Unlicensed Co-proxamol (dextropropoxyphene and paracetamol) Prescribing Factsheet

Aim

To undertake a review of patients with chronic pain treated with unlicensed co-proxamol and consider changing them to licensed alternatives.

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in each tablet is at a lower dose (325mg) than in standard OTC preparations (500mg) .[1] Licensed co-proxamol was fully withdrawn from the market in December 2007[1] on the advice of the Committee on Safety of Medicines (CSM) amid serious safety concerns in January 2005.[1] The Medicines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** and it has to be obtained from specific suppliers and this incurring variable and significantly high costs. In 2016/17 Lambeth CCG is projected to spend approximately £80,000 on co-proxamol.[2]

Key points

- Co-proxamol is an unlicensed medicine so all prescribing responsibility rests solely with the prescriber.[1]
- There is no robust clinical evidence that co-proxamol is more effective than full strength paracetamol in either acute[1,3] 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: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]
- 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]
- Anecdotal evidence suggests that the number of forged co-proxamol prescriptions is on the increase.[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.[4]

Recommendations[1]

New patients

- **No new patients should be started on co-proxamol.[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 codeine[1] might be beneficial.
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 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[1]
    - Patients who are suicidal or have history of addiction[1]

In exceptional cases if continuing treatment:

1. Document clinical reason(s) for continuing to prescribe co-proxamol and efforts made to switch to suitable alternatives.[1]
    - 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.[1]
    - Review safe keeping procedures for repeat prescriptions for co-proxamol as the number of forged prescriptions for this drug is on the increase.[1]

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South East London Area Prescribing Committee. A partnership between NHS organisations in South East London: Bexley/ Bromley/ Greenwich/ Lambeth/ Lewisham & Southwark Clinical Commissioning Groups (CCGs) & GSTFT/KCH/SLAM/Oxleas NHS Foundation Trusts & Lewisham & Greenwich NHS Trust

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References

1. PrescQIPP NHS Bulletin Co-proxamol Bulletin 42 version 2.0 May 2013. https://www.prescqipp.info/resources/send/90-co-proxamol/658-reviewingexistingco-proxamolpatientsbulletinv20 accessed 9 March 2016
2. NHSBSA, ePACT local prescribing data for co-proxamol 2015/16. Accessed online at: www.nhsbsa.nhs.uk 1st Febraury 2017
3. Co-proxamol or paracetamol for acute pain? Drug and Therapeutics Bulletin, vol 36 No 10 October 1998. http://dtb.bmj.com/content/36/10/80.full.pdf+html accessed 1st August 2016
4. Dextro(propoxyphene: new studies confirm cardiac risks. Drug Safety Update 2011; 4 (6). https://www.gov.uk/drug-safety-update/-dextro-propoxyphene-new-studies-confirm-cardiac-risks accessed 16 August 2016

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