Market release
3 December 2018

New trial of MAXIGESIC® pain relief published in major international journal

U.S. formulation of MAXIGESIC® fixed dose paracetamol and ibuprofen combination resulted in more rapid and effective pain relief than paracetamol or ibuprofen alone.

A new large randomised trial just published in *Clinical Therapeutics* comparing a U.S. formulation of MAXIGESIC® (MAXIGESIC® USA) to equivalent doses of paracetamol and ibuprofen shows that MAXIGESIC® provides significantly superior pain relief than either paracetamol or ibuprofen on their own[1].

The MAXIGESIC® USA formulation used in the study was specifically developed for product registration in the USA, and is bioequivalent to the Australian / New Zealand formulation of MAXIGESIC®.[i]

The study was carried out in four centres in the United States and New Zealand and took patients with moderate to severe post-operative dental pain and were allocated randomly to one of four groups: ibuprofen alone, paracetamol alone, MAXIGESIC® USA (paracetamol/ibuprofen fixed dose) and placebo.

“We chose impacted wisdom tooth extraction pain because it is recognised as less affected by other variables and more reproducible,” says one of the authors, pharmacologist Dr Hartley Atkinson. Dr Atkinson, who is also the Founder and CEO of AFT Pharmaceuticals, developed MAXIGESIC® while trying to find a codeine-free alternative to other combination pain relief products.

“It was a large study with over 400 participants and the most important question asked by the trial, meaning the primary endpoint, was the sum total of pain relief over 48 hours, with

secondary outcomes including need for opioid rescue medication and time to meaningful pain relief. Drug administration was supervised and the onset of pain relief was carefully timed. We also controlled for other medications and whether the surgery was performed under local or general anaesthesia."

"What we found was that at maximum dosage MAXIGESIC® USA was 36% more effective than ibuprofen alone and 78% more effective than paracetamol alone. MAXIGESIC® USA also reduced opioid rescue medication use and shortened time to meaningful pain relief. Only one in four patients in the MAXIGESIC® USA group needed rescue medication compared to nearly 50% in the paracetamol and ibuprofen groups and 80% in the placebo patients. There were no differences in adverse events between the different groups."

"Patients using MAXIGESIC® USA also experienced significantly less pain within the first dosing interval (6 hours) than Paracetamol, Ibuprofen or placebo."

"These findings are consistent with those found in an earlier randomised trial published in the *British Journal of Anaesthesia*[2] which applied an Intention to Treat analysis," explains Dr Atkinson. "What we have now are two studies using completely different study designs but showing consistent outcomes in terms of the primary endpoint, which was the pain relief over 48 hours. The new Daniels study[1] also conducted extensive sensitivity analyses of the primary endpoint by analysing it in five different ways based around use of rescue medication, which supports the results are consistent regardless of the data analysis methods."

"These studies provide supporting evidence that MAXIGESIC®'s fixed dose combination provides significant analgesia with no added side effects," finished Dr Atkinson.

MAXIGESIC® is now licensed in 128 countries worldwide and is also the only paracetamol / ibuprofen combination approved by regulators in every major European country.

[End of release]

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Photos available here.

About MAXIGESIC®

MAXIGESIC® is a unique, patented combination of paracetamol and ibuprofen that provides fast, effective double action pain relief from a wide range of pain. MAXIGESIC® is now licensed in 128 countries worldwide. https://www.aftpharm.com

Study Details

Merry study analysis uses ITT [Intent to Treat] patient groups (including data following use of rescue medication).

Daniels study analysis uses adjustment for rescue medication by LOCF 6 hours. Please see Daniels et al 2018 for details but the primary endpoint significance was maintained independent of the five methods of analysis around rescue medication and specific patient populations.

Daniels et al study was not conducted under fasting conditions.

References

1. Daniels SE et al. Analgesic efficacy of an acetaminophen/Ibuprofen fixed dose combination in moderate to severe post-operative dental pain: a randomised, double-blind, parallel group, placebo-controlled trial. *Clinical Therapeutics* 40 (10): 1765-1776 (2018).

2. Merry AF et al. Combined acetaminophen and ibuprofen for pain relief after oral surgery in adults: a randomised controlled trial. *British Journal of Anaesthesia* 104 (1); 80-8 (2010)

About AFT

AFT is a growing multinational pharmaceutical business with a broad range of products, both developed itself and in-licensed from third parties. AFT's products cover all major pharmaceutical distribution channels: over-the-counter, prescription and hospital. Historically, AFT's home markets have been Australia, New Zealand and South-East Asia. However the company is out-licensing its own products to licensees and distributors to sell in an increasing number of countries around the world. The company's intensive Research and Development programme forms the basis of its international sales strategy. For more information about the company, visit aftpharm.com

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[i] MAXIGESIC® USA is a fixed dose combination of Paracetamol 325mg + Ibuprofen 97.5mg given as three tablets per dose [Paracetamol 975mg + Ibuprofen 292.5mg] and is bioequivalent under fed conditions to MAXIGESIC® Paracetamol 500mg + Ibuprofen 150mg (New Zealand/Australian formulation) given as two tablets per dose [Paracetamol 1000mg + Ibuprofen 300mg]. Aitken P, Salem II, Stanescu I, Playne R, Atkinson HC (2018) A Single Dose, Four-Way, Open-Label Bioavailability Study of Oral Acetaminophen and Ibuprofen Combinations (Maxigesic®) under both Fasting and Fed Conditions. J Bioequiv Availab 10: 84-91. 383. doi:10.4172/0975-0851.1000383