448. Document first published 30/11/17. https://www.england.nhs.uk/publication/items-which-should-not-be-routinely-prescribed-in-primary-care-guidance-for-ccgs/ Accessed 9/8/18
2. PresQIPP bulletin 194i. Reviewing existing co-proxamol patients. PrescQIPP Reviewing existing co-proxamol patients 2018. Accessed 8/8/18 (subscription required)