



# INFLAMMATORY BOWEL DISEASE AFRICA

## RESEARCH • EDUCATION • ADVOCACY

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### **Isotretinoin and Inflammatory Bowel Disease**

Isotretinoin (Roccutane®, Oratane®, Acnetane®, Acnetret®, Apex Isotretinoin®) is a vitamin A derivative that was FDA approved for the treatment of severe acne in 1982. It is a very effective treatment for acne but can cause high cholesterol, liver abnormalities, affect a growing fetus amongst many other side effects and needs to be used under strict medical supervision.

The initial clinical trials did not show any relationship between isotretinoin and IBD but once on the market there emerged case reports (post marketing surveillance) of isotretinoin being associated with ulcerative colitis. The cases, reported between 1997 and 2002, identified 83 new cases of IBD who were exposed to isotretinoin.

The potential connection between isotretinoin and IBD, particularly ulcerative colitis, spurred a number of multi-million dollar law suits against Roche, the makers of Accutane (the original isotretinoin product), in 2007. Following this IBD was listed in the package insert as a possible side effect of isotretinoin. In 2009 Roche removed their product from the US market but it is important to note that the drug patent had expired by then and a number of cheaper generic isotretinoin were now available on the US market. Roche also wanted to avoid further lawsuits.

### **Does isotretinoin cause ulcerative colitis?**

Association vs Causation.

This is one of the concepts important in drug side effect evaluation. For example, imagine there was a drug that could treat hearing loss in the elderly. It is easy to understand that the majority of users of this drug would be in their 70s, 80s and 90s. It would also be very easy to report cases of this drug causing dementia. This would most likely be an association but not causation. The people using the drug are also the people who are most likely to develop dementia.

Ulcerative colitis is a disease of young people and most patients are diagnosed in their late teens and early twenties. This is also the age that most people would get acne and require treatment with isotretinoin if severe. Is it that both acne and ulcerative colitis occur in young people and the use of isotretinoin is merely an association?

### **Case Reports vs Meta-analysis**

Case reports are treated with caution by the medical fraternity. The internet is flooded with miraculous treatments for IBD. "I cured my Crohn's disease by eating parsley for 3 months". We know that Crohn's disease has its own inherent rhythm and can wax and wane over time. If you happen to start taking parsley at the beginning of a natural easing of your disease you have "stumbled across an amazing treatment" and this would make a great case report! Although interesting, case reports need to be viewed with a degree of skepticism.

The medical fraternity prefers large sets of data where UC patients previously exposed to isotretinoin are carefully compared to those that were not. A meta-analysis will combine all the studies from around the world and try control as many of the patient and disease variables so that difference, just due to the effect of isotretinoin, can be studied. A number of meta-analysis studies have failed to show that isotretinoin causes ulcerative colitis.

### **Should IBD patients be prescribed isotretinoin?**

IBD patients could be eligible for isotretinoin treatment. As we know young people get both acne and IBD. In addition steroid treatment used in IBD can cause severe, disfiguring acne. However isotretinoin may interact with your existing IBD medication causing a drug interaction which could be dangerous. IBD patients are also prone to develop liver

problems and we know isotretinoin can affect the liver. Isotretinoin can also cause side effects such as nausea and diarrhoea which may be confused with IBD symptoms. For these reasons isotretinoin is best avoided in IBD patients and safer alternatives considered.

**If you have a family history of IBD, and are otherwise healthy, can you use isotretinoin?**

Yes. The relationship between IBD and isotretinoin has not been confirmed on meta-analysis.

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