"Canadian Quality You Can Trust"

파마사이언스 코리아는 우수한 품질의 의약품을 공급합니다.

카나보센® 정 62.5mg, 125mg

(Bosentan)

Bosentan is strongly recommended to improve 6MWD for PAH WHO FC Ⅲ patients.[1]

* **6MWD** : 6-min walk distance, **PAH** : Pulmonary arterial hypertension, **WHO FC** : World Health Organization functional class

pharma science Korea

Canabosen® Tab.

Bosentan 62.5mg, 125mg

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Bosentan 62.5mg, 125mg

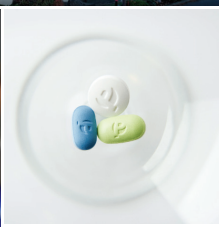
파마사이언스 캐나다는 ClassA인증을 받은 기업으로 Health Canada의 엄격한 심사기준에 의거하여 승인된 우수한 의약품을 미국, 유럽 등 세계 60여 나라에 수출하고 있습니다.

ClassA란?

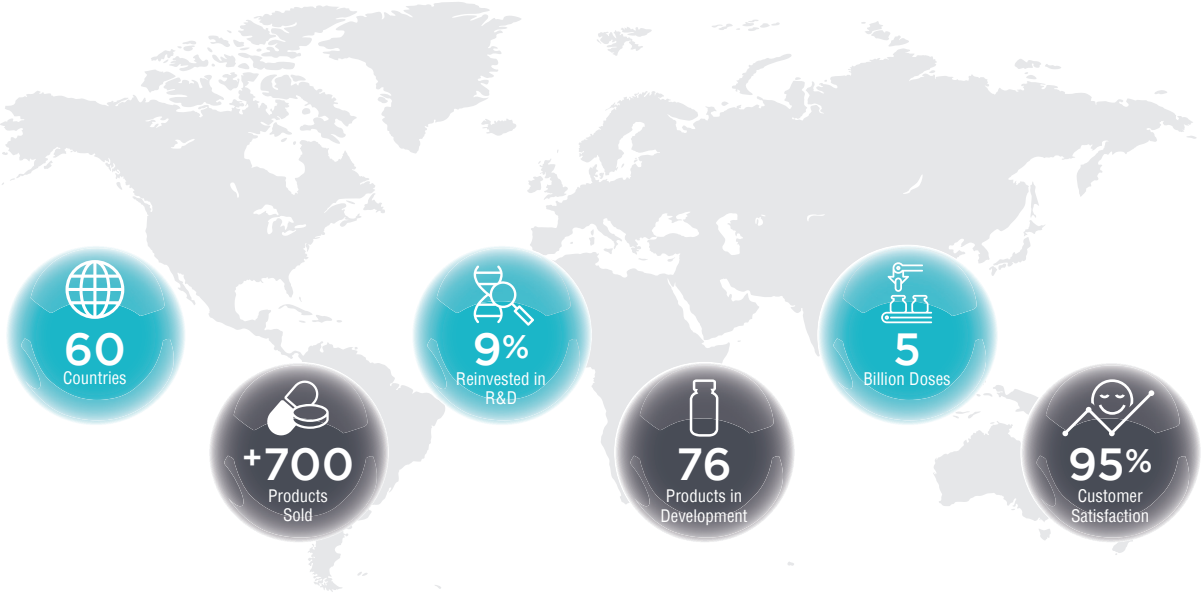
전체 140여개의 주요 기준 운영 및 관리평가를 통하여 **캐나다 내의 0.5%이내의 상위기업**에게 주어지는 인증입니다. **파마사이언스 캐나다는 ClassA 인증을 획득**하였습니다.(2012년)

Headquartered in Montreal. We are the largest pharmaceutical employer in Quebec with over 1,500 employees and product distribution in over 60 countries.

Our focus is on high-quality generic medications



All products are manufactured under strict cGMP standards.



