UPDATES

Health notices · Monday 21 September

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

FDA approval for extended-release tapentadol for certain severe pain

FDA · Approval

If you are an adult with severe, persistent pain that needs an extended treatment period with a daily opioid, and other treatment options are inadequate, this new FDA-approved medicine may be relevant.

It is also approved for severe, persistent nerve pain from diabetic peripheral neuropathy (DPN)-pain caused by damaged peripheral nerves in diabetes-when alternative options are inadequate.

Tapentadol extended-release tablets are not meant for as-needed (prn) use, and the label highlights risks of addiction, misuse, and overdose with long-acting opioid medicines.

What to do

Read the original notice

- Use tapentadol extended-release tablets only for the indicated extended treatment of severe persistent pain or DPN when alternative options are inadequate, ineffective, not tolerated, or otherwise inadequate.
- Do not use tapentadol extended-release tablets as-needed (prn) analgesic.

Mycophenolate mofetil for injection carton label recall

FDA · Recall

If you receive mycophenolate mofetil for injection, the US Food and Drug Administration (FDA) says there's a Class II recall for specific packaged versions.

The notice reports that the carton label failed dissolution specifications. "Dissolution" means how the medicine breaks down, so it can work as intended.

The FDA publication date is 2026-09-09. The notice says the product was distributed in the U.S., nationwide.

Read the original notice

Recall: SPF 50 sunscreen gel may not provide labeled protection

FDA · Recall

If you use THE ONE SPF 50 Invisible Sunscreen Gel, the FDA says firm testing showed the product may not reliably provide the SPF 50 protection stated on the label.

SPF 50 is a measure of how much sunburn protection a sunscreen provides. If it doesn't perform as labeled, you may get less protection than expected.

What to do

Read the original notice

- Follow the FDA's recall instructions for THE ONE SPF 50 Invisible Sunscreen Gel, listed in the recall notice.

Where this comes from

- FDA approval for extended-release tapentadol for certain severe pain

  US Food and Drug Administration - Drugs@FDA · https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=220865
- Mycophenolate mofetil for injection carton label recall

  US Food and Drug Administration - enforcement report · https://www.fda.gov/drugs/drug-safety-and-availability/drug-recalls
- Recall: SPF 50 sunscreen gel may not provide labeled protection

  US Food and Drug Administration - enforcement report · https://www.fda.gov/drugs/drug-safety-and-availability/drug-recalls