

Drug Safety Update



Latest advice for medicines users

The monthly newsletter from the Medicines and Healthcare products Regulatory Agency and its independent advisor the Commission on Human Medicines

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The Medicines and Healthcare products Regulatory Agency is the government agency which is responsible for ensuring that medicines and medical devices work, and are acceptably safe.

The Commission on Human Medicines gives independent advice to ministers about the safety, quality, and efficacy of medicines. The Commission is supported in its work by Expert Advisory Groups that cover various therapeutic areas of medicine.



The MHRA is accredited by NICE to provide Drug Safety Update. Further information can be found on the NICE Evidence Search portal: www.evidence.nhs.uk/

Prescribing information for etoricoxib (Arcoxia) has been updated to introduce a lower recommended dose of 60 mg daily for patients with rheumatoid arthritis or ankylosing spondylitis. In patients with insufficient relief from symptoms, an increased dose of 90 mg once daily may improve efficacy. However, once the patient is clinically stabilised, down-titration to 60 mg once daily may be appropriate.

Our article this month reminds you that the cardiovascular and other important risks of etoricoxib (Arcoxia) may increase with dose and duration of exposure. Therefore, the lowest effective daily dose should be used, and the need for treatment should be regularly reassessed (see page 2).

Our summary of recent letters to healthcare professionals includes [important information](#) for professionals who specialise in the treatment of epilepsy, informing them of the withdrawal of retigabine (Trobalt) from the market in June 2017. This product is being discontinued because of limited and declining use.

The [letter](#) outlines advice for healthcare providers to begin seeking alternative treatment for affected patients, and to withdraw treatment with a gradual dose reduction over at least 3 weeks. No new patients should start retigabine treatment (page 3).

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Etoricoxib (Arcoxia): revised dose recommendation for rheumatoid arthritis and ankylosing spondylitis

Prescribing information has been updated to introduce a lower recommended dose of 60 mg daily for patients with rheumatoid arthritis or ankylosing spondylitis.

Advice for healthcare professionals:

- the cardiovascular and other important risks of etoricoxib (Arcoxia) may increase with dose and duration of exposure. Therefore, the lowest effective daily dose should be used, and the need for treatment should be regularly reassessed
- the recommended dose is 60 mg once daily
- in patients with insufficient relief from symptoms, an increased dose of 90 mg once daily may improve efficacy
- once the patient is clinically stabilised, down-titration to 60 mg once daily may be appropriate
- in the absence of therapeutic benefit, other treatment options should be considered

Background

Etoricoxib belongs to the selective COX-2 inhibitor class of drugs and may be associated with an increased risk of coronary and cerebrovascular thrombotic events, heart failure, hypertension, and oedema (compared with placebo and some non-steroidal anti-inflammatory drugs).

Other important risks to consider with etoricoxib are effects on the gastrointestinal system, particularly those of perforation, ulceration, or bleeding.

Further information on these risks is described in section 4.4 of the [Summary of Product Characteristics](#).

Following an [EU-wide review](#) in 2008 of the benefits and risks of etoricoxib, the marketing authorisation holder was required to do clinical trials to assess the efficacy and safety of etoricoxib 60 mg once daily for the treatment of [rheumatoid arthritis](#) and [ankylosing spondylitis](#) including comparison with etoricoxib 90 mg.

Trial results

From these trials, there is evidence that the 60-mg dose is effective in rheumatoid arthritis and ankylosing spondylitis. However, for some patients, the 90-mg dose will be more efficacious, although prediction of which patients might benefit from the higher dose is not possible.

Therefore, the recommended starting dose for treatment of rheumatoid arthritis

or ankylosing spondylitis has been reduced to 60 mg once daily, with the option to increase to a maximum of 90 mg once daily if necessary.

Further information

[Letter sent to healthcare professionals](#) in September 2016

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Letters sent to healthcare professionals in September 2016, including retigabine withdrawal

In September 2016, an [important communication](#) was sent to professionals who specialise in the treatment of epilepsy to inform them of the withdrawal of retigabine (Trobalt) from the market in June 2017. This product is being discontinued because of limited and declining use.

The [letter](#) outlines advice for healthcare providers to begin seeking alternative treatment for affected patients, and to withdraw treatment with a gradual dose reduction over at least 3 weeks. No new patients should start retigabine treatment.

In September 2016, letters were also sent for the following medicines:

- [Levonorgestrel-containing emergency hormonal contraception: interaction](#) with hepatic enzyme inducers (see also [September 2016 issue of Drug Safety Update](#))
- [Etoricoxib: revised dose](#) recommendation (see also article, page 2)

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