

Advisory re: Medsafe alert "Arthrem – potential risk of harm to the liver"



www.medsafe.govt.nz/safety/EWS/2018/Arthrem.asp

19 February 2018

THE ISSUE

Late last week Medsafe issued an advisory relating to 14 reports of liver toxicity associated with the use of Arthrem, from February 2016 up until 31 December 2017.

Many of the reports included jaundice as a reaction. Where information was provided (liver function tests and biopsy results), the pattern of liver toxicity was either hepatocellular or mixed (hepatocellular and cholestatic). All the patients stopped taking Arthrem and at the time of reporting most had already recovered or were improving.

Arthrem is a dietary supplement for maintenance and support of healthy joints. It is sold as soft gel capsules that each contain 150 mg extract of *Artemisia annua*, grape-seed oil, glycerine and gelatine.

IS ARTHREM SAFE?

When taken as directed, Arthrem is safe and effective.

Safety is – and has always been - our top priority. That is why Arthrem is the world's only clinically trialled and safety trialled *artemisia annua* joint support product. Both trials were conducted by Otago University, and published in peer-reviewed journals (*Clinical Rheumatology* and *New Zealand Medical Journal*). The clinical trial informed the product formulation and dosage advice. Unlike other *artemisia annua*-based joint support products on the market, Arthrem is formulated deliberately in twice-daily dosages (rather than a larger dose once daily) in order to reduce the risk of toxicity.

There have been an extremely small number of reported cases of adverse reaction. This level of adverse reaction is considered to be very rare by the World Health Organization's adverse reactions guidelines – less than 0.007% of all bottles sold (i.e. under 1 in 14,000).

WHAT WE ARE DOING

Promisia takes this Medsafe Alert very seriously. In addition to communication with pharmacies, retailers and health professionals, we are also taking the following steps:

- Update bottle labelling to note that 'in rare circumstances *artemisia annua* may be associated with liver harm'. Until new labels are available a sticker will be produced and sent to all pharmacies with the above caution.
- Amending the advice provided on our website to note the potential but rare risk of liver harm, identifying potential symptoms including: nausea (feeling sick), stomach pain, pale stools, dark urine, itching all over, the whites of the eyes turning yellow or the skin is yellow (jaundice). In the event of these symptoms being observed the person is advised to stop taking Arthrem and consult their doctor.
- Amending messaging on labels, point-of-sale material, etc., to stress that the product must be taken strictly as directed.
- The amended point of sale material will be included with all product sold via our website

WHAT TO ADVISE CUSTOMERS WHO ARE BUYING OR INQUIRING ABOUT ARTHREM

At the point of sale, please stress the importance of taking Arthrem strictly as directed and to stop taking it immediately if they experience any adverse reactions. Adverse reactions may include (but are not limited to):

- nausea (feeling sick)
- stomach pain
- pale stools
- dark urine
- itching all-over
- the whites of the eyes have turned yellow or the skin is yellow (jaundice)

Remind the customer that this is the case when taking any kind of pharmaceutical medication or natural health remedy.

Please note that it is perfectly safe to keep taking Arthrem provided the person is not suffering adverse effects or has any contraindicated condition/s. Arthrem is not suitable for:

- People who have elevated liver enzymes, liver disease or liver cancer
- Anyone who is pregnant, planning to become pregnant or breastfeeding
- People who are taking antiretroviral drugs for HIV
- Anyone who is taking drugs that are known to prolong QT interval
- Children

FOR FURTHER INFORMATION

Please don't hesitate to contact us on our 24 x 7 toll-free helpline (0800 995 034) if you have any questions or concerns.