

Notice to Providers from California Department of Public Health: FDA & CDC Temporarily Suspend Use of Rotarix (GSK)

As a precaution, the U.S. Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) are recommending that providers temporarily suspend their use of the GSK rotavirus vaccine, *Rotarix*, for at least the next 4-6 weeks.

Using a new lab technique, an independent academic research team has detected DNA from a pig virus (*porcine circovirus type 1*) in Rotarix but has not confirmed whether infectious circovirus is actually present in the vaccine. There is no evidence yet that this laboratory finding poses a safety risk. This virus has been commonly found in certain meat and other food products, and is not known to cause disease in either animals or humans. Moreover, Rotarix has been used widely around the world in recent years with a good track record for safety in the infants receiving it. (After its initial review of these findings, the European counterpart to the FDA, the European Medicines Agency, has not suspended use of Rotarix in the European Union at this time, in contrast to FDA.)

FDA is conducting a thorough investigation on this issue and expects to convene an expert advisory committee to review the investigation over the next 4-6 weeks. Until then, if you have doses of Rotarix on hand, mark those doses “Do Not Use” and keep them stored properly in your refrigerator to maintain their potency until the advisory committee and FDA recommend that they can be used again.

Meanwhile, providers should continue to immunize infants against rotavirus with the other licensed rotavirus vaccine, Rotateq (Merck), but there is no need to repeat doses that have already been given. Preliminary studies have found no pig circovirus DNA in the RotaTeq rotavirus vaccine. Rotateq is given in a 3-dose series at 2, 4, and 6 months of age. Two doses of Rotateq are needed for an infant who has received 1 dose of Rotarix. No doses of Rotateq are needed for an infant who has received 2 doses of Rotarix. See Table 8 of [ACIP recommendations](#) for appropriate age limits and intervals for doses.

VFC Providers will be sent instructions on how to order Rotateq. If you are not a VFC provider, you can order Rotateq through your vaccine distributor or directly from Merck at www.merckvaccines.com.

Questions and Answers Section

I've given two doses of Rotarix to an infant – does the infant need additional rotavirus vaccine?

No, if a child has already received two doses of Rotarix, the vaccine series is completed - no additional doses of rotavirus vaccine are needed. There is no concern about the potency of Rotarix if appropriately refrigerated.

I've given one dose of Rotarix to an infant – does the infant need two additional doses of RotaTeq?

Yes. We recommend that your practice complete the rotavirus vaccine series by giving two additional doses of RotaTeq vaccine. Preliminary studies have found no pig circovirus DNA in the RotaTeq rotavirus vaccine.

How long is this temporary suspension of Rotarix going to last?

The FDA will convene an expert advisory committee to conduct a thorough investigation over the next 4-6 weeks. FDA is expected to update *its* recommendations for the use of Rotarix at that time. Until then, please maintain your inventory of Rotarix under its current proper refrigeration.

Update on Rotarix Vaccine from FDA

FDA is updating clinicians on information that recently has become available about Rotarix, a vaccine used to prevent rotavirus disease. FDA has learned that components of an extraneous virus, PCV1, are present in Rotarix. There is no evidence at this time that this finding poses a safety risk. While the agency is learning more about the situation, FDA is recommending that clinicians and public health professionals in the United States temporarily suspend the use of Rotarix. FDA will keep the public and the clinical community updated as more information becomes available.

Updated Info:

<http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm205539.htm>