

Finasteride 1 mg: Review of US FDA-mandated Suicidality ADR Disclosure Among ‘Big 3’ Hair-loss Telemedicine Services

Post-Finasteride Syndrome Foundation, Aug. 25, 2022

<p>Telemed</p> <p><small>All fields based on information collected from respective websites as of press time.</small></p>	<p>Does digital content contain any textual references to suicidality as an adverse drug reaction (ADR) to finasteride 1 mg? (Emphasis ours.)</p>	<p>Type of FDA-approved finasteride product literature linked from digital content:</p> <ul style="list-style-type: none"> • Prescribing Information (PI), a.k.a. product label, or package insert • Patient Product Information (PPI), a.k.a. Patient Package Insert 	<p>Revision date of most recent FDA-approved finasteride product literature linked from digital content.</p>	<p>Ease of finding links to FDA-approved finasteride product literature in digital content:</p> <p><small>Scale of 1 to 5 1 = very easy 2 = easy 3 = difficult 4 = very difficult 5 = nearly impossible</small></p> <p>(Emphasis ours.)</p>	<p>Does digital content contain links to finasteride product literature, revised per 2022 FDA mandate, that includes “suicidal ideation and behavior” as an ADR reported during post-approval use of finasteride 1 mg?</p>
<p>hims</p>	<p>Yes</p> <p>For example:</p> <p><i>[PFS] is also said to involve mental and neurological symptoms. According to the [PFS] Foundation, these may include...[d]epression, anxiety and/or suicidal ideation.</i></p> <p><i>According to the [PFS] Foundation, [PFS] may result in an increased risk of suicide attempts.</i></p> <p>—Post Finasteride Syndrome: What is It?</p>	<p>PI and PPI</p>	<p>*June 2021</p> <p>For example:</p> <p><i>[I]n a one-year trial, men with male pattern baldness who were treated with 1 mg of finasteride per day reported the following side effects...</i></p> <p>—Post Finasteride Syndrome: What is It?</p> <p>However...</p> <p>The PI to which the above excerpt links was last revised in April 2012.[*] The June 2021 PI can only be found in a Sources section at the bottom of the page. To access it, users need to click a plus (+) icon. When users click on any source in that section, the section minimizes (-), rather than linking to the original source material.</p> <p><small>*Precedes FDA-mandated references to suicidality</small></p>	<p>3</p>	<p>No</p> <p>However...</p> <p>On the Finasteride page, there is an <i>Important Safety Information</i> section containing the subsection <i>Does Finasteride cause depression?</i> which links to a MedPage Today story titled Renewed Concerns About Finasteride and Mental Health, which in turn contains this passage:</p> <p><i>In 2011, reports of finasteride-related depression and suicidality led to an FDA post-marketing report. Depression was added to the adverse reactions section of the drug’s label.</i></p> <p>The latter link is to Organon’s PI (though, notably, without any PPI), revised in August 2022, thus containing the ADR “suicidal ideation and behavior.”</p>
<p>Keeps</p>	<p>No</p> <p>However...</p> <p>At the bottom of several pages, including The Interesting Hair Loss Research You Should Know About and How to Buy Finasteride for Hair Loss, in a font about 40% smaller than that of text on the rest of the page, is this message:</p> <p><i>If you are contemplating suicide, call 911 or call/text the National Suicide and Crisis Lifeline at 988.</i></p>	<p>PI only</p>	<p>*November 2021</p> <p>For example:</p> <p><i>If you would like to learn more about finasteride, please see the full prescription information here.</i></p> <p>—How to Buy Finasteride for Hair Loss</p> <p><small>*Precedes FDA-mandated references to suicidality</small></p>	<p>2</p> <p>However...</p> <p>At the bottom of the Finasteride vs. Minoxidil page, is this message:</p> <p><i>If you would like to learn more about finasteride, please see the full prescription information here.</i></p> <p>But the latter link is to MedlinePlus’s Finasteride page, rather than to the FDA-approved PI or PPI.</p>	<p>No</p>
<p>roman</p>	<p>Yes</p> <p>For example:</p> <p><i>Other possible side effects of finasteride are less common, but include... Depression and suicidal thoughts.</i></p> <p>—What are the side effects of finasteride?</p>	<p>PI and PPI</p>	<p>*June 2021</p> <p>For example:</p> <p><i>[A]lways let a healthcare professional know about any medications you are taking before starting finasteride (FDA, 2021).</i></p> <p>—What are the side effects of finasteride?</p> <p>Notably, the What are the side effects of finasteride? page also contains an <i>Important Safety Information</i> link, which pops up a text box, at the end of which is this:</p> <p><i>Please see the full Prescribing Information for complete safety information.</i></p> <p>The latter link is to Merck’s PI and PPI, revised in April 2012.[*] So there are two different versions of these labels on the same page.</p> <p><small>*Precedes FDA-mandated references to suicidality</small></p>	<p>2</p>	<p>No</p>