UPDATES

Health notices · Thursday 27 August

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

CDC updates information about stillbirth

CDC · Guidance

Stillbirth is the loss of a pregnancy at or after the 20th week. It is different from miscarriage, which is usually defined as loss before the 20th week.

Stillbirth can affect families of all backgrounds. It occurs more commonly among people 35 years or older, people with low socioeconomic status, people who smoke during pregnancy, and people with certain medical conditions such as high blood pressure.

CDC says that if you're pregnant and notice something that feels unusual or worries you, talk to your doctor.

CDC also continues work to track stillbirth and research possible causes to help develop prevention programs.

What to do

Read the original notice

- Talk to your doctor if you're pregnant and notice something that feels unusual or worries you.

FDA approves buprenorphine hydrochloride for opioid dependence

FDA · Approval

If you have opioid dependence, the FDA has approved buprenorphine hydrochloride sublingual tablets. These are placed under the tongue.

This medicine contains buprenorphine, a partial opioid agonist (a medicine that activates opioid receptors but not fully). It is indicated for opioid dependence, and is preferred for induction.

The label says it should be used as part of a complete treatment plan, including counseling and psychosocial support.

What to do

Read the original notice

- Use buprenorphine sublingual tablets as part of a complete treatment plan that includes counseling and psychosocial support.

Changes to isotretinoin prescribing requirements and risk measures

MHRA · Safety

If you are prescribed isotretinoin, the MHRA has endorsed updated risk minimisation measures. The second prescriber regulatory requirement for patients under 18 has been replaced by alternative measures.

The updated "Acknowledgement of Risk Form" is revised and asks you to confirm you understand the intended use, that you can seek a second opinion, and that you are aware of a patient information video about the risks.

What to do

Read the original notice

- If you are starting isotretinoin, watch the patient information video produced by the British Association of Dermatologists (BAD).
- When you complete the updated Acknowledgement of Risk Form, confirm you are aware of the video.

Where this comes from

- CDC updates information about stillbirth

  Centers for Disease Control and Prevention · https://tools.cdc.gov/api/v2/resources/purls/0NCDW
- FDA approves buprenorphine hydrochloride for opioid dependence

  US Food and Drug Administration - Drugs@FDA · https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=090622
- Changes to isotretinoin prescribing requirements and risk measures

  mhra · https://www.gov.uk/drug-safety-update/isotretinoin-changes-to-prescribing-guidance-and-additional-risk-minimisation-me