The Trouble With Norvir

Abbott’s manufacturing malady is hard to swallow

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In late July, Abbott Labs alerted the AIDS community to a production snafu discovered during routine quality-assurance tests: “Undesired” crystals in the capsules of its protease inhibitor, Norvir (ritonavir). Because the crystals affect absorption, Abbott halted production indefinitely.

“The crystals aren’t contamination,” Abbott spokesperson Melissa Brotz said. “We don’t know how they got there, or what it’s going to take to make them go away.” Luckily for Abbott -- and the 65,000 Norvir-popping PWAs around the world -- the defective drugs were caught prior to distribution. With production suspended, however, the company said pharmacy shelves would be soon wiped clean of existing capsules.

Since the glitch is likely mechanical and won’t require altering the Norvir brew, FDA re-approval may not be necessary. Shelves should be restocked a few weeks after the problem is pinpointed; however, when *that* will happen is another mystery. (Some say it could take up to a year; at press time, Abbott hadn’t released any official timetables).

Until it dissolves its cryptic crystals, Norvir-users must make do with a liquid version identical to the capsules in both price and HIV-fighting composition. Abbott and several treatment gurus say switching to liquid should neither affect antiretroviral regimens nor foster additional side effects.

Nevertheless, there are important differences -- and potential problems -- between the two formulations. Unlike capsules, which require refrigeration, the liquid should *not* be kept in the fridge. And its high-alcohol content -- 43 percent -- may be of concern to recovering alcoholics and people with liver disease or hepatitis. But what many label as the biggest burden is liquid Norvir’s taste. “It’s like awful liquor that makes your mouth and gut tingle and sting the whole way down,” said treatment advocate Dave Gilden after sampling the elixir. “I kept burping it up.” For those who can’t stomach it, nonadherence could become the big issue.

For more info and updates, log on to the IAPAC Norvir Advisory at http://www.iapac.org/. For tips on how to make the med palatable, see The Bitter End.

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