



Antiepileptic Drug Pregnancy Registry

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Breastfeeding While Taking AEDs

Breastfeeding is an important topic for pregnant women. There is a wealth of information about the benefits of breastfeeding for the infant and for the mother. However, for women with epilepsy there are some additional factors and concerns to take into consideration. For most women with epilepsy, breastfeeding is a safe option. All AEDs appear in breast milk (inversely to the degree of maternal plasma protein binding) and in a relatively low concentration. This usually does not affect the baby who has already been exposed to the mother's medication during pregnancy. Term infants have already had nine months of AED exposure and most can metabolize the medication effectively.

Talk with your physician about your specific medications and breastfeeding, particularly if you are taking Phenobarbital, primidone (Mysoline®), or benzodiazepines (Valium®, lorazepam, and clonazepam). Taking these medications while breastfeeding can cause excessive sleepiness or irritability in a baby. Women who take these medications and are breast-feeding will need to watch their baby carefully for these symptoms. If your baby doesn't gain weight because it is too sleepy to eat, you should follow up with your pediatrician, the nurse, or a lactation consultant about possibly switching to formula. Depending on your baby's symptoms, a combination of breast and bottle may be a better option for you and your baby. Your health care provider may ask you to keep careful records of your baby's feedings and bowel movements in order for them to be able to evaluate how much nourishment your baby is getting. If you are taking both Phenobarbital and primidone (Mysoline®) together, you should not breastfeed your baby. Ethosuximide (Zarontin®) is an anticonvulsant that has been measured at high levels in breast milk. If you take this drug, breastfeed with caution. (*continued on page 2*)

The Publications of the Registry

- A North American Registry for Epilepsy and Pregnancy, a unique public/private partnership of health surveillance. *Epilepsia* 1998;39:793-798.
- Holmes LB, Lieberman ES. Report of first positive findings [Phenobarbital] from hospital-based AED Pregnancy Registry. *Teratology* 2001; 63:250.
- Holmes L, Wyszynski D, Mittendorf R. Evidence for an increased risk of birth defects in the offspring of women exposed to valproate during pregnancy: findings from the AED Pregnancy Registry. *Am J Ob Gyn* 2003; 187(Suppl):S137.
- Nambisan, M, Wyszynski, DF, Holmes, LB. No evidence of a protective effect due to periconceptional folic acid (PCFA) intake on risk for congenital anomalies in the offspring of mothers exposed to antiepileptic drugs (AEDs). *Birth Defects Research* (formerly *Teratology*) 2003; 67:5.

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Breastfeeding (Continued from Page 1)

While breastfeeding is good for both you and your baby, it will create more demands on you, especially at night with loss of sleep. It may be a good idea to keep the baby next to your bed at night, and feed your baby in bed with you. Whenever you are feeding your baby, sit or lie down – this is a perfect time to put your feet up and relax. If there is a concern that loss of sleep may trigger your seizures, breast milk can be pumped in advance and used for nighttime feedings by your partner/spouse or another family member. Having a family member feed the baby at night is best, but not always possible.

As always, it is best to consult with your physician about breastfeeding and your specific medications. The following are resources that you can use to answer any questions or concerns you have about breastfeeding in general, and about breastfeeding while taking AEDs.

- Lactation Study Center at the University of Rochester, NY: Provides excellent information about drugs/chemicals and lactation. Telephone: (585) 275-0088
- American Academy of Pediatrics: A Woman's Guide to Breastfeeding <http://www.aap.org/family/brstguid.htm>
- La Leche League: National Nonprofit Breastfeeding education and support group, with local chapters. <http://www.lalecheleague.org>

Please visit the Information for Women section of the Registry's web site at www.aedpregnancyregistry.org for more breastfeeding links and resources.

Great Friends, Great Prizes, Great Cause!

You may have received recently a mailing or an email from the Registry about our efforts to enroll a control group. The response from Registry participants has been wonderful! Our sincere appreciation and thanks go out to those of you who have already referred controls to the Registry. But we still need your help! The Registry is continuing to recruit women to be part of our control group. In order to participate as a control, a woman must currently be pregnant and **NOT** taking any antiepileptic medication of any kind. If you know someone who could serve as a control, please ask her to call us TOLL FREE: **1-888-233-2334**.

As a token of our appreciation, if you refer your friend and she enrolls in our control group, each of you will get an entry into a raffle for a chance at winning one of 5 great prizes, each worth **\$400**. The prize choices include: a portable DVD player, a digital video camera, a \$400 SuperCertificate to giftcertificates.com, a digital camera, or a home theater system. You can learn more about the prizes on our web site at www.aedpregnancyregistry.org. Remember, you get one raffle entry for *each* woman you refer who becomes part of our control group. Even if you have already referred one friend, you can refer another! The more controls you refer, the better your chances are of winning a great prize!