- **60**개국 **700**품목 이상 수출
- 매년 **9**% 이상의 R&D 투자와 평균 **76**품목 개발
- 매년 **50**억 단위의 의약품 생산
- **95**% 이상의 고객만족 달성

pharma science

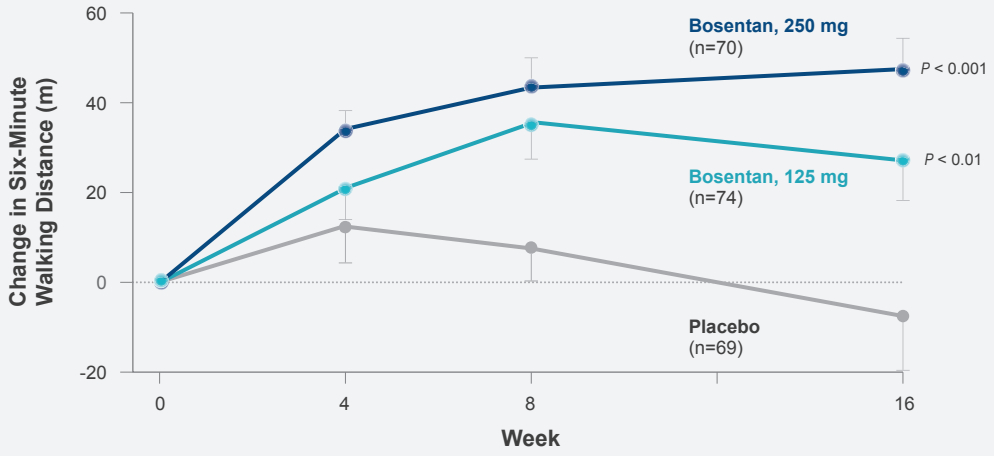
Bosentan 125 mg은 PAH 환자에서 운동능력을 증가시켰으며 placebo군 대비 중대한 부작용을 증가시키지 않았습니다.[2]

* **PAH**: Pulmonary arterial hypertension

STUDY DESIGN

In this double-blind, placebo-controlled study, 213 patients with pulmonary arterial hypertension (WHO functional class Ⅲ or Ⅳ) were assigned to receive placebo or to receive 62.5mg of bosentan twice daily for 4 weeks followed by either of two doses of bosentan (125 or 250mg twice daily) for a minimum of 12 weeks. The primary end point was the degree of change in exercise capacity indicated by the distance a patient could walk in six minutes.

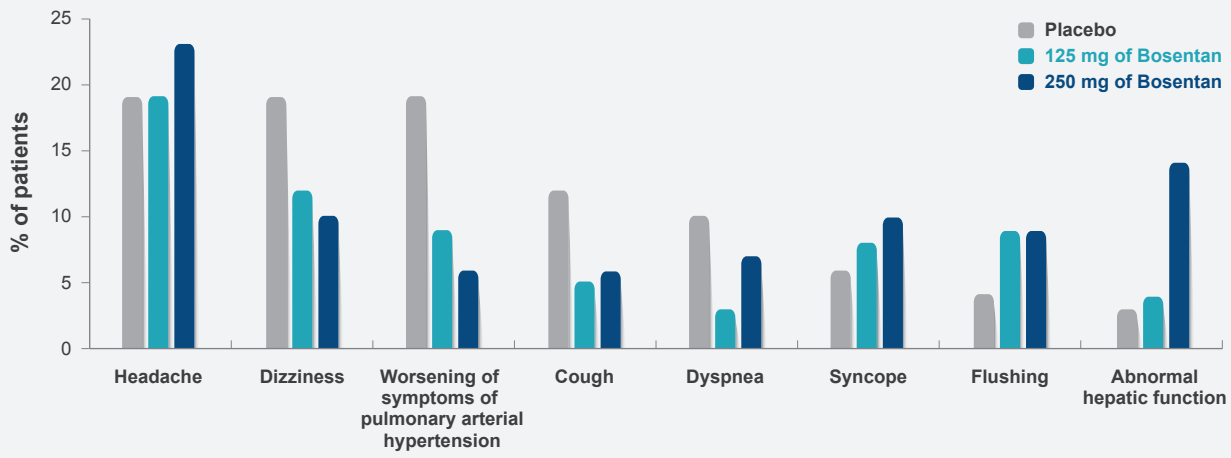
- After 16 weeks of treatment, **the distance walked in six minutes was increased by 36 m in the combined bosentan groups**, whereas a deterioration of 8m occurred in the placebo group.



There was no significant difference between the two bosentan groups (P = 0.18 by the Mann-Whitney U test)

- Treatment with **125 mg of bosentan twice daily was not associated with a significant increase in adverse events** or with a change in their nature when compared with placebo.

