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Ten Drugs Make New FDA Watch List

Robert Lowes | April 03, 2017

Ten drugs or drug classes treating everything from obesity to arthritis made the latest watch list of drugs with possible safety issues that was released by the US Food and Drug Administration (FDA) last week.

The list reflects potential signals of serious risk or new safety information collected by the FDA Adverse Event Reporting System (FAERS) in the fourth quarter of 2016.

The combination of naltrexone and bupropion (*Contrave*, Orexigen Therapeutics) for weight loss was flagged because the FDA received reports that some patients were losing consciousness. Likewise, the agency detected a possible signal of diarrhea, vomiting, and nausea for the arthritis drug apremilast (*Otezla*, Celgene).

The FDA cautions that a drug's appearance on a quarterly FAERS watch list does not mean the agency has established a causal relationship with the cited adverse event. Instead, the agency is studying the need for regulatory action. If the FDA concludes that there is a causal link, it can collect more information to better describe the threat, revise the drug's label, order a risk evaluation and mitigation strategy, or withdraw the drug from the market.

Sometimes the FDA already has put the matter of a drug's potential risk signal to rest before it publishes the watch list. This kind of regulatory resolution was true for the diabetes drug glyburide (*Diabeta*, Sanofi-Aventis) in the fourth quarter list for 2016. The agency has updated the adverse-events section of the drug's label to include bullous reactions, erythema multiforme, and exfoliative dermatitis. Another example is ibrutinib (*Imbruvica*, Pharmacyclics and Janssen), indicated for chronic lymphocytic leukemia/small lymphocytic lymphoma, and two other types of lymphoma. The label was updated to warn about the risk for *Pneumocystis jirovecii* pneumonia.

Product Name: Trade (Active Ingredient) or Product Class	**Potential Signal of a Serious Risk / New Safety Information**	**Additional Information (as of March 31, 2017)**
Contrave (naltrexone HCl and bupropion HCl) extended-release tablets	Loss of consciousness	FDA is evaluating the need for regulatory action.
Coumadin (warfarin sodium) tablets, for oral use Eliquis (apixaban) tablets, for oral use Pradaxa (dabigatran etexilate mesylate) caps Savaysa (edoxaban tosylate) tablets, for oral use Xarelto	Menorrhagia	FDA decided that no action is necessary at this time based on available information.

(rivaroxaban) tablets, for oral use		
Depo-Medrol (methylprednisolone acetate) injectable suspension, USP, not for use in neonates, contains benzyl alcohol intravenous use Depo-Provera (medroxyprogesterone acetate), injectable suspension, USP Depo-Provera CI (medroxyprogesterone acetate), injectable suspension, for intramuscular use	Medication errors	The carton and container labeling was revised to help differentiate between Depo-Medrol and Depo-Provera products. Depo-Provera labeling
Diabeta (glyburide) tablets, USP	Skin reactions	The Adverse Reactions section of the labeling for Diabeta was updated to include bullous reactions, erythema multiforme, and exfoliative dermatitis. Diabeta labeling
Imbruvica (ibrutinib), capsules, for oral use	*Pneumocystis jirovecii* pneumonia (PJP)	The Warnings and Precautions section of the labeling for Imbruvica was updated to include PJP. Imbruvica labeling
Nitropress (sodium nitroprusside) injection	Carboxyhemoglobinemia	FDA is evaluating the need for regulatory action.
Northera (droxidopa) capsules, for oral use	Cerebrovascular accident	The Warnings and Precautions section of the labeling for Northera was updated to include information about stroke. The Adverse Reactions section of the labeling for Northera was updated with information about cerebrovascular accident. Northera labeling FDA is evaluating the need for other regulatory action.
Nucala (mepolizumab) for injection, for subcutaneous use	Anaphylaxis	The Warning and Precautions section of the labeling for Nucala was updated to include anaphylaxis. Nucala labeling
Opsumit (macitentan) tablets, for oral use	Fluid overload	The Warnings and Precautions section of the labeling for Opsumit was updated to include information

		about fluid retention. Opsumit labeling
Otezla (apremilast) tablets, for oral use	Diarrhea, nausea, and vomiting	FDA is evaluating the need for regulatory action.

Source: FDA

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