Statistics Update

Enrollment:

3429 participants as of November 2003

Participants: (range is for the five most commonly used anticonvulsants)

Ethnicity:

White: 82.9-89.5%

Black: 3.3-5.1%

Hispanic: 3.5-7.6%

Education:

<12 yrs 19.9-25.3%

>12 yrs: 65.6-79.3%

Gravidity 1 or 2:

49.7-60.3%

Private Insurance:

72.7-82.7%

Drugs Taken:

29 different monotherapies and 204 different polytherapy combinations

To date, almost 600 women have enrolled who were taking Dilantin, Tegretol or Lamictal. Once a sufficient number have enrolled, the findings will be released.

The Diversity Initiative

It is a priority of the AED Pregnancy Registry to release the most accurate information on the risks of taking anticonvulsant drugs during pregnancy. In order to provide this information, the demographics of our study population should reflect the distribution of ethnic, racial, socio-economic and educational backgrounds of women in the United States and Canada, as well as be comparable to the demographics of our control population.

In response to this need, the Registry launched its Diversity Initiative in September 2003. The Diversity Initiative team has identified problem areas in recruitment practices that may impede the enrollment of a diverse study population. A strategy has been developed to improve the recruitment of women of target ethnic backgrounds and health insurance status. The Diversity Initiative team is currently marketing the Registry to health care providers who serve a diverse patient population. These providers will receive information about the Registry, and recruitment materials will be provided various languages for distribution to their patients.

The Registry hopes that by broadening the scope of its recruitment efforts, the demographics of enrolled participants will become more diverse, enabling the Registry to provide the most accurate data possible. If you would like more information about the Diversity Initiative, please call the Registry TOLL FREE at **1-888-233-2334**.

Medications being Studied by the AED Pregnancy Registry *:

Ativan® (lorazepam)
 Carbatrol® (carbamazepine)
 Celontin® (methsuximide)
 Depakene® (valproic acid)
 Depakote® & Depakote ER (divalproex sodium)
 Diamox® (acetazolamide)
 Dilantin® (phenytoin)
 Felbatol® (felbamate)
 Frisium® (clobazam)
 Gabitril® (tiagabine)
 Keppra® (levetiracetam)
 Klonopin® (clonazepam)
 Lamictal® (lamotrigine)
 Mesantoin® (mephenytoin)
 Milontin® (phensuximide)
 Mysoline® (primidone)
 Neurontin® (gabapentin)
 Paradione® (paramethadione)
 Peganone® (ethotoin)
 Phenobarbital (generic)
 Phenytek® (extended phenytoin sodium)
 Sabril® (vigabatrin)
 Serax® (oxazepam)
 Tegretol® (carbamazepine)
 Topamax® (topiramate)
 Tranxene® (clorazepate dipotassium)
 Tridione® (trimethadione)
 Trileptal® (oxcarbazepine)
 Valium® (diazepam)
 Xanax® (alprazolam)
 Zarontin® (ethosuximide)
 Zonegran® (zonisamide)

* This is *not* a complete list. Please call TOLL FREE **1-888-233-2334** to determine if the Registry is studying your specific medication.

Please visit our web site at:

www.aedpregnancyregistry.org

AED Pregnancy Registry

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We're on the Web!

Visit us at:

www.aedpregnancyregistry.org

1-888-233-2334

CALL TOLL-FREE



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Have You Visited Our Web Site?

The Registry is pleased to announce the launch of its new web site at www.aedpregnancyregistry.org. The new website features general information about the Registry as well as updated information with separate sections specifically targeted for women and for health care providers. Visitors will find a "press room" which provides links and downloads of the Registry's media coverage, as well as sources of information for members of the press. The new site includes a page with information about joining the Registry's control group. Visitors can register to join the Registry's email and mailing list directly from the home page. Visitors can also update their contact information, so that the Registry can continue to communicate with them. Please visit us on the web, sign up, and let us know what you think of the new site!

Who we are Looking for:

The Registry is currently enrolling pregnant women who are taking anticonvulsant medication for any reason. Participating in the Registry only requires 3 telephone interviews of about 10 minutes each, and all information is kept strictly confidential.

Enrollment is open to women during any stage of pregnancy, but not after the birth of the infant. Ideally, the Registry would prefer to enroll women before they reach the 16th week of pregnancy, or before they have had any prenatal screening. To enroll, or get more information please call **1-888-233-2334**.

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