UPDATES

Health notices · Friday 20 November

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

FDA approval of OXDERYS for multiple cancer uses

FDA · Approval

If you have a cancer listed on the OXDERYS label, the US Food and Drug Administration has approved OXDERYS (doxorubicin hydrochloride) for use in treatment.

Doxorubicin is an anti-cancer medicine. The label lists uses for several blood cancers and solid tumors, including adjuvant breast cancer after surgery and axillary lymph node involvement.

If you might be eligible for a doxorubicin-based treatment, ask your oncology care team whether OXDERYS is appropriate for your situation.

Read the original notice

FDA approved fludarabine phosphate injection for CLL after prior treatment

FDA · Approval

If you have B-cell chronic lymphocytic leukemia (CLL), the FDA has approved fludarabine phosphate injection for adults whose disease has not responded to, or has progressed during, treatment with at least one standard alkylating-agent containing regimen.

This approval is for people treated after that type of prior therapy; benefit in people who are newly diagnosed or who have not had refractory disease is not established in the label.

Read the original notice

FDA approval: SOLIRIS

FDA · Approval

If you have paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis, atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy, generalized myasthenia gravis (gMG), or neuromyelitis optica spectrum disorder (NMOSD), this approval may matter for you.

Complement is part of the immune system. The label describes using SOLIRIS to reduce the disease activity in conditions where complement contributes to symptoms. It is not indicated for Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).

Read the original notice

Where this comes from

- FDA approval of OXDERYS for multiple cancer uses

  US Food and Drug Administration - Drugs@FDA · https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=221093
- FDA approved fludarabine phosphate injection for CLL after prior treatment

  US Food and Drug Administration - Drugs@FDA · https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=090724
- FDA approval: SOLIRIS

  US Food and Drug Administration - Drugs@FDA · https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125166