

450 cases of birth defects from anti-epilepsy drug in France: health officials

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A common drug used to treat epilepsy has caused congenital defects in around 450 babies in France who were exposed to the medication before birth in the uterus, according to an estimate by health authorities published Tuesday.

The report put at between 425 and 450 "the number of cases of children born alive or stillborn exposed to valproate in utero between 2006 and 2014 who have <u>congenital defects</u>."

The estimate for all of France was extrapolated from data obtained in the Rhone-Alpes region, it said.

Starting on March 1, the warning for pregnant women—which is already in the notice that comes with valproate—will also be written on the box, the country's general director of health, Benoit Vallet, told AFP.

The anti-convulsion drug has been flagged for several years due to the high risk of birth defects—around 10 percent—but also for increased risks of <u>mental retardation</u> and autism.

A European report in 2014 urged all countries on the continent to review their conditions for prescribing valproate "to minimise risks".

It also called on them to take steps to ensure the medication is not prescribed to women of child-bearing age—15 to 49 years—or pregnant women, unless no alternative treatment for epilepsy was effective.



In France, the new report noted, the drug has also been prescribed for the treatment of <u>bipolar disorder</u>.

Valproate has been marketed in France by pharmaceutical company Sanofi under the brand name Depakine since 1967.

Also available as a generic, the <u>drug</u> is sold by Sanofi in some 120 countries, the manufacturer said.

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