

Acyclovir labeling now includes details for treating premature infants infected with herpes virus

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Newborns infected with herpes simplex virus (HSV) can be appropriately treated with acyclovir, a drug typically prescribed to adults for the treatment of HSV infections. Acyclovir's drug label now includes

information for healthcare providers on recommended usage and dosage in newborns up to 3 months of age. The data that informed this label change came from a study funded by the National Institutes of Health's Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD).

"Until now, doctors did not have complete information about the dosing and use of acyclovir to treat newborns and [premature infants](#), who are vulnerable to serious and potentially life-threatening complications from HSV infection," said Perdita Taylor-Zapata, M.D., program lead for the Best Pharmaceuticals for Children Act (BPCA) at NICHD. "With this label change, [healthcare providers](#) have clear guidance on how to use and prescribe this drug for their youngest patients."

HSV causes [genital herpes](#) in adults, but newborns can become infected with the virus during pregnancy, labor and delivery or shortly after birth if the mother develops genital herpes near the end of her pregnancy. HSV infection in newborns can cause death or long-term problems such as blindness and damage to the brain and other organs.

NICHD's BPCA program supports the Pediatric Trials Network (PTN), which studies drugs and therapies commonly prescribed for infants and children but never specifically tested in them. Results from these studies provide information on the most appropriate use of these therapies and may inform an update to the drug's label by the U.S. Food and Drug Administration. Up-to-date drug labels provide important information for healthcare providers on how to appropriately prescribe an existing drug for different patient populations.

Results from the PTN study that generated data for acyclovir's label change is available online at NICHD's Data and Specimen Hub.

Provided by National Institutes of Health

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