Dextropropoxyphene-containing medicines to be withdrawn

Medsafe has announced that all medicines that contain dextropropoxyphene (Paradex and Capadex) will soon be withdrawn from the New Zealand market. This follows a review of their safety and effectiveness which showed that their risks outweighed their possible benefits. Similar actions have been taken in the UK, Europe and Singapore.

The actual date for withdrawal has not yet been set and preparations will remain available for several months to allow patients to be changed to alternative medicines. Prescribers have been asked not to start any new patients on Paradex or Capadex and to review the analgesic requirements of those currently taking them.

Most patients can be transferred to full doses of paracetamol alone. If pain relief is not sufficient, the next step is to add a weak opioid such as codeine (or use a combined paracetamol/codeine preparation). Alternatively, codeine alone could be trialled.

Oxycodone should not be prescribed in place of dextropropoxyphene unless there has been inadequate response to a weak opioid such as codeine. Oxycodone is a strong opioid and is only indicated as an alternative to morphine at step three on the WHO analgesic ladder.

For more information on the findings of the safety review see:
www.medsafe.govt.nz/hot/media/2010/paradexandcapadex.asp

Sibutramine (Reductil) withdrawn from European markets

European Medicines Agency recommend the suspension of marketing authorisations for sibutramine

In January 2010 the European Medicines Agency recommended the suspension of marketing authorisations for sibutramine following a safety review that found the risks of the medicine outweighed the benefits. The review was initiated due to the results of the Sibutramine Cardiovascular OUTcomes (SCOUT) trial which showed a 16% rise in the risk of serious, non-fatal cardiovascular events, such as stroke or myocardial infarction with the use of sibutramine.[1]

The SCOUT trial

The six-year SCOUT trial involved nearly 10,000 patients who were aged 55 years or older, overweight or obese, and had a history of cardiovascular disease or type 2 diabetes plus one additional cardiovascular risk factor. In Europe (and New Zealand) sibutramine is contraindicated in patients with known cardiovascular disease, and treatment duration in the study was longer than usually recommended. Therefore the use of sibutramine in this trial was not in accordance with prescribing information.

The European Medicines Agency noted that while sibutramine was used outside its licence in this study, the data from SCOUT was relevant for the use of sibutramine in clinical practice, because obese and overweight patients are likely to have a higher risk of cardiovascular events. In addition, they found that the weight loss achieved with the use of sibutramine was only modest, with patients losing on average two to four kilograms more than those taking a placebo. Therefore they have advised that doctors should no longer prescribe and pharmacists should no longer dispense sibutramine and patients taking it should consult their doctor.[1]

The FDA decide to leave sibutramine on the market but with additional contraindications

The US Food and Drug Administration (FDA), in comparison, have decided to leave sibutramine on the market but with additional contraindications. Sibutramine drug information in the US will now list a history of cardiovascular disease as a contraindication. Previously this information was provided as a warning. The reason the FDA gave for its decision, was that additional data from SCOUT indicate that the increased risk for cardiovascular events with sibutramine, occurred only in patients with a history of cardiovascular disease. The FDA has stated that it will issue further advice about sibutramine once a full review of the SCOUT trial is completed in March 2010.[2]

Medsafe are reviewing the balance of risks and benefits of using sibutramine

In New Zealand, sibutramine is available on prescription with the contraindication of cardiovascular disease. Medsafe has stated that it is now reviewing the balance of risks and benefits of using sibutramine in light of the new study results and will also be seeking expert advice from the Medicines Adverse Reaction Committee (MARC).

Prescribers are reminded that sibutramine is contraindicated in New Zealand in patients with a

history of coronary artery disease, congestive heart failure, tachycardia, peripheral arterial occlusive disease, arrhythmia or stroke.[3]

Further information about the pharmacological treatment of obesity will appear in a future edition of Best Practice Journal.

References:

1. European Medicines Agency. European Medicines Agency recommends suspension of marking authorisations for sibutramine. Press release 21/1/10. Available from: www.ema.europa.eu (Accessed January, 2010).
2. U.S. Food and Drug Administration. Follow-Up to the November 2009 early communication about an ongoing safety review of sibutramine, marketed as Meridia. Press release 21/1/10. Available from: www.fda.gov (Accessed January, 2010).
3. Medsafe. Sibutramine/Reductil. Media release 22/1/10. Available from: www.medsafe.govt.nz/hot/media/2010/sibutramine.asp (Accessed January, 2010).

Mirtazapine newly funded on special authority

Mirtazapine is a medicine used to treat depression. It has recently become funded on Special Authority in New Zealand.

To meet the Special Authority criteria for funding the patient must have severe depression, and have been unable to tolerate or have failed to respond to, two different antidepressants. Alternatively if the patient has been admitted to hospital with a depressive episode, they can qualify for funded mirtazapine treatment, if they have failed to respond to or have been unable to tolerate one other antidepressant.

Mirtazapine is a noradrenaline and specific serotonin antidepressant. It blocks postsynaptic serotonin 5-HT2 and 5-HT3 receptors and presynaptic central alpha-2 adrenergic inhibitory autoreceptors.[1]

The most common adverse effects of mirtazapine include sedation, weight gain and dry mouth. Sedation appears to be greater at lower doses and may make mirtazapine useful for depressed people also suffering from insomnia. Weight gain may occur because of an increase in appetite associated with mirtazapine. Mirtazapine is thought to cause less sexual dysfunction than SSRIs, TCAs and MAOIs.[1]

Overall, mirtazapine is as effective as other antidepressants, has less drug interactions than SSRIs and may cause less adverse effects, such as sexual dysfunction, leading to fewer patients discontinuing treatment early.[2]

References:

1. Hirsch M, Birnbaum R, Antidepressant medication in adults: MAO inhibitors and others. UpToDate 2009. Available from: www.uptodate.com (Accessed January, 2010).
2. National Institute for Health and Clinical Excellence (NICE). Depression: the treatment and management of depression in adults. NICE, 2009. Available from: www.nice.org.uk (Accessed January, 2010).

Do you have a brilliant idea that you would like to share with your colleagues? Can you tell us about a mistake that you have learnt from so others don't fall into the same trap? What's new in primary care that people would want to know? Share your practice tips with us. Email: **editor@bpac.org.nz**