New Morning-After Pill Ella Wins FDA Approval

Pill Effective Up to 5 Days After Sex

Aug. 13, 2010 -- The FDA has approved Ella, a new morning-after contraceptive pill effective for up to five days after unprotected sex or contraceptive failure.

An FDA expert advisory panel last June unanimously urged the FDA to approve the drug. Called Ella in the U.S., the drug already is approved in Europe and sold there as EllaOne.

The only other emergency contraceptive is Plan B. Unlike Ella, which will be available only by prescription, Plan B is sold without a prescription for women aged 17 and older.

Side effects of Ella, similar to those of Plan B, include headache, nausea, abdominal pain, pain/discomfort during menstruation (dysmenorrhea), fatigue, and dizziness. The drug should not be taken by women who are pregnant or nursing.

The two emergency contraceptives work differently:
Plan B contains levonorgestrel, a progestin hormone used in lower doses in many birth control pills.
Elara contains ulipristal, a non-hormonal drug that blocks the effects of key hormones necessary for conception.
Plan B should be taken as soon as possible after sex. It may work for up to 72 hours after sex.
While emergency contraception should not be delayed, Elara’s effectiveness does not fade for 120 hours (five days) after sex, regardless of whether the hormonal surge has occurred.

Elara is manufactured by Paris-based Laboratoire HRA Pharma. It will be distributed by Watson Pharma Inc., of Morristown, N.J.

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SOURCES:
News release, FDA.
FDA briefing document, June 17 meeting of Advisory Committee for Reproductive Health Drugs.
HRA Pharma briefing document, June 17 meeting of Advisory Committee for Reproductive Health Drugs.
Elaine Gansz Bobo, FDA press officer.
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