통증엔-

maxigesic® IV

2x PAIN RELIEF

Maxigesic® IV provides approximately **DOUBLE the pain relief** than that provided by acetaminophen IV or ibuprofen IV alone.*,1

OPIOID CONSUMPTION **LESS**

Median opioid consumption in the Maxigesic® IV group was approximately **55.6% less** than placebo, **30% less** than the active comparator groups.**,1

SUSTAINED RELIEF

Maxigesic® IV provided **significantly greater pain relief** than acetaminophen IV and ibuprofen IV at the majority of scheduled time periods over a 48 hour period.***,1

SAME SAFETY

No compromise in safety - postoperative safety profile equivalent with that of acetaminophen IV or ibuprofen IV, with no novel adverse events reported.1

PRODUCT INFORMATION

복지부분류	114 (해열, 진통, 소염제) / 전문의약품		
제 품 명	**맥시제식** 주 IV / **Maxigesic** Inj. IV		
성분·함량	Acetaminophen 1,000mg + Ibuprofen 300mg ····· 100mL/vial		
보험코드·약가	665003111 · 비급여		
성 상	무색투명한 액이 무색투명한 바이알에 든 주사제		
효능·효과	중등도 ~ 중증의 통증(특히 수술 후)의 단기간 치료		
용법·용량	성인 : 1바이알을 필요에 따라 매 6시간 간격으로 정맥내 주입으로 투여한다. 1일 최대 투여량은 아세트아미노펜으로서 4g을 초과하지 않는다. (15분 동안 정맥 투여)		
사용상의 주의사항	제품설명서 참조	포장단위	10 바이알/상자(100mL/바이알X10)
저장방법	밀봉용기, 차광하여 실온(1~25℃) 보관, 냉장 또는 냉동하지 말 것	사용기간	제조일로부터 24개월

※ 제품에 대한 보다 자세한 정보는 제품설명서를 참조하여 주시길 바랍니다.

경보제약 ■ 서울사무소 : 서울특별시 서대문구 충정로 8 종근당빌딩 4층 ■ 본사 · 공장 : 충청남도 아산시 실옥로 174 ■ 소비자상담실 : 02-365-2312
■ 자세한 제품 정보 : www.kbpharma.co.kr

통증엔-

maxigesic® IV

A fixed dose acetaminophen 1000 mg and ibuprofen 300 mg in 100 mL solution for infusion

- 단일성분 투여 대비 **두배 이상**의 **통증완화 효과**를 제공합니다.*,1
- Median opioid의 사용량을 **55.6%** (than placebo), **30% 감소**(than comparator groups)시켰습니다.**,1
- 단일성분 대비하여 **약물 효과 지속력**이 **우수**합니다.***,1
- 단일성분과 **동일한 안전성**을 나타냅니다.1

경보제약 AFT pharmaceuticals

* Based on time-adjusted SPID48, calculated from VAS pain intensity scores recorded up until the time of consumption of the first dose of rescue.1 ** Based on the total oral Morphine Milligram Equivalent (MME) dose of all rescue medication over the full 48 hour study period.1
*** According to VAS pain intensity, Pain Intensity Differences and Pain Relief scores. Dosed as one vial every 6 hours over 48 hour period.1

References : 1. Daniels, S.E, Playne, R., Stanescu, I., Zhang, J., Gottlieb, I.J, Atkinson, H.C. (2019). Efficacy and safety of an intravenous acetaminophen/ibuprofen fixed-dose combination after bunionectomy: A randomized, double-blind, factorial, placebo-controlled trial. Clinical Therapeutics https://doi. org/10.1016/j.clinthera.2019.07.008 . Research sponsored by AFT Pharmaceuticals.

