Co-Proxamol

For pain management

Commissioning Statement

Fylde and Wyre Clinical Commissioning Group has agreed not to fund the prescribing of Co-Proxamol for pain.

- This is in line with the Medicines and Healthcare products Regulatory Agency's announcement in January 2005[1].
- No new patients should be started and all existing patients should be reviewed

This medicine is classified as BLACK

Supporting information:

- Co-proxamol is no longer licensed in the UK and is now only available on a named patient basis. Prescribers take on full responsibility for unlicensed medicines.
- Paracetamol has been proven to work as well as co-proxamol and causes fewer side effects. Co-proxamol's opioid based side effects can be more problematic in the elderly.
- Many manufacturers are stopping producing co-proxamol and this is pushing the price up making the products no longer a cost effective option.
- Co-proxamol is used to treat mild to moderate pain and is a combination of two active ingredients dextropropoxyphene (a weak opioid) and paracetamol. The paracetamol content in each tablet is a lower dose (325mg) than in standard preparations of paracetamol (500mg) which have the associated evidence.
- There is no robust evidence that co-proxamol is more effective than full strength paracetamol used alone in either acute or chronic use. No patient group was identified in which the risk:benefit of co-proxamol was positive[2].
- 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.
- Clinical data shows that dextropropoxyphene, even at normal therapeutic doses, has serious effects on the electrical activity of the heart resulting in prolongation of the P-R and Q-T intervals and widening QRS complexes[3].
- The licence was withdrawn for co-proxamol due to concerns about the high incidence of suicide. In England and Wales in 1997–1999, 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 may occur rapidly, the lethal dose can be relatively low, and the effects are potentiated by alcohol and other CNS depressants. The majority of co-proxamol overdose deaths occur before hospital treatment can be received. The risk can extend to others in the household of the person for whom the drug is prescribed. The risk of dying after co-proxamol overdose was 2.3 times greater than for tricyclic antidepressants and 28.1 times greater than for paracetamol.

Since the withdrawal of the licence, the number of deaths associated with co-proxamol has fallen dramatically from 388 in 1999 to 18 deaths in 2011 in England and Wales.

- A six-year follow-up study to the withdrawal of co-proxamol reported in 2012 that there has been a significant reduction in poisoning deaths involving co-proxamol without a significant increase in deaths involving other analgesics, even though prescribing of other analgesics rose[4].
- There is a risk of addiction and abuse associated with co-proxamol.
- Anecdotal evidence suggests that the number of forged co-proxamol prescriptions is on the increase.

For details around the colour classification system please refer to the website of the Lancashire Medicines Management Group at: http://www.lancsmmg.nhs.uk/

References:

1. MHRA Safety warnings, alerts and recalls for medicines: Co-proxamol. http://www.mhra.gov.uk/Safetyinformation/Safetywarningsalertsandrecalls/Safetywarningsandmessagesformedicines/CON1004254
2. The withdrawal of co-proxamol: alternative analgesics for mild to moderate pain. MeRec Bulletin; 2006; 16 (4) 5.
3. (Dextro)propoxyphene: new studies confirm cardiac risks. Drug Safety Update 2011; 4 (6): H1 http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON105759
4. Hawton K, Bergen H, Simkin S, et al. Six-year follow-up of impact of co-proxamol withdrawal in England and Wales on prescribing and deaths: Time-series study. PLoS Med 2012; 9(5): e1001213. http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001213
5. Reviewing existing co-proxamol patients. PrescQIPP Bulletin 42 (briefing) Mat 2013-v 2.0