[Most frequent adverse events in the placebo and bosentan groups]



Bosentan은 소아 PAH 환자의 임상적 증상을 완화시켰으며 좋은 내약성을 보였습니다.[3]

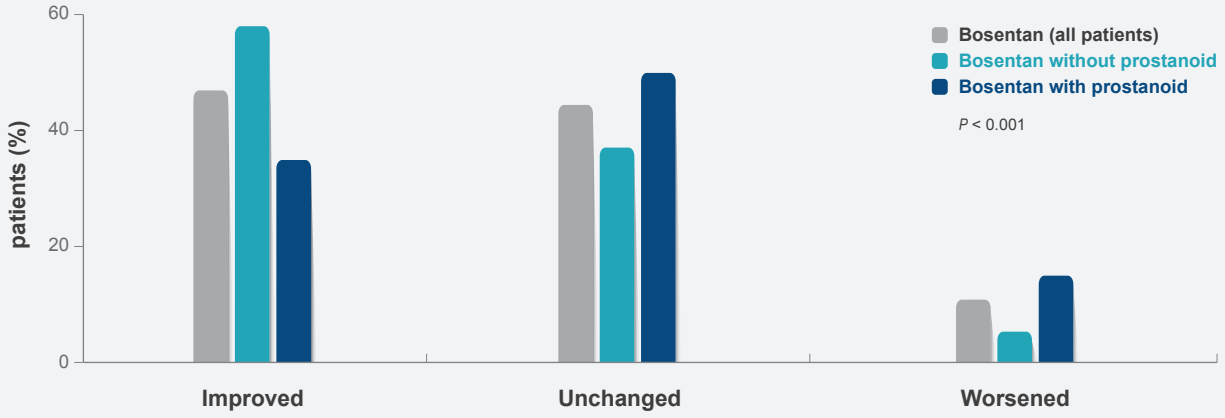
* **PAH**: Pulmonary arterial hypertension

STUDY DESIGN

In this study, 86 children (ranged in age from 9 months to 18 years at the start of bosentan therapy) with PAH in WHO functional class Ⅰ to Ⅳ were treated with bosentan with or without concomitant intravenous epoprostenol or subcutaneous treprostinil therapy. The median exposure time to bosentan was 14 months (range 2 to 28 months). Hemodynamics, WHO functional class, and safety data were collected.

- Overall, **36 patients (46%) improved by at least one class, 34 patients (44%) remained in the same functional class**, and 8 patients (10%) worsened by one class.

[WHO Functional Class]



World Health Organization functional class at bosentan initiation and after at least eight weeks of treatment with bosentan. The median follow-up of these patients was 12 months (range 3 to 25 months).

- At data cutoff date, **68 of the 86 patients (79%) continued bosentan**. Fatigue leading to discontinuation was observed in two patients, and two patients with unrepaired CHD discontinued bosentan.

* **CHD**: Congenital heart disease

[Patient Survival and Treatment Status at Data Cutoff Date]

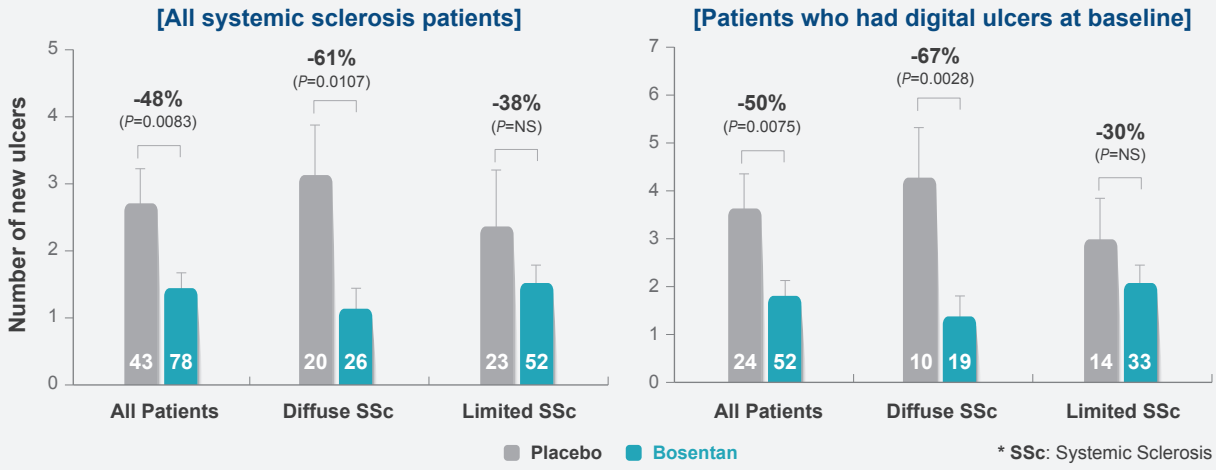
	All patients (n = 86)	Bosentan without prostanoid (n = 42)	Bosentan with prostanoid (n = 44)
Continued bosentan treatment, n (%)	68 (79%)	35 (83%)	33 (75%)
Discontinuation, n (%)			
Increase in liver enzymes	3 (3%)	2 (5%)	1 (2%)
Other adverse event	4 (5%)	2 (5%)	2 (4%)
Treatment failure	6 (7%)	1 (2%)	5 (11%)
Deaths, n (%)	5 (6%)	2 (5%)	3 (7%)

