

## **Q&A Regarding FDA Release On alli & Liver Injury**



### **What is the recent communication from FDA regarding orlistat, the active ingredient in alli?**

On August 24<sup>th</sup> the FDA reported that it is continuing its safety review of orlistat, the active ingredient in alli, and identified 32 serious adverse events for orlistat. These reports were received over a ten year period.

To put this into context, to date more than 40 million people have used orlistat since it first became available as a prescription medicine in 1998. Orlistat is the most studied weight loss medicine, with safety established through more than 100 clinical studies involving more than 30,000 patients.

### **What did FDA recommend alli users do?**

FDA stated that alli users continue to use alli as directed, and that healthcare professionals continue their prescribing (or recommending) practices.

### **How does alli work?**

**alli** contains the active ingredient orlistat at 60 mg. Orlistat is also available by prescription and is produced by Roche and marketed as Xenical at 120 mg. Orlistat works primarily in the digestive tract and prevents some of the fat from a meal from being absorbed. Orlistat is a non-systemically acting medicine — it is minimally absorbed in the blood and works locally in the gastro-intestinal

tract. Because of its mechanism of action, there is no obvious biological mechanism to suggest liver damage can occur with alli.

### **What is hepatotoxicity?**

Hepatotoxicity is liver injury that can be caused by many factors, including chemical or drug substances or by injury brought about by viruses and bacteria.

Liver changes (specifically elevation in liver function tests) can have many causes. It is estimated that about 15-20% of obese people have liver injury due to excessive fat in the liver.<sup>[1]</sup> Additionally, in obese individuals, gradual weight loss can prevent or improve liver function.

### **How does GSK monitor adverse effects among alli users?**

GSK continually monitors, reports, and evaluates adverse event reports. This includes regular review of emerging safety data from multiple sources including clinical studies and post-marketing case reports from both consumers and health care professionals.

### **Where can questions regarding alli be answered?**

If you would like to find out more about alli and the support plan, please call our healthcare professional line at 1-877-475-2554 or visit [www.allihcp.com](http://www.allihcp.com).

In addition, if your patients have questions about alli, they can call 1-800-671-2544.

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<sup>[1]</sup> Preiss, D., Sattar, N. Non-alcoholic fatty liver disease: An overview of prevalence, diagnosis, pathogenesis and treatment considerations. (2008) Clinical Science, 115 (5-6), pp. 141-150.