



★ ★ ★ DESTINATION 2012 ★ ★ ★

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Experts want suicide risk warning on ADHD drug

REUTERS By Anna Yukhananov | Reuters – Mon, Jan 30, 2012

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GAITHERSBURG, Maryland (Reuters) - Children who take a common drug for attention deficit disorder should be warned about the risk of suicidal thoughts, U.S. pediatric health advisers said on Monday.

Several members of an advisory committee to the Food and Drug Administration asked the agency to change the label for Focalin, an attention deficit medicine made by Swiss drugmaker Novartis AG, to reflect this risk. The drug is approved for children aged 6 or older.

The FDA often follows the advice of its committees, although it is not required to.

The FDA said it received eight reports of suicidal thoughts for children or adolescents who took the drug over the past six years, and four of the cases appeared to be linked to the medicine. The link for the remaining cases was less clear.

"The suicidal ideation seems to be pretty serious," said Dr. Sheldon Kaplan, panel member and chief of infectious diseases at Texas Children's Hospital.

But the FDA said the risk of suicidal thoughts did not appear in clinical trials for Focalin, and the later reports were a tiny number compared to how many children used the drug.

"I'm somewhat puzzled by the focus of suicidal ideation," said Tom Laughren, head of the FDA's psychiatric products division, in response to the panel's recommendation.

"These drugs are very widely used. And what you're seeing here are a handful of reports that are difficult to interpret with regard to causality," he said.

The number of children diagnosed with attention deficit hyperactivity disorder (ADHD) has skyrocketed in recent years, with the condition now affecting 3 to 5 percent of kids globally.

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Children with ADHD are excessively restless, impulsive and easily distracted, and often have trouble at home and in school. There is no cure, but the symptoms can be kept in check by a combination of behavioral therapy and medication.

In the United States, some 2.7 million people have prescriptions for ADHD drugs including Novartis' Ritalin, Johnson & Johnson's Concerta, Shire's Adderall and Vyvanse and Eli Lilly's Strattera.

Some patient advocates say doctors and parents may be too quick to diagnose kids with the condition, and the drugs may cause side effects that can damage children's health.

The FDA said about 1.8 million children received prescriptions for Focalin or its generic versions from May 2005 to July 2011.

The label for Focalin already warns patients that they may have new psychotic or manic symptoms after taking the drug, but does not mention suicidal thoughts.

Out of other ADHD drugs, only Strattera's label mentions thoughts of suicide as a side effect, as part of a restrictive "black box" warning.

The FDA monitors reports of side effects from medicines after they've been approved in order to discover potential safety problems. For drugs that are used by children, the agency must hold regular advisory meetings to review their safety.

The advisory committee and FDA reviewers also recommended a change to Focalin's label to reflect the risk of anaphylaxis, an allergic reaction, and angioedema, a type of swelling beneath the skin.

Novartis said it will make any necessary changes to Focalin's label after discussing them with the FDA.

"Novartis is committed to patient safety and will continue to work closely with the FDA as the agency completes its review," said Brandi Robinson, spokeswoman for the company.

(Reporting by Anna Yukhananov; Editing by Richard Chang)

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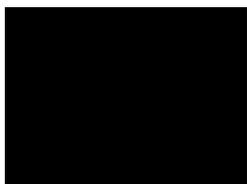
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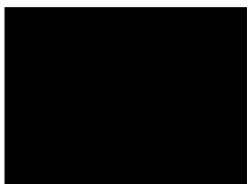
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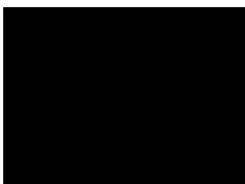
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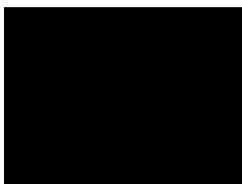
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• [Phoenix, Arizona](#) • 7 hrs ago

1   1

what they don't tell you is that there's no way to attribute the suicidal ideation to the drug; it's just a CORRELATION. these kids, who are obviously at the doc for mental health needs anyway, are probably more likely to BE suicidal. oy.