Effective treatment for postoperative pain management

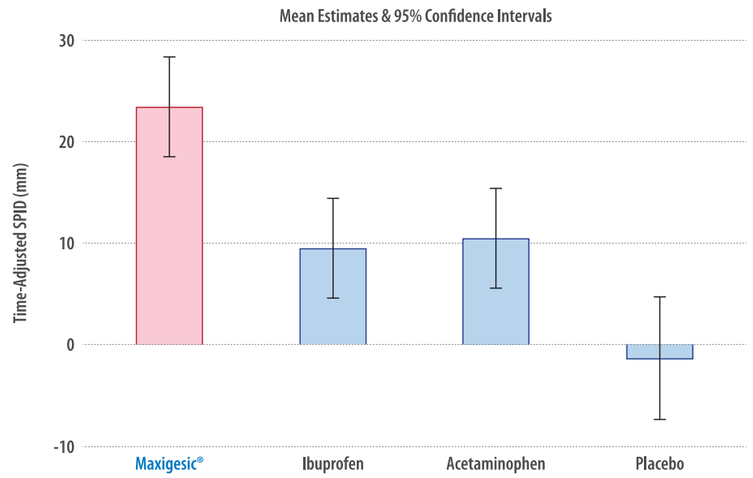
- New clinical data demonstrates that Maxigesic® IV provides significantly more analgesia than comparable doses of acetaminophen IV, ibuprofen IV and placebo.[1]
- All study medicines were administered to patients intravenously over 15 minutes every 6 hours over a 48 hour period, for a total of 8 doses.
- Maxigesic® IV provided significantly superior pain relief than comparable doses of ibuprofen or acetaminophen, and placebo.[1]

DOUBLE THE PAIN RELIEF[1]

The amount of pain relief provided by Maxigesic® IV was approximately DOUBLE that of acetaminophen IV and ibuprofen IV alone.*,[1]

Maxigesic® provided the greatest amount of pain relief, far exceeding the amount required for a clinically significant difference, with all pairwise comparisons being highly significant.*

Fig 1: Time-adjusted $SPID_{48}$ up to first dose of rescue medication [primary endpoint]



*Based on time-adjusted $SPID_{48}$, calculated from VAS pain intensity scores recorded up until the time of consumption of the first dose of rescue.

MEDIAN OPIOID CONSUMPTION

Maxigesic® IV was 55.6% less than placebo, 30% less than acetaminophen, ibuprofen.[1]

Results across all efficacy end points.

Outcome	FDC (n = 75)	IBU (n = 76)	APAP (n = 75)	Placebo (n = 50)
Time to onset of analgesia, median (95% CI), min	23.8 (9.8; –)	– (176.2; –)	– (25.0; –)	– (–; –)
Achieved, no. (%)	45 (60)	29 (38)	37 (49)	12 (24)
P†	–	0.01	0.13	<0.001
Peak pain relief, no. (%)				
"No relief"	12 (16)	22 (29)	21 (28)	25 (50)
"A little relief"	16 (21)	17 (22)	19 (25)	13 (26)
"Some relief"	12 (16)	13 (17)	5 (7)	7 (14)
"A lot of relief"	13 (17)	20 (26)	19 (25)	2 (4)
"Complete relief"	22 (30)	4 (5)	11 (15)	3 (6)
P†	–	0.004	0.04	<0.001
Time to peak pain relief, median (95% CI), h	0.52 (0.25; 0.75)	0.25 (0.08; 0.50)	0.27 (0.25; 0.75)	0.08 (–; –)
P†	–	0.002	0.21	<0.001
Used rescue medication, no. (%)	56 (75)	70 (92)	70 (93)	48 (99)
Odds ratio (95% CI)	–	4.13 (1.52; 11.20)	5.49 (1.89; 15.96)	9.03 (1.97; 41.47)
P§	–	0.005	0.002	0.005
Time to first rescue medication, median (95% CI), h	3.32 (2.53; 4.92)	1.68 (1.38; 2.20)	2.08 (1.62; 3.00)	1.18 (1.12; 2.12)
P‡	–	<0.001	0.006	<0.001
Rescue medication used in 24 h, median (95% CI), MME**	22.5 (15; 30)	30.0 (30; 42)	42.0 (30; 45)	45.0 (45; 60)
P†	–	0.01	0.003	<0.001
Rescue medication used in 48 h, median (95% CI), MME	**30.3** (15; 42)	**43.5** (30; 60)	**45.0** (30; 60)	**67.5** (45; 90)
P†	–	0.008	0.004	<0.001

APAP = acetaminophen; FDC = fixed-dose combination; IBU = ibuprofen; MME = morphine milligram equivalents. † Mann-Whitney *U* test. ‡ Kplan-Meier test. ¶ Percentage of patients experiencing ≥50% reduction in visual analog scale score from baseline, before the use of rescue medication. § Logistic regression with baseline pain intensity as covariate.

