

LANDMARK STUDY BACKS NEW-GENERATION IBUPROFEN

New OTC painkiller 'can be considered first-line option' for patient self-management of flaring joint pain

Data from a large-scale, primary care, clinical study is backing the use of lipid-formulation ibuprofen in relieving flaring joint pain.¹ The new formulation is being made available in UK pharmacies today (24 January 2018) under the brand name Flarin®.

Findings from the FLARE* study, recently-published in *Osteoarthritis and Cartilage*, showed lipid-formulated ibuprofen (Flarin®) 1200mg/day to be as effective as prescription-strength ibuprofen (2400mg/day) at relieving flaring joint pain.¹

The double-blind, randomised study involved 462 patients across 27 primary care centres in the UK and the Netherlands and is the first to investigate episodic knee pain flares in primary care patients. It comprised 58.9% males with a mean age of 52.2 years, which is younger than the general osteoarthritis population.¹

According to the researchers, 86% people who took Flarin had an improvement in their flare ups after five days². Patients also reported a reduction in stiffness and swelling.¹

“We now have good clinical evidence to show that combining ibuprofen in a lipid formulation can provide effective flare up control,” says Philip Conaghan, Professor of Musculoskeletal Medicine, University of Leeds, and one of the FLARE study’s authors.

In addition to efficacy, the trial also demonstrated fewer incidences of drug-related adverse GI events with Flarin® than prescription-strength ibuprofen capsules (2400 mg/day).¹ Due to its patented, lipid-formulation technology (which encases ibuprofen in lipids), Flarin® appears to be absorbed through the lymphatic part of the immune system, thus helping to shield the stomach from damage.^{1,3}

“Based on the results of this study, Flarin® can be considered as a first-line OTC treatment option for the self-management of flaring joint pain,” adds Professor Conaghan.

As part of a cost-cutting drive, NHS England has recently outlined plans to restrict OTC prescribing by doctors for self-limiting illnesses – which includes everyday painkillers.⁴

Dr Natalie Carter, head of research liaison and evaluation at Arthritis Research UK said:

“We know that pain management is incredibly important, and believe that all of the 10 million people living with arthritis in the UK have the right to live pain free. We’re really pleased to see more treatment options enter the market for people with arthritis, offering an alternative solution to help manage the daily pain and in this case, potentially reduce side effects.

“We’d encourage anyone struggling with pain management to speak to their doctor or a health professional, who will be able to work with them to develop a plan incorporating medication, pain management techniques and exercise.”

Flarin® 200mg (ibuprofen) soft capsules is a pharmacy-only product available without a prescription and indicated for adults and children over 12 years for the relief of rheumatic or muscular pain, joint pain, back pain, also for the relief of pain of non-serious arthritic conditions. It can also be used for the relief of neuralgia (sharp pain along the nerves), dental pain, period pain, feverishness, as well as cold and flu symptoms. Always read the label.⁵

Flarin® has been developed and is manufactured by UK-based, infirst Healthcare Ltd, and is available in packs of 30 capsules. For more information visit www.flarin.co.uk and www.facebook.com/FlarinUK/

-ends-

Note to editors:

Flarin® 200mg soft capsules will initially be available in LloydsPharmacy stores - and in other pharmacies across the UK from the end of March. Flarin® comes in packs of 30 and retails at £9.95 (equivalent of 33 pence per single capsule or £1.99 per day for the maximum daily dose). It is indicated for adults and children over the age of 12 years. Always read the label.²

About the FLARE* study:

The double-blind, randomised, multicentre **FL**arin **AR**thralgia **RE**lief **E**valuation in episodic knee pain (FLARE) study, recently published in *Osteoarthritis and Cartilage*, demonstrated that combining ibuprofen in a lipid formulation can deliver effective flare-up control.¹

The study was conducted among 462 patients in 27 primary care centres (in the Netherlands and UK). Its primary objective was to determine if a five-day course of lipid formulated ibuprofen

capsules (1200 mg total daily dose) was non-inferior to standard soft gel ibuprofen capsules (1200mg /day or 2400mg/day) for the pain subscale of the WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index).¹

The study comprised 58.9% males with a mean age of 52.2 years, which is younger than the general osteoarthritis population (the most common joint disease) and may represent a population which includes patients with early OA.¹

