UPDATES

Health notices · Sunday 11 October

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

FDA class II recall for sodium chloride hypertonicity eye solution

FDA · Recall

The US Food and Drug Administration (FDA) classed a recall (Class II: Reliable-1 Laboratories) for Sodium Chloride Hypertonicity Ophthalmic Solution, 5%, in 0.5 FL OZ (15 mL) sterile bottles.

The concern is "lack of assurance of sterility." This means the product's sterility cannot be fully confirmed, which matters if the drops are placed in the eye.

The notice provided does not list specific next steps for patients. Look for any recall instructions that come with the alert for your product and bottle.

Read the original notice

FDA approval for amantadine extended-release capsules

FDA · Approval

If you take amantadine hydrochloride extended-release capsules, the FDA-approved label says it's used for preventing and treating flu-like signs and symptoms caused by influenza A virus.

The label also says it can be used for parkinsonism and drug-induced extrapyramidal reactions, which are movement side effects from some medicines.

The label warns it is not a substitute for yearly flu vaccination and that influenza A viruses can change, which may affect how well the drug works.

Read the original notice

FDA approves buprenorphine for opioid dependence treatment

FDA · Approval

If you have opioid dependence, the US Food and Drug Administration has approved buprenorphine (a partial opioid agonist) sublingual tablets to treat it.

This medicine is meant to be used as part of a complete treatment plan, including counseling and psychosocial support.

The label also says buprenorphine is preferred for induction (starting treatment).

What to do

Read the original notice

- Use buprenorphine sublingual tablet as part of a complete treatment plan to include counseling and psychosocial support.

Where this comes from

- FDA class II recall for sodium chloride hypertonicity eye solution

  US Food and Drug Administration - enforcement report · https://www.fda.gov/drugs/drug-safety-and-availability/drug-recalls
- FDA approval for amantadine extended-release capsules

  US Food and Drug Administration - Drugs@FDA · https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=214897
- FDA approves buprenorphine for opioid dependence treatment

  US Food and Drug Administration - Drugs@FDA · https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=207276