

FDA Cites Bayer on Yaz BirthControl Pill

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The commercial minimizes the risks of YAZ. Blood clots are among the potential side effects like all Birth Control Pills.

The commercial suggests taking YAZ will get rid of premenstrual symptoms – there is no clinical evidence.

The commercial suggests that YAZ is approved for acne of all severities - this is not true.

A drug used in YAZ is associated with increasing potassium which can affect the kidneys.

Two television commercials for Bayer AG's birth control pill Yaz give a misleading impression of its benefits, U.S. health regulators warned the company in a letter released on Tuesday.

The ads wrongly suggest the pills are approved for relieving premenstrual syndrome, the U.S. Food and Drug Administration said in a letter dated October 3. The ads also minimize the drug's risks, the agency said.

Bayer will stop running the only one of the two ads currently in use, company spokeswoman Rose Talarico said. The other campaign ended in 2007.

The commercial no longer being broadcast featured women singing "We're not gonna take it" and kicking, punching and pushing balloons with words such as "irritability," "moodiness" and "bloating."

Those symptoms are common with PMS. Yaz, however, is cleared for a more serious condition called premenstrual dysphoric disorder (PMDD), which causes anxiety, tension, persistent anger and other symptoms.

"The TV ads misleadingly suggest that Yaz is approved to treat women with any severity of the symptoms presented, regardless of whether their symptoms are actually severe enough to constitute PMDD," the FDA letter said.

A second ad featured the song “Good-Bye to You” with women releasing balloons labeled with symptoms. The commercial suggests “women are saying ‘goodbye’ to their symptoms and are now symptom-free, when such an elimination of symptoms has not been demonstrated by substantial evidence or substantial clinical experience,” the FDA said.

Bayer will pull that ad and work with the FDA regarding other promotions for Yaz, Talarico said.

The FDA said both commercials “suggest that Yaz is approved for acne of all severities when this is not the case,” the agency said.

In addition, the FDA said the ads distracted viewers with fast-moving images and background music, while information about potential side effects was described.

“These complex presentations distract from and make it difficult for viewers to process and comprehend the important risks being conveyed. This is particularly troubling as some of the risks being conveyed are serious, even life-threatening,” the agency said.

Blood clots are among the potential side effects.

The letter was posted on the FDA Website at http://www.fda.gov/cder/warn/2008/YAZ_wl.pdf.

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http://news.yahoo.com/s/nm/20081008/us_nm/us_bayer_yaz&printer=1;_ylt=AtUep_djRS93bt_0Ee1bqFoXIr0F