**Based on the total oral Morphine Milligram Equivalent (MME) dose of all rescue medication consumed over the full 48 hour study period.

References : 1. Daniels, S.E, Playne, R., Stanescu, I., Zhang, J., Gottlieb, I.J, Atkinson, H.C. (2019). Efficacy and safety of an intravenous acetaminophen/ibuprofen fixed-dose combination after bunionectomy: A randomized, double-blind, factorial, placebo-controlled trial. Clinical Therapeutics https://doi. org/10.1016/j.clinthera.2019.07.008 . Research sponsored by AFT Pharmaceuticals. **2**. Merry AF, Gibbs RD, Edwards J, Ting GS, Frampton C, Davies E, Anderson BJ. Br J Anaesth. 2010 Jan;104(1):80-8. doi. **3**. Hung KKC, Graham CA, Lo RSL, Leung YK, Leung LY, Man SY, et al. (2018) Oral. **4**. Wells LK, Drum M, Nusstein J, Reader A, Beck M. Dec;37(12):1608-12. doi: 10.1016. **5**. Dahl V, Dybvik T, Steen T, Aune AK, Rosenlund EK, Raeder JC. Eur J Anaesthesiol. 2004 Jun;21(6):471-5. doi.

Safety and Tolerability of Fixed-Dose Combination

- A total of 493 adverse events (AEs) were reported among 194 participants during the double-blind treatment period.[1]
- All AEs, nonserious and serious, occurring during the 48-hour treatment period were included in the safety analysis.[1]
- The safety profile of the FDC was comparable to that of intravenous ibuprofen or acetaminophen alone.[1]

NO COMPROMISE IN SAFETY[1]

There was no difference in the rate of nausea or dizziness between the Maxigesic® group and the comparators.[1]

Table. Number and frequency of adverse events (AEs).
Values are given as no. (%) of patients unless otherwise indicated.

Variable	FDC (n = 75)	IBU (n = 76)	APAP (n = 75)	Placebo (n = 50)
No. of AEs reported	142	131	112	108
Discontinuations due to AEs	0	2 (3)	1 (1)	0
Participants with ≥1 AE	52 (69)	58 (76)	45 (60)	39 (78)
Participants with ≥1 drug-related AE*	34 (45)	35 (46)	22 (29)	23 (46)
Participants with ≥1 severe AE	3 (4)	4 (5)	6 (8)	1 (2)
AEs affecting ≥5% of participants				
Nausea	22 (29)	26 (34)	25 (33)	16 (32)
Dizziness	13 (17)	7 (9)	7 (9)	8 (16)
Vomiting	16 (21)	5 (7)	11 (15)	1 (2)
Headache	4 (5)	5 (7)	5 (7)	10 (20)
Somnolence	5 (7)	6 (8)	6 (8)	3 (6)
Infusion site pain	10 (13)	7 (9)	0	1 (2)
Constipation	4 (5)	4 (5)	4 (5)	4 (8)
Infusion site extravasation	2 (3)	5 (7)	2 (3)	7 (14)
Pruritus	5 (7)	4 (5)	3 (4)	2 (4)

APAP = acetaminophen; FDC = fixed-dose combination; IBU = ibuprofen.

* Classified as possibly, probably, or definitely related to the study drug. This does not include AEs classified as nonrelated or unlikely to be related.

- Better pain relief than monotherapy.[2]
- Compared to the high content (400/600/800mg) of ibuprofen, the analgesic effect is significant, but the side effects are comparable.[3]

SYNERGY EFFECT : OPTIMAL COMBINATION

The importance of dose –ration : Optimal combination acetaminophen and ibuprofen

Study	Dose (AAP/IBU)	Ratio (AAP/IBU)	Result
Merry et al. 2010[2]	1,000/300	3.3 : 1	Synergy effect
Daniels et al. 2018	975/292.5	3.3 : 1	Synergy effect
Hung et al. 2018[3]	1,000/400	2.5 : 1	No Synergy effect
Wells et al. 2011[4]	1,000/600	1.67 : 1	Increasing AE
Dahl et al. 2004[5]	1,000/800	1.25 : 1	Increasing AE

MAXIGESIC IP

등재특허 No.	특 허	주요 사항	요 약	비 고
10-1370712	조성물	Ratio (3.3:1)	AAP : IBU = 3.3 : 1 비율의 synergetic effect	등록특허