UPDATES

Health notices · Thursday 12 November

3 notices from the agencies today, in plain words, each with the original linked.

FDA approval for Fluoxetine capsules

FDA · Approval

If you take Fluoxetine, this FDA approval confirms it can be prescribed for certain mental health conditions, including major depressive disorder and obsessive-compulsive disorder (OCD).

The label also supports use for bulimia nervosa, panic disorder, and-when used together with olanzapine-for acute depressive episodes in bipolar I disorder.

What this changes for you is that your clinician may be able to choose Fluoxetine for these approved uses, depending on your diagnosis and treatment plan, as of the approval date.

Read the original notice

Recall notice for antimicrobial hand soap distributed nationwide

FDA · Recall

If you use Spurrier antimicrobial hand soap, this FDA notice says it is being recalled. A Class II recall means health risk is generally lower than with higher-class recalls.

The notice does not describe patient illness, but it lists quality manufacturing issues ("CGMP deviations") for the product made by ABC Compounding Co., Inc.

What to do

Read the original notice

- Do not use the Spurrier antimicrobial hand soap that is listed in this recall notice.

FDA approves Synjardy (empagliflozin and metformin)

FDA · Approval

If you have type 2 diabetes, the US Food and Drug Administration has approved Synjardy (empagliflozin and metformin) as an add-on to diet and exercise to improve glycemic control.

Synjardy includes an SGLT2 inhibitor (empagliflozin) and metformin. The metformin part means it is for type 2 diabetes, not type 1 diabetes.

The label also describes additional heart and kidney-related risk reductions in certain adults who take empagliflozin. The FDA labeling notes higher risk of diabetic ketoacidosis in people with type 1 diabetes.

Read the original notice

Where this comes from

- FDA approval for Fluoxetine capsules

  US Food and Drug Administration - Drugs@FDA · https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=075807
- Recall notice for antimicrobial hand soap distributed nationwide

  US Food and Drug Administration - enforcement report · https://www.fda.gov/drugs/drug-safety-and-availability/drug-recalls
- FDA approves Synjardy (empagliflozin and metformin)

  US Food and Drug Administration - Drugs@FDA · https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=206111