Bosentan은
systemic sclerosis 환자에서
새로운 Digital Ulcer의 발생을 감소시켰습니다.[4]

STUDY DESIGN

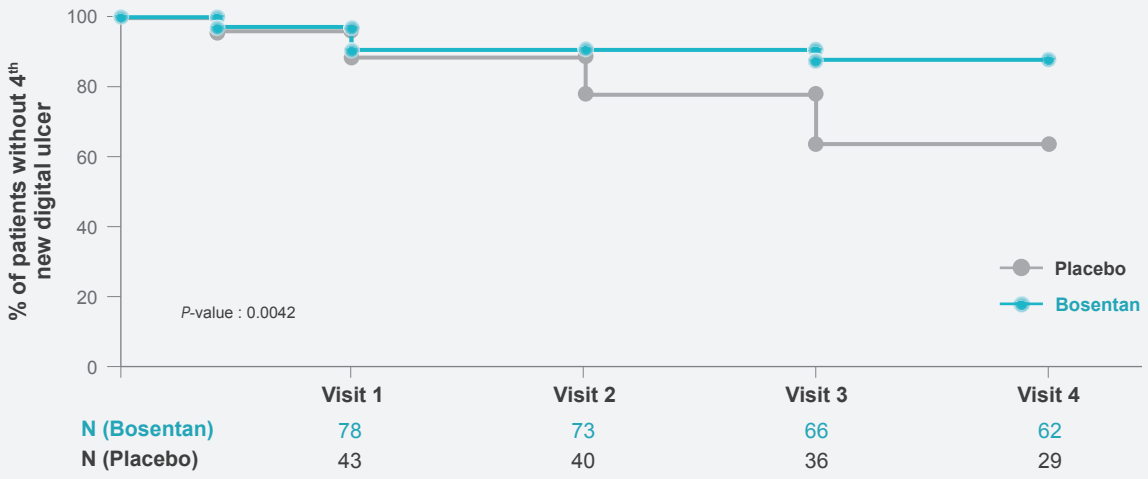
This study was a double-blind, placebo-controlled study evaluating bosentan treatment for digital ulcers. 122 patients who had limited or diffuse SSc were randomized into 2 parallel groups using a 2:1 bosentan-to-placebo ratio and were treated for 16 weeks. Subjects received 62.5 mg of bosentan twice daily for 4 weeks, or placebo. For the next 12 weeks, patients received 125 mg of bosentan twice daily or placebo. The primary outcome variable was the number of new digital ulcers developing during the 16- week study period.

- The **overall number of new ulcers was significantly reduced in patients receiving bosentan**. Among patients in the bosentan group, a mean of 1.4 new ulcers per patient developed, compared with 2.7 ulcers per patient among those receiving placebo.



Development of new digital ulcers in all systemic sclerosis (SSc) patients (left) and those who had digital ulcers at baseline (right), including comparisons between patients with diffuse disease and those with limited disease. The number of patients in each group is shown superimposed on the bars. NS = not significant.

- Using a Kaplan-Meier-type estimate for risk of onset of subsequent ulcers, **the protective effect of bosentan persisted throughout the study** but was most evident after 8 weeks of treatment.

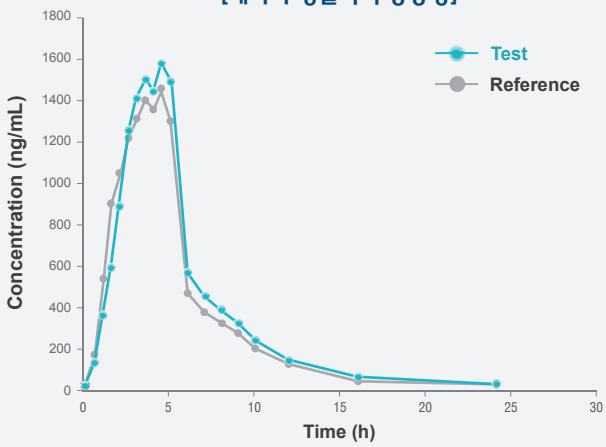


Visits occurred at 4, 8, 12, and 16 weeks (±12 days) after starting the study drug. The number of patients remaining at risk is shown on the abscissa.

