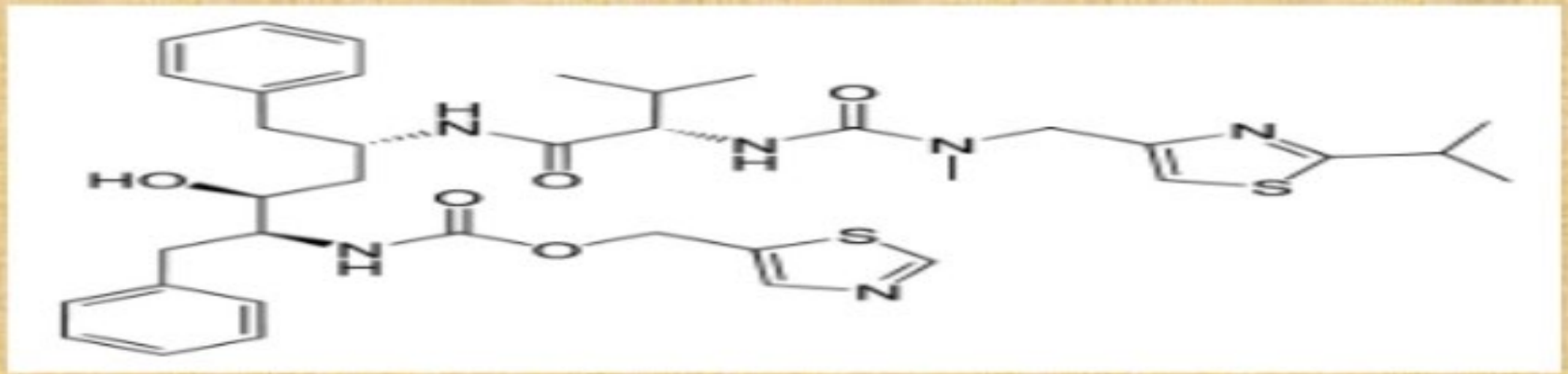
The Ritonavir Story

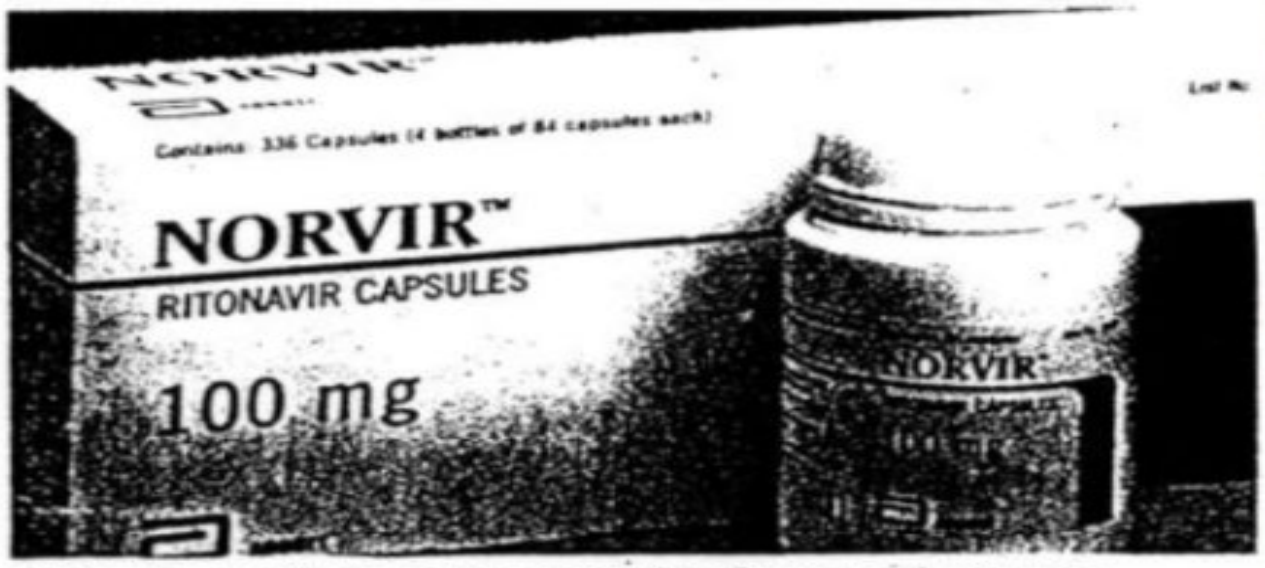


Ritonavir, or Norvir, was patented in 1993 and marketed in 1996 by Abbott Laboratories.

The drug was on the market for 18 months before a serious problem emerged: the drug began precipitating out of formulation in large quantities.

Manufacturing problems hit Abbott's HIV drug ritonavir

Capsules of Abbott Laboratories' protease inhibitor Norvir (ritonavir) are likely to become unavailable by the middle of August. The company has a problem with the manufacture of the anti-HIV capsules which it cannot resolve at present.



Capsules unlikely to be available from mid-August

The problem relates to "undesirable" crystal formation. Abbott says that a series of recent production batches of Norvir capsules failed the approved test for dissolution, and were not released for marketing. Investigation of the reason for the failure showed the presence of a new crystalline form of ritonavir which affects the way it dissolves, and possibly its absorption. Retained samples from a number of marketed batches of capsules were examined and there was no evidence of the unwanted crystalline form.

Mr Mark Haywood (managing director, Abbott Laboratories) said that teams were working round the clock to try to resolve the issue, but at present the company had no idea why the problem was occurring.

The new form was dubbed **Form 2, and was found to be** less soluble, greatly reducing bioavailability.

Abbott was forced to **remove Ritonavir from the market** until they solved the problem, resulting in extreme losses:

- $250 million in sales.
- Estimated hundreds of millions of dollars in R&D trying to recover the original Form I.

Ritonavir : The Solution Proposed

International Association of Physicians in AIDS Care

The Problem | Consequences | Tolerability | Temperature | Portability | Adherence | Regimens

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Norvir Advisory

Abbott Laboratories Submits New Drug Application to U.S. FDA for Reformulated Norvir

ABBOTT PARK, Ill., March 31 – Abbott Laboratories today announced it has submitted an application to the U.S. Food and Drug Administration (FDA) seeking approval for Norvir (ritonavir) soft-gel capsules. Norvir is an HIV protease inhibitor for the treatment of patients with HIV infection and AIDS. A regulatory filing is currently under review by the European Agency for the Evaluation of Medicinal Products (EMEA) following a submission to the agency in January 1999. Regulatory filings in other countries where Norvir is sold will occur throughout 1999.

The filing follows intense reformulation work at Abbott after an announcement in July 1998 that a new crystalline structure of ritonavir, which affected how the capsule dissolved, would interrupt the production of Norvir capsules....

Ritonavir – The Solution Approved

Abbott Laboratories Receives U.S. FDA Approval for Reformulated Norvir (ritonavir) Capsule

New Soft-Gelatin Capsules Offer Non-Refrigerated, Twice-Daily Treatment Option

ABBOTT PARK, Ill., June 30, 1999 – Abbott Laboratories announced today it has received U.S. Food and Drug Administration (FDA) approval for Norvir (ritonavir) soft-gelatin capsules…Norvir soft-gelatin capsules require refrigerated storage between 36-degrees F to 46-degrees F until dispensed to patients…

The approval of Norvir soft-gelatin capsules follows intense reformulation work at Abbott after an announcement in July 1998 that a new crystalline structure of ritonavir, which affected how the semi-solid capsule dissolved, would interrupt the production of Norvir semi-solid capsules.