[▶ Reply](#)

• [Orlando, Florida](#) • 14 hrs ago

2   0

Most children can be restless, impulsive and easily distracted....its part of childhood...our 21st century expectations for children to sit still, don't fidget and "be like an adult" are most likely unattainable. Human beings come with a wide range of personalities, 'high strung' being one of them.... [More](#)

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• [Cleveland, Ohio](#) • 1 day 9 hrs ago

1   0

maybe your just better off adhd!!!!!!!!!!!!!!!!!!!!!! or is it ahdh my attention span is so short!!!!!!!!!!!!!!!!!!!!!!

[▶ Reply](#)

• 15 hrs ago

1   1

ADHD is vastly over diagnosed. Usually hormones are the cause for growing children to be "restless, impulsive and easily distracted, and often have trouble at home and in school".

[▶ Reply](#)

• 18 hrs ago

2   0

Seems to me i remember so called "experts" told us that these drugs were helpful.

▶ Reply

• Arlington Heights, Illinois • 8 hrs ago

2   0

Most of you probably DONT have an ADHD kid and are truly clueless about this medical condition. All you know is what you hear in the media and this ridiculous posting

▶ Reply

• 1 day 9 hrs ago

1   1

Out the warning on. Doctors sometimes need reminders too.

▶ Reply

• 15 hrs ago

2   0

Try Zoloft first.....12.5 mg (tiny dose) worked for my child!!!

▶ Reply

• Austin, Texas • 1 day 5 hrs ago

2   1

Focalin is a good drug when used alongside a healthy diet, plenty of sleep and exercise. Considering how widely it's prescribed, these handful of cases is actually reassuring.

▶ Reply

• 14 hrs ago

2   1

Strange as it may sound, Adderall lifts my mood a bit. Ive been taking it for 10 years now for ADD and in my particular case it has dramatically improved my life. I wish I was diagnosed in my childhood, my experience in school would have been much better.

▶ Reply

• Pleasanton, California • 18 hrs ago

3   0

"Suicial ideation seems serious,"... BRILLIANT!

▶ Reply

• 11 hrs ago

1   0

DRs are makin HUGE PROFITS for prescribing ADHD meds to just about anyone. Plenty of peeps out there sellin their meds just to pay their mortgage... survival of the fittest. Darwin loves you - greed KILZ THIS JUST IN!!! LITTLE KIDS ARE HYPER -- THEY ARE AFTER ALL LITTLE FRIGGIN KIDS!!! Send them... [More](#)

▶ Reply

• 18 hrs ago

1   0

Here, take this little pill... you won't be so awake or aware but hey it'll kill ya anyway... so....

▶ Reply

• Norfolk, Virginia • 20 hrs ago

1   1

These kids do not need "liberal application of the paddle", that was just an ignorant person talking about something they don't know anything about. We are not drugging our children, you can't think that as a parent we would do anything to harm our children! Diet is not the answer, all that and red... [More](#)

▶ 3 Replies

• Buffalo, New York • 1 day 8 hrs ago

6 2

i threw all of my kids medications out when he was 7. hes 12 now and no angel but drug free. the only ones that are nuts are the shrinks that prescribe these meds like they are candy. he is who is now and not a medicated kid, much better off.

▶ Reply

• 1 day 9 hrs ago

5 2

there is an entire panople of psychotropics, and anti-psychotis, and anti-dpressents causing murders and suicides all over the country.

Both of my wounded warrior sons were given these horrible drugs by the Army and the VA. I finally got them off of these things, and got my sons back... [More](#)

▶ 1 Reply

• New Hartford, New York • 18 hrs ago

4 0

when you stop treating it like a disease, and stop medicating it like a disease - perhaps we won't have these issues. ADHD is just another type of FUNCTIONING brain.. it's like trying to medicate someone left handed...

▶ 1 Reply

• Norwich, Canada • 1 day 8 hrs ago

4 4

Totally agree on the diet thing. People and doctors who give this to the kids should be charged with child abuse and child endangerment. The principal of my sons school tried to push this on my kid hardcore, talk about drug pushers! My own doc said not! Then he said to get it to get the school off... [More](#)

▶ 1 Reply

• 1 day 4 hrs ago

8 2

STOP DRUGGING YOUR CHILDREN!!!

▶ 1 Reply

• 18 hrs ago

3 2

ADD and ADHD are invented illnesses !!! Soon the drug companies will get stupidity classified as an "illness" and BAM, another drug for them to sell us.

Anyone see a trend here?

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