UPDATES

Health notices · Sunday 1 November

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

FDA approves naloxone hydrochloride for use with pentazocine tablets

FDA · Approval

If you have severe pain that requires an opioid pain medicine and alternative treatments are inadequate, not tolerated, or won't work well enough, the FDA has approved a naloxone hydrochloride product used with pentazocine.

Naloxone hydrochloride is included in PENTAZOCINE HYDROCHLORIDE AND NALOXONE HYDROCHLORIDE. The label warns about risks of addiction, abuse, misuse, overdose, and death with opioid analgesics at any dose or duration.

What matters for you tomorrow is that this opioid combination is intended for situations where other treatment options don't meet your pain needs, and the safety risks remain important throughout use.

Read the original notice

FDA approves ENTRESTO (sacubitril/valsartan) for certain heart failure

FDA · Approval

If you take ENTRESTO, it may now be available for people with chronic heart failure, including adults, and for symptomatic heart failure in children aged 1 year and older.

The treatment combines sacubitril and valsartan. The goal is to reduce the risk of cardiovascular death and hospitalization for heart failure.

The notice says benefits are most clear in people with left ventricular ejection fraction (LVEF) below normal, and that LVEF is a measure doctors use when choosing treatment.

What to do

Read the original notice

- Use ENTRESTO only as indicated in the FDA-approved prescribing information.

FDA approval expands mycophenolate mofetil use after transplants

FDA · Approval

If you're an adult or child age 3 months or older who received a kidney, heart, or liver transplant, the FDA has approved mycophenolate mofetil to help prevent organ rejection.

Mycophenolate mofetil is an immunosuppressant, meaning it helps your immune system not attack the new organ, and it is used alongside other medicines.

This can matter because it gives your transplant team another option to reduce the risk of rejection starting after your transplant.

Read the original notice

Where this comes from

- FDA approves naloxone hydrochloride for use with pentazocine tablets

  US Food and Drug Administration - Drugs@FDA · https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=219942
- FDA approves ENTRESTO (sacubitril/valsartan) for certain heart failure

  US Food and Drug Administration - Drugs@FDA · https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=219946
- FDA approval expands mycophenolate mofetil use after transplants

  US Food and Drug Administration - Drugs@FDA · https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=211272