

Drug Injury Watch: Leukemia Drug Iclusig Had More Safety Warnings Added In November 2016

(Posted by Tom Lamb at www.DrugInjuryWatch.com on January 19, 2017)

Here is overview of this rather significant and substantial November 2016 Iclusig Prescribing Information revision which was mandated by the FDA.

In the Boxed Warning section of the Iclusig drug label there was some additional safety information put in the pre-existing parts about (1) various types of arterial occlusions and (2) heart failure. Also, there is a new part entitled Venous Thromboembolism which addresses venous occlusive events.

Under the Warnings and Precautions section of the Iclusig drug label there were some additional facts and new information put in the following pre-existing parts, which are presented the order in which they were set forth on the FDA CDER SLC page for Iclusig:

- 5.1 Arterial Occlusion
- 5.10 Hemorrhage
- 5.11 Fluid Retention
- 5.12 Cardiac Arrhythmias
- 5.13 Myelosuppression
- 5.14 Tumor Lysis Syndrome
- 5.17 Embryo-Fetal Toxicity
- 5.2 Venous Thromboembolism
- 5.3 Heart Failure
- 5.4 Hepatotoxicity
- 5.5 Hypertension
- 5.6 Pancreatitis
- 5.8 Neuropathy
- 5.9 Ocular Toxicity

Further, under Warnings and Precaution, there is this new part: 5.15 Reversible Posterior Leukoencephalopathy Syndrome (RPLS).

Iclusig (ponatinib) is a kinase inhibitor approved by the FDA as a treatment for certain types of leukemia in adult patients.

Finally as regards this limited Iclusig label changes overview, under the Adverse Reactions section of the Iclusig drug label there was some additional facts and new information put in this pre-existing part, 6.1 Clinical Trial Experience.

The complete set of new side effects warnings can be seen on the FDA's Drug Safety Labeling Changes (SLC) page for Iclusig.

We will continue to monitor the safety profile of the leukemia drug Iclusig and to report significant future developments.

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Attorney [Tom Lamb](#) represents people in personal injury and wrongful death cases involving unsafe prescription drugs or medication errors. The above article was posted originally on his blog, **Drug Injury Watch** – with live links and readers' Comments.
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