

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

Questions and Answers

What are NSAIDs?

Non-steroidal anti-inflammatory drugs (NSAIDs) are widely used and important medicines in the treatment of arthritis and many other painful conditions including headache, fever, and minor ailments. There are many medicines in the NSAID class. Some, like diclofenac and naproxen are only available on prescription, whilst ibuprofen can be also be bought in shops and pharmacies.

What are selective COX-2 inhibitors?

COX-2 selective inhibitors (coxibs) are a relatively new type of anti-inflammatory medicine which are thought to produce less in the way of gastrointestinal side effects than older 'non-selective' NSAIDs. Available coxibs include celecoxib (Celebrex), etoricoxib (Arcoxia) and parecoxib (Dynastat – which is given by injection for short-term use in hospitals).

What is the concern about cardiovascular reactions with selective COX-2 inhibitors?

COX-2 selective anti-inflammatory medicines may be useful for some patients, as they are thought cause less harmful gastrointestinal effects than traditional non-steroidal anti-inflammatory drugs (NSAIDs). However, recent evidence indicates that patients treated with selective COX-2 inhibitors may be at a slightly increased risk of heart attacks and strokes. It is not possible to measure the increased risk precisely from the available evidence, but COX-2 inhibitors are unlikely to cause more than one extra heart attack or stroke per 100 patients treated for one year, over the normal risk (not on any treatment).

What about other NSAIDs? Do they have the same cardiovascular (heart disease and stroke) risks as suggested by a new study in the British Medical Journal?

Like all effective medicines, non-steroidal anti-inflammatory drugs (NSAIDs) have the potential to cause side effects in some people. There is less clinical trial evidence available for older NSAIDs, compared to the selective COX-2 inhibitors. Although some evidence (like the new study published in the British Medical Journal) suggests that non-selective NSAIDs might also increase the risk of heart attacks and strokes, it is important to view this in the context of other evidence that does not suggest an increased risk. A full review of all available evidence relating to non-selective NSAIDs is underway in Europe, and the MHRA will issue further advice as necessary, once this review is complete.

The new BMJ study showed an increased risk with ibuprofen – is this medicine safe to be bought over the counter?

Ibuprofen has an excellent safety record which is why it has been made available as an over-the-counter medicine. There are a number of epidemiological studies regarding the cardiovascular safety of ibuprofen. The new BMJ study has limitations as identified by the authors and needs to be viewed in the context of a number of other studies which have not shown an increased risk of MI with ibuprofen. The MHRA is reviewing the new study in the context of all other available evidence and will issue new advice as appropriate.

What advice has the MHRA/CSM given to prescribers and patients about the use of selective COX-2 inhibitors and NSAIDs?

For all NSAIDs including selective COX-2 inhibitors, patients should take the lowest effective dose for the shortest period necessary. Patients with established coronary heart disease or cerebrovascular disease should not take selective COX-2 inhibitors (e.g. celecoxib, etoricoxib). Patients who are concerned should discuss this with their pharmacist or doctor, at a routine appointment.

Why has it taken so long to find out that NSAIDs may cause an increased risk of heart attacks?

The evidence relating to older non-selective NSAIDs is not as clear as that for COX-2 inhibitors. The available evidence is of variable quality and has shown mixed results. However, in light of the recent concerns over COX-2 inhibitors, a major review of the available evidence is underway in Europe. Once this is complete, the MHRA will issue further advice as necessary.