UPDATES

Health notices · Monday 16 November

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

FDA Class II recall for phenylephrine infusion due to sterility concern

FDA · Recall

The US Food and Drug Administration (FDA) issued a Class II notice for PHENYLephrine HCL infusion (100 mg per 250 mL in 0.9% sodium chloride), 0.4 mg/mL, sterile, in a single-use container.

The reason given is lack of assurance of sterility. The product (NDC 69852-100-25) was distributed nationwide within the U.S.

If you were given this infusion, your care team should be aware of this recall if they're checking which medicines you received.

Read the original notice

FDA approval expands Kerendia uses in kidney and heart disease

FDA · Approval

If you have chronic kidney disease with type 2 diabetes, Kerendia is approved to help reduce the risk of ongoing loss of kidney function, kidney failure, and certain serious heart outcomes.

If you have chronic kidney disease with type 1 diabetes, it is approved to reduce urinary albumin (a protein marker), which is expected to lower the risk of ongoing kidney function decline and kidney failure.

If you have heart failure with left ventricular ejection fraction (LVEF) of 40% or higher, Kerendia is approved to reduce the risk of cardiovascular death and heart-failure hospital visits.

Read the original notice

FDA approved FYARRO for malignant PEComa

FDA · Approval

If you're an adult with malignant PEComa that is locally advanced, unresectable, or has spread to other parts of the body, the FDA has approved FYARRO.

FYARRO is an mTOR inhibitor and a kinase inhibitor, medicines that are used to treat this cancer in the way the label specifies.

This approval may change what treatments are available for your condition going forward.

Read the original notice

Where this comes from

- FDA Class II recall for phenylephrine infusion due to sterility concern

  US Food and Drug Administration - enforcement report · https://www.fda.gov/drugs/drug-safety-and-availability/drug-recalls
- FDA approval expands Kerendia uses in kidney and heart disease

  US Food and Drug Administration - Drugs@FDA · https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=215341
- FDA approved FYARRO for malignant PEComa

  US Food and Drug Administration - Drugs@FDA · https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=213312