

Question and Answer Document

CO-PROXAMOL: OUTCOME OF THE REVIEW OF RISKS AND BENEFITS

1 What is co-proxamol?

Co-proxamol is a prescription only medicine used to treat mild to moderate pain. It contains a combination of a low dose of paracetamol (325 milligrams per tablet) and a painkiller called dextropropoxyphene (DXP). (Ordinary paracetamol tablets normally contain 500 milligrams). Several pharmaceutical companies market it as 'Co-proxamol' and it is also marketed under the brand names Distalgesic, Cosalgesic and Dolgesic.

2 What is the problem with co-proxamol?

There is little evidence that co-proxamol is more effective in treating pain than normal paracetamol in the recommended dose. Around 300-400 self-poisoning deaths each year, of which around a fifth are accidental, involve co-proxamol. Prescribers are aware of the serious risks to patients who exceed the recommended dose on co-proxamol. The MHRA has conducted a review of the risks and benefits of co-proxamol and the Committee on Safety of Medicines (CSM) has advised that the balance of risks and benefits of co-proxamol is unfavourable.

3 What was the outcome of the review of the use of co-proxamol and request for information on risk: benefit?

The CSM, the independent expert body which advises the government on medicines, has considered the responses to the public request for further information on the risks and benefits of co-proxamol. After careful consideration, the CSM has advised that co-proxamol should be withdrawn from the market on the grounds that the benefits of taking co-proxamol are not considered to outweigh the risks.

4 If co-proxamol has been available for over 40 years, why has action only been taken now?

Co-proxamol has been marketed since the 1960's, and was firmly established as a treatment for mild to moderate pain before modern standards of clinical research. Current evidence is that previous advice in 1985 to strengthen warnings about co-proxamol overdose has not impacted on the problem.

5 When will co-proxamol be withdrawn from the market?

Co-proxamol will be phased out of the market place gradually to give patients time to discuss their treatment with their doctor and change to a suitable alternative. The Committee on Safety of Medicines (CSM) advised that the

withdrawal of co-proxamol should be phased over a period up to 36 months or to an earlier timetable to be agreed with Marketing Authorisation (MA) holders. Most MA holders have indicated they intend to withdraw co-proxamol over a period of approximately 6-12 months. A few MA holders, have however, indicated that their current plans are to phase the withdrawal until the end of 2007 to meet remaining demand depending on their stock situation. Over the phased withdrawal period we expect the prescribing of co-proxamol to decline as patients are transferred to suitable alternatives. As more data are gathered over the coming months on the uptake and continued patient need for co-proxamol, we will be better placed to predict the final date for withdrawal.

6 What about patients who have not managed to find suitable alternatives?

There are a number of alternatives to co-proxamol and the MHRA has issued CSM pain management guidance to help doctors find suitable alternatives for individual patients. There may, however, be a minority of patients at the end of the phased withdrawal period who are unable to use alternatives. For this group of patients, the provision would remain for the supply of unlicensed preparations. Individual patient use of preparations of co-proxamol could continue with the responsibility for that use falling primarily on the prescriber.

7 How will patients who use co-proxamol now treat their conditions?

There are a number of options for managing painful conditions and CSM has recently issued advice. There is no need for urgent medical advice – patients taking co-proxamol can have the management of their treatment reviewed at their next routine check.

8 If the CSM has advised that co-proxamol should be withdrawn from the market why is it not being done immediately - is it safe for me to carry on taking medicines containing co-proxamol until it is no longer available?

The CSM advised that co-proxamol should be phased out over a period of time rather than withdrawn from the market immediately, to give patients currently taking the medicine time to discuss their medication with their doctor and move to a suitable alternative. No medicine is absolutely free of possible side-effects. It is important that you:

- Only take the medicine if it has been prescribed for you
- Always read the patient information leaflet supplied with your medicine and follow the instructions carefully
- Do not take more than the recommended dose
- Never take it with alcohol, sedatives, tranquillisers or other medicines containing paracetamol
- Store your medicine out of the sight and reach of children and adolescents
- Destroy any unused tablets or return them to your pharmacist as soon as possible

9 Is it safe to stop co-proxamol straight away? What else can I take?

If you have been taking co-proxamol continuously for a long time, you should not stop without consulting your doctor. If you only take co-proxamol intermittently, there is no problem with stopping straight away. Remember to destroy any unused supplies or return them to the pharmacist as soon as possible. There are other medicines available with or without prescription that do not contain the ingredient dextropropoxyphene (DXP). Your pharmacist or doctor can advise you on the choice available.

10 How can I get further information?

For further information call: NHS Direct on 08 45 46 47.

MHRA
July 2005