Treatment allocation comprised 148 patients in the lipid 1200mg/day group, 155 patients in the soft-gel 1200mg/day group, and 159 patients in the soft-gel 2400mg/day group. WOMAC pain subscale scores decreased in all groups, the scores in the lipid 1200mg/day group being non-inferior to soft-gel 1200mg/day group (adjusted mean difference -0.26 [95% CI-0.69, 0.17]) and non-inferior to the soft-gel 2400mg/day group (difference 0.19 [95% CI -0.24, 0.62]). No differences were seen in mean GSRS total scores. NRS secondary endpoints suggested greater improvements (pain, activity, stiffness and swelling) in the lipid 1200mg group compared to soft-gel 1200mg, with similar results to soft-gel 2400mg.¹

Adverse events occurred with lowest frequency in the lipid 1200mg/day (Flarin) group and at highest frequency in the soft-gel 2400mg/day ibuprofen group.¹

The most frequent adverse events (AEs)/drug-related AEs were gastrointestinal (GI) disorders, a known ibuprofen adverse effect. A post-hoc analysis revealed significantly less drug-related GI AEs in the lipid 1200mg/day group (p=0.01) compared to the soft-gel 2400mg group the data generated with the lipid 1200mg/day group indicate the formulation is likely to be gastro-sparing.¹

About Flarin®:

Flarin's active ingredient is 200mg of ibuprofen. Flarin® encases ibuprofen in lipids. Flarin's patented lipid technology is based on complex manufacturing process which involves heating and dissolving specific pharmaceutical grade lipids, ibuprofen and other excipients together in a process lasting three days.

Whilst the mechanism of action for the benefits of the lipid formulation are not yet fully defined, it is known that lipid drug delivery systems are taken up by the gut lymphatic system, which targets the immune system contained within. Theoretically this means there is potential for higher ibuprofen exposure to important lymphatic immune cells which can target sites of pain and inflammation. This potential immune targeting effect could explain the results of the FLARE study where lipid formulated ibuprofen was found to have to have the same effect as high dose non-lipid formulated ibuprofen.^{1,3}

The recommended dose of Flarin® is one or two capsules (200 mg – 400 mg) up to three times a day, as required. Patients should leave at least four hours between doses and not take more than 1200 mg (6 capsules) in any 24- hour period. If symptoms worsen or persist after 10 days, GP advice should be sought. Most patients in the FLARE study used two capsules of Flarin three times a day for five days. For a list of potential side effects or contraindications consult the Flarin® Patient Information Leaflet (PIL).⁵

About Infirst Healthcare Ltd:

Infirst Healthcare is a small, international healthcare company, based in London. It focuses on breathing new life into well-established medicines for everyday ailments: *'making known drugs*

better'. As well as working in the field of inflammatory pain, Infirist Healthcare works in the field of chronic wound care, cough and colds and GI (digestive) symptoms.

<http://www.infirst.co.uk/>

About Arthritis Research UK

Arthritis Research UK invests in breakthrough treatments, the best information and vital support for everyone affected by arthritis. We believe that by harnessing the power of exceptional science we can overcome the pain, isolation and fatigue arthritis causes. Our work has already uncovered breakthrough treatments, and we're dedicated to uncovering new ideas to help people push back the ways arthritis limits their lives. Arthritis Research UK and Arthritis Care have joined together so that we can do more to help people with arthritis to live full and active lives.

For more information, please visit www.arthritisresearchuk.org;

Twitter: www.twitter.com/arthritisRUK;

Facebook: www.facebook.com/arthritisresearchuk

References:

1. Bierma -Zeinstra SMA, Conaghan PG, Brew J et al. *Osteoarthr Cartil*: 2017 25; 12: 1942–1951 Open Access: <http://dx.doi.org/10.1016/j.joca.2017.09.002> Accessed at: [http://www.oarsijournal.com/article/S1063-4584\(17\)31197-4/fulltext](http://www.oarsijournal.com/article/S1063-4584(17)31197-4/fulltext)
2. Data on File, Infirist Healthcare Ltd
3. NL Trevaskis et al. Nature Reviews Drug Discovery. Volume 14, November 2015: 781
4. NHS England media centre, accessed at: <https://www.england.nhs.uk/2017/07/medicine-consultation/>
5. Flarin® 200mg (Ibuprofen soft capsules) Patient Information Leaflet <https://flarin.co.uk/wp-content/uploads/2017/10/patientinformationleaflet.pdf>

PP376 2018 Date of Preparation January 2018

For further information, please contact:

Lynsey Conway

Communications Consultant for Infirist Healthcare Ltd

Tel: +44 7778 304233

email@lynseyconway.co.uk