

# Virginia Hopkins Health Watch

## Buyer be Aware: Reglan Gets a Black Box Warning

### Heartburn Drug Can Cause Irreversible Nerve Damage

When it comes to the anti-nausea drug Reglan (metoclopramide), the FDA and the New England Journal of Medicine (NEJM) appear to be incommunicado, and the U.S. media has its head in the sand.

In a stunning demonstration of “la la la la I can’t hear you,” in June 2009 the NEJM published Israeli research extolling the safety (to the fetus) of metoclopramide (Reglan) for the treatment of nausea during pregnancy. And yet, just a few months earlier, the FDA issued a black box warning for Reglan, its strongest caution for a drug, short of pulling it off the market. There was zero mention of the black box warning in the NEJM article, nor any of the other serious safety issues with Reglan. Granted, the risks are low and usually occur after long term use, but we're talking about pregnant women here. Furthermore, the study only looked at obvious measures of harm in newborn infants, such as birth defects. No mention was made of side effects in the mothers, nor followup on the health and wellbeing of the infants.

Following closely on the heels of the NEJM article, the mass market “Reglan is Safe for Morning Sickness” story appeared in nearly identical articles and news reports in most major media outlets in the U.S., an indication that the piece was simply culled from a corporate press release without in-depth research. Little or no mention was made in these clone articles of the black box warning, or the fact that the drug is not FDA-approved for morning sickness.

### The FDA Black Box Warning

Reglan is a prescription drug used to treat heartburn and reflux, but its popularity has waned since the introduction of the safer and more effective proton pump inhibitors (e.g. Nexium) and H2 blockers (e.g. Tagamet). According to a March 2009 U.S. Food & Drug Administration (FDA) Weekly Digest Bulletin, “FDA is requiring that manufacturers of metoclopramide [e.g. Reglan] add a boxed warning to the label about the risk of tardive dyskinesia if the drug is used for long periods of time or at high doses. ...Tardive dyskinesia is characterized by involuntary, repetitive movements of the extremities, as well as grimacing, rapid blinking and impaired movement of the fingers. The risk of tardive dyskinesia associated with metoclopramide is increased among long-term users of the drug, and also among elderly patients, especially women.”

### But Wait, There’s More

The FDA bulletin neglected to mention that the risk of these types of symptoms is increased in infants and children. They also forgot to mention that this drug can cause tardive dyskinesia even with short term use (the risk goes up with long-term use).

And by the way, the tardive dyskinesia caused by Reglan is almost always irreversible.

Reglan also stimulates the release of prolactin, the hormone that stimulates milk production in nursing mothers. Believe it or not, in another off-label use, Reglan is recommended to nursing mothers to stimulate milk production, even though the drug sheet states that when mothers take it, it passes into breast milk.

Reglan is a dopamine antagonist, which explains its other possible side effects, including severe depression, anxiety, agitation, pacing, inability to sit still, jitteriness, and insomnia.

Reglan also increases aldosterone levels. Aldosterone is involved with kidney function, and an increase can cause severe fluid retention, which can be dangerous for people with high blood pressure, congestive heart failure and liver damage.

Reglan also increases catecholamines which can cause a “hypertensive crisis” in those with high blood pressure and/or taking drugs for high blood pressure.

While it is true that the above side effects of Reglan are not common, why take a chance? Why spend resources studying a drug for use during pregnancy that has rare but potentially devastating side effects? Using Reglan to treat morning sickness is like using a sledgehammer to push in a thumbtack.

### **Severe Nausea in Pregnancy is Serious**

None of the above is meant to downplay the seriousness of severe morning sickness, but one of the most recommended treatments by Ob/Gyns is bedrest and fluids. There are also safe and effective non-prescription alternatives. For example, a Canadian study that compared the use of Reglan to acupuncture found that while the acupuncture didn't help as quickly as Reglan, within a few days it worked slightly better.

Even the American College of Obstetricians and Gynecologists (ACOG) recommends eating small, frequent meals, soda crackers, vitamin B6 and ginger to treat moderate to severe nausea and vomiting of pregnancy.

Here's a good website, Morning Sickness Help, that offers a variety of time-tested natural remedies. I checked the ingredients in their herbal teas, and all are considered safe for pregnancy by the German Commission E Monographs, the go-to source for the safety and

efficacy of herbal medicines. That being said, when it comes to pregnancy, “use as directed,” and “everything in moderation” are rules to live by.

## **References**

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