Canabosen® Tab.
Bosentan 62.5mg, 125mg

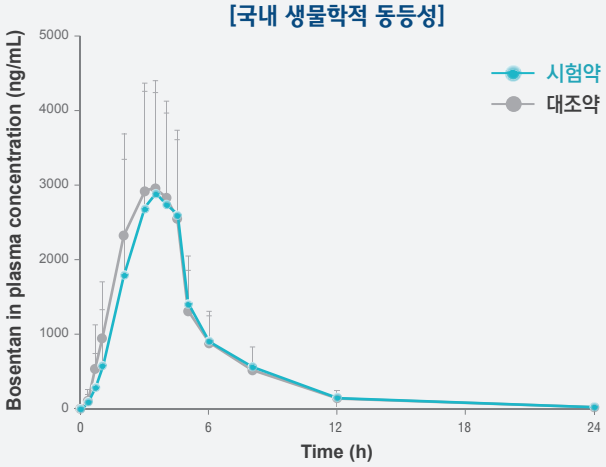
카나보센®정은
캐나다와 국내에서 모두
생물학적 동등성을 입증하였습니다.

[캐나다 생물학적 동등성]



Bioequivalence conducted between bosentan tablets
(Geometric Mean)
(N = 22)

[국내 생물학적 동등성]



Bosentan의 투약군별 평균 혈중 농도-시간 곡선
(Inset의 세로축은 로그 눈금 사용)
(N = 31, Mean + S.D.)

카나보센®정 62.5 밀리그램

카나보센®정 125 밀리그램

[카나보센®정 62.5 밀리그램, 125 밀리그램(보센탄수화물(미분화))]

전문의약품 | 수입의약품

[효능효과] 1. 폐동맥고혈압(WHO 기능 분류 클래스Ⅲ 및 Ⅳ에 해당하는 폐동맥고혈압(WHO Group I) 환자의 운동능력 및 증상개선 2. 기능 분류 클래스II에 해당하는 폐동맥고혈압 환자의 임상적 악화의 지연 3. 전신경화증에 기인한 활동성 수지/족지 궤양증이 있는 환자의 새로운 수지/족지 궤양증 발생감소 **[용법용량]** 1. 폐동맥고혈압: 투여용량은 환자의 증상, 내약성 등에 따라 적절히 조절. 초기용량으로 투약 첫 4주간 1일 2회, 1회 62.5 mg을 투여하며, 투약 5주째부터 유지용량으로 1일 2회, 1회 125 mg 투여. 이 약은 식사에 상관없이 아침, 저녁에 투여. 2. 전신경화증에 기인한 활동성 수지/족지 궤양증: 초기용량으로 투약 첫 4주간 1일 2회, 1회 62.5 mg을 투여하며, 이후로 유지용량으로 1일 2회, 1회 125mg 투여. 이 약은 식사에 상관없이 아침, 저녁에 투여. 치료에 대한 환자의 반응과 치료의 지속여부는 정기적으로 재평가. **[사용상의주의사항]** 투여금기 : 1. 임부 또는 임신하고 있을 가능성이 있는 여성 2. 중등도 또는 중증의 간장애 환자 3. 투여전 아미노전이효소치(즉 AST 그리고/또는 ALT)가 기준값 상한의 3배가 넘는 환자 4. 사이클로스포린 또는 타크로리무스 또는 시롤리무스를 투여중인 환자 5. 글리벤클라미드를 투여중인 환자 6. 이 약 또는 이 약의 구성성분에 과민증이 있는 환자 **[저장방법]** 기밀용기, 실온보관(1~30℃) **[사용기간]** 제조일로부터 36개월 **[제조원]** 파마사이언스 **[판매원]** 파마사이언스코리아㈜

* 기타 상세한 내용은 제품허가사항을 참고하시기 바랍니다.

[Reference] 1. CHEST 2019; 155(3):565-586. 2. N Engl J Med 2002;346:896-903. 3. J Am Coll Cardiol 2005;46:697-704 4. Arthritis & Rheumatism, December 2004, 50(12):3985-3993

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