



Prescription Drug Information for Consumers & Professionals

[Home](#)[New
Drugs](#)[Latest
News](#)[Drug
Interactions](#)[Pill
Identification](#)[Images](#)[Forum](#)

Drugs.com - prescription drug and medicine information available on over 24,000 approved medications and pharmaceuticals, including side effects and drug interactions.

[Log-in](#)[Register](#)

Advertisement

[Buy a Link Now](#)

Special Offers

From our sponsors

SEARCH >>

[Advanced
Search](#)

Or click the first letter of a drug name: [A](#) [B](#) [C](#) [D](#) [E](#) [F](#) [G](#)
[H](#) [I](#) [J](#) [K](#) [L](#) [M](#) [N](#) [O](#) [P](#) [Q](#) [R](#) [S](#) [T](#) [U](#) [V](#) [W](#) [X](#) [Y](#) [Z](#)

Popular Searches

[Lipitor](#)
[Viagra](#)
[Cialis](#)
[Levitra](#)
[Zoloft](#)
[Hair Transplant](#)
[Health Insurance](#)
[Healthy Diet](#)
[Lose Weight](#)
[Pain Relief](#)

Advertisement

Categories

[Allergies &
Hayfever](#)

[Diabetes](#)

[Gastro Center](#)

[Weight Loss](#)

[AIDS/HIV](#)

[Cancer &
Oncology](#)

[Mental Health
& Depression](#)

[Cholesterol](#)

[Hair Loss](#)

[Muscular Injuries](#)

Back to [Latest News on New Drug Application Submissions](#)

Vicuron Pharmaceuticals Submits New Drug Application for Dalbavancin to U.S. Food and Drug Administration

Once-Weekly Antibiotic Designed to Treat Growing Problem of Hospital Staph Infections

KING OF PRUSSIA, Pa., December 21, 2004 -- Vicuron Pharmaceuticals Inc. (Nasdaq: MICU; Nuovo Mercato: MICU) today announced that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for dalbavancin, a novel antibiotic for the treatment of complicated skin and soft tissue infections (cSSTIs). Dalbavancin is a unique, once weekly IV lipoglycopeptide for the treatment of cSSTIs caused by Gram-positive bacteria, including the most difficult-to-treat strains of Staphylococcus-methicillin-resistant Staphylococcus aureus (MRSA).

"This is a major milestone for us as we move closer to

[& Arthritis](#)

[Pain Relief](#)

[Sexual Health](#)

Advertisement

Recent Drug Searches

[Adderall](#)

[Epzicom](#)

[Codeprex](#)

[Fazaclo](#)

[Risperdal](#)

[Clindamycin](#)

[Zelnorm](#)

[Ibuprofen](#)

[Metvix](#)

[Viagra](#)

bringing this promising antibiotic to the market," said George F. Horner III, President and CEO of Vicuron. "With the increase of infections caused by Gram-positive bacteria in the hospital, we believe dalbavancin will offer a potent alternative to older agents such as vancomycin. In addition, two doses of dalbavancin in complicated skin infections in place of other antibiotics requiring up to 28 doses, can potentially change the course of treatment for this serious disease."

The NDA includes results from more than 1,850 subjects and three Phase 3 trials which evaluated the safety and efficacy of dalbavancin in patients with SSTIs caused by Gram-positive bacteria. The Phase 3 clinical trials also met the primary and secondary endpoints of non-inferiority when compared to linezolid, cefazolin or vancomycin -- three commonly used standard-of-care agents for SSTIs. The vast majority of the patients treated in these studies had SSTIs caused by Staph aureus bacteria, with more than 400 patients infected with methicillin-resistant Staph aureus (MRSA), one of the most difficult-to-treat strains of bacteria.

"Given the promising benefits shown by this product, we believe dalbavancin represents an important achievement for both Vicuron and the hospital antibiotic category," added Mr. Horner.

About Dalbavancin

Dalbavancin, a novel second-generation lipoglycopeptide agent, belongs to the same class as vancomycin, the most widely-used and one of the few treatments available to patients infected with the most difficult-to-treat strains of Staphylococcus (Staph.): MRSA (methicillin-resistant Staphylococcus aureus) and MRSE (methicillin-resistant Staphylococcus epidermidis). Dalbavancin has been specifically designed as an improved alternative to vancomycin. In vitro studies have shown that in addition to being potent against clinically important Gram-positive bacteria, it is bactericidal (i.e., kills bacteria rather than merely inhibiting their growth). The potency, tissue penetration and half-life of dalbavancin may allow for more flexible and convenient dosing regimens than vancomycin. In preclinical and clinical studies to date, dalbavancin appears to be one of the most potent antibiotics in its class against MRSA and MRSE.

About Vicuron Pharmaceuticals

Vicuron Pharmaceuticals is a biopharmaceutical company focused on discovering, developing, manufacturing and

commercializing vital medicine for seriously ill patients. The company has two New Drug Applications pending with the U.S. Food and Drug Administration for its lead products, dalbavancin, a novel intravenous antibiotic for the treatment of serious Gram-positive infections, and anidulafungin, a novel antifungal agent. Vicuron's versatile research engine integrates industry-leading expertise in functional genomics, natural products discovery, mechanism-based drug design and combinatorial and medicinal chemistry. These approaches are yielding promising novel and next-generation compounds, many of which are in the later stages of preclinical development. In addition, the company has research and development collaborations with leading pharmaceutical companies, such as Novartis and Pfizer.

ADVERTISEMENT

[Home](#) - [Drug Interactions](#) - [Pill Identifier](#) - [Image Search](#) - [Latest News](#) - [New Drugs](#) - [Forum](#)
[Advertisers](#) - [FAQs](#) - [Links](#) - [Privacy Policy](#) - [Terms of Use](#) - [Contact Us](#) - [Top Drugs](#) - [Merchandise Store](#) - [About Drugs.com](#)

The drugs.com drug database is powered by Micromedex™ and Multum™.

* Micromedex data last updated 6 June 2005.

Micromedex Physicians Desk Reference data last updated 18 May 2005.

Multum data last updated 28 June 2005.

© Copyright 2005 Drugs.com



We subscribe to the HONcode principles. [Verify here.](#)