



# Innovation of the Year

Infirst Healthcare’s Flarin is the winner of the CHI Award for Innovation of the Year, with one judge describing the medicine for flaring joint pain and inflammation as a “potential game changer”.

“Known drugs – made better” is how Infirst Healthcare sums up its approach to OTC innovation. Speaking to OTCToolbox in 2014, Chief Executive Officer Manfred Scheske said the OTC industry needed to rethink its approach to innovation, buy into the concept of constantly improving drugs and treatments, and be ready to conduct clinical trials to generate evidence. “Only then will the industry be able to fully unlock its fantastic potential,” he commented.

In January 2018, Infirst launched Flarin in the UK following a “significant investment in pioneering research and development”. Flarin is backed by the FLARE clinical trial. The pharmacy-only medicine comprises oral capsules containing 200mg ibuprofen. During the manufacturing process, ibuprofen is fully dissolved into melted lipid excipients, explains Infirst, and the ibuprofen remains in this lipid solution even when the product is encapsulated and cooled. Infirst adds that the ibuprofen remains encased in the lipids during transit through the stomach.

At the time of the launch, Infirst said Flarin was the “first and only OTC lipid-formulated ibuprofen which helps relieve flaring joint pain and inflammation”. The company added that Flarin’s unique lipid formulation “helps shield the stomach from damage”.



Infirst Healthcare launched Flarin in the UK in early 2018

## Findings of the FLARE study

The company highlighted the findings of its FLARE study, which it said demonstrated that lipid-formulated ibuprofen at 1,200mg a day – Flarin – was as effective as the prescription dose of 2,400mg standard ibuprofen a day at relieving flaring joint pain.

FLARE was a double-blind, randomised study involving 462 patients across 27 primary care centres in the UK and the Netherlands. The findings were published in *Osteoarthritis and Cartilage*.

Around 86% of people who took Flarin had an improvement in their flare ups after five days, said Infirst, adding that patients also reported a reduction in stiffness and swelling.

Based on the findings of FLARE, Infirst’s marketing campaign for Flarin promises “joint pain relief as effective as prescription strength ibuprofen without a prescription”.

One judge who gave Flarin the maximum five points said the product “impacts one of the largest OTC categories and has the potential to be multi-country”. Flarin served a “large consumer base of dissatisfied sufferers”, continued this judge, adding that it was “another option in the quest to reduce opioid consumption”.

According to this judge, Flarin was a “potential game changer in chronic pain/oral analgesics”. A second judge, Tim Brady of Thornton & Ross, observed there was “so little innovation in analgesia”. “To invest so much in improving the safety and efficacy of one we use already was high risk but could be a huge benefit to patients,” he said.

A third judge said Flarin could “empower more pain sufferers to self-care rather than having to visit the doctor for prescription pain relief”.

Nine judges evaluated eight candidates for this CHI Award

Rank	Innovation	Points (from a maximum of 45)
1	Infirst Healthcare’s Flarin	23

## **Note to editors:**

### **About Flarin®:**

Flarin® is a pharmacy-only medicine indicated 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 nerves), dental pain, period pain, feverishness, as well as cold and flu symptoms.

Its active ingredient is 200mg of ibuprofen. Flarin® encases ibuprofen in lipids. This helps it to travel through the stomach and into the small intestine where the lipids are broken down, allowing the ibuprofen to be transported around the body to the sites of pain and inflammation.<sup>3</sup> Flarin's patented lipid technology is based on a complex manufacturing process which involves heating and dissolving specific pharmaceutical grade lipids, ibuprofen and other excipients together in a process lasting three days.

The recommended dose of Flarin® is one or two capsules (200 mg – 400 mg) up to three times a day, as required. People 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, a doctor's 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 Summary of Product Characteristics (SPC):

<http://www.mhra.gov.uk/home/groups/spcpil/documents/spcpil/con1513315064311.pdf>

### **About the FLARE study:**

The double-blind, randomised, multicentre **FLaring Arthralgia Relief Evaluation** in episodic knee pain (FLARE)<sup>1</sup> study, recently published in *Osteoarthritis and Cartilage*, demonstrated that combining ibuprofen in a lipid formulation can deliver effective flare-up control.

FLARE is a landmark study. It is the first large-scale trial to investigate episodic knee pain flares in primary care patients - and the first ibuprofen study in decades demonstrating reduction of pain in active flares.

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).<sup>2</sup>

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.<sup>2</sup>

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.

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.

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.

**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'*. The company is also committed to bringing innovation and efficacy to the consumer healthcare and primary care markets - which have seen very few, new products in recent times. As well as working in the field of inflammatory pain, infirst Healthcare works in the field of chronic wound care, cough and colds and GI (digestive) symptoms. <http://www.infirst.co.uk/>

**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, Infirst Healthcare Ltd
3. NL Trevaskis et al. *Nature Reviews Drug Discovery*. Volume 14, November 2015: 781