



# *Emergency Contraception and HPV Vaccine: Dispensing Meds & Dispelling Myths*

Don Downing, R.Ph.

Institute for Innovative Pharmacy Practice  
University of Washington School of Pharmacy  
dondown@u.washington.edu



## *Myth or Fact?*

- Emergency Birth Control (emergency contraception) causes abortions?



## *Myth!*

- **FACTS:**
- Emergency Birth Control Pills work just like all hormonal methods of contraception such as birth control pills, the ring, the patch and the IUD. Emergency Birth Control Pills are a more concentrated dose of the same hormones found in regular birth control pills.
- Emergency Birth Control Pills are an entirely different medication than RU-486 or mifepristone, also known as the “abortion pill.” Emergency Birth Control Pills, in fact, will not work if a woman is already pregnant.



## *Myth or Fact?*

- Access to Emergency Birth Control Pills promotes promiscuity and unsafe sexual behaviors



## *Myth!*

- Emergency Birth Control Pills are a responsible option for responsible women
- Women who obtain Emergency Birth Control Pills in advance do not abandon other methods of contraception
- Easy access to emergency contraception *does not* increase unprotected sexual activity among the young women (i.e. still used condoms)



# *Why are Emergency Birth Control Pills Needed?*

- In the U.S., there are 3 million unintended pregnancies each year
  - That is nearly  $\frac{1}{2}$  of ALL pregnancies (48%)
- 48% of women aged 15-44 have had an unintended pregnancy
- Unintended pregnancy is a major public health problem that affects individuals and society
- Emergency contraception has the potential to reduce unintended pregnancy significantly



# *Consequences of Unintended Pregnancy*

- Men and women may not continue their education
- Earning power likely to be decreased
- 3 x more likely to be involved in sexual violence
- **Less opportunity to prepare:**
  - Pre-pregnancy risk identification
  - Management of preexisting conditions
  - Changes in diet and vitamins
  - Avoidance of alcohol, toxic exposure, and smoking



# OTC Plan B™



### Drug Facts

**Active ingredient (in each tablet)**      **Purpose**  
Levonorgestrel 0.75mg.....Emergency contraceptive

**Use** reduces chance of pregnancy after unprotected sex (if a contraceptive failed or if you did not use birth control)

### Warnings

**Allergy alert:** Do not use if you have ever had an allergic reaction to levonorgestrel

**Sexually transmitted diseases (STDs) alert:** This product does not protect against HIV/AIDS or other STDs

### Do not use

- if you are already pregnant (because it will not work)
- for regular birth control

### When using this product you may have

- nausea                      ■ vomiting              ■ stomach pain
- tiredness                  ■ diarrhea              ■ dizziness
- menstrual changes      ■ breast pain          ■ headache

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control center right away.

### Directions

- women 18 years of age and over:
  - take the first tablet as soon as possible but no later than 72 hours (3 days) after unprotected sex. The sooner you take the first tablet, the more effective it will be. ▶

### Drug Facts (continued)

- take the second tablet 12 hours after you take the first tablet
- prescription only for age 17 and under. If age 17 or under, see a healthcare professional.

### Other information

- before using this product read the enclosed consumer information leaflet for complete directions and information
- this product is not recommended for regular birth control. It does not work as well as most other birth control methods used correctly.
- this product works mainly by preventing ovulation (egg release). It may also prevent fertilization of a released egg (joining of sperm and egg) or attachment of a fertilized egg to the uterus (implantation). See consumer information leaflet.
- when used correctly every time you have sex, latex condoms greatly reduce, but do not eliminate, the risk of pregnancy and the risk of catching or spreading HIV, the virus that causes AIDS. See condom labeling for additional STD information.
- this package is sealed with 2 seals imprinted with Plan B®. Do not use if these printed seals have either been removed or broken.
- store at 20-25°C (68-77°F)

### Inactive ingredients

colloidal silicon dioxide, corn starch, gelatin, lactose monohydrate, magnesium stearate, potato starch, talc

### Questions or comments?

For more information or to speak to a healthcare professional, call 1-800-330-1271, 24 hours a day/7 days a week. Visit our Web site at [www.go2planb.com](http://www.go2planb.com)

Place Label Here



Mfg. by Gedeon Richter, Ltd., Budapest, Hungary  
for Duramed Pharmaceuticals, Inc.  
Subsidiary of Barr Pharmaceuticals, Inc.  
Pomona, New York 10970

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# *Combination oral contraceptives*

Ethinyl estradiol 0.1 mg + DL-norgestrel 1.0 mg  
*TWO (2) doses: 12 hours apart*

- Ovral 2 white tablets
- Lo-Ovral 4 white tablets
- Nordette 4 light orange tablets
- Levlen 4 light orange tablets
- Alesse 5 pink tablets
- Trilevlen 4 yellow tablets
- Triphasil 4 yellow tablets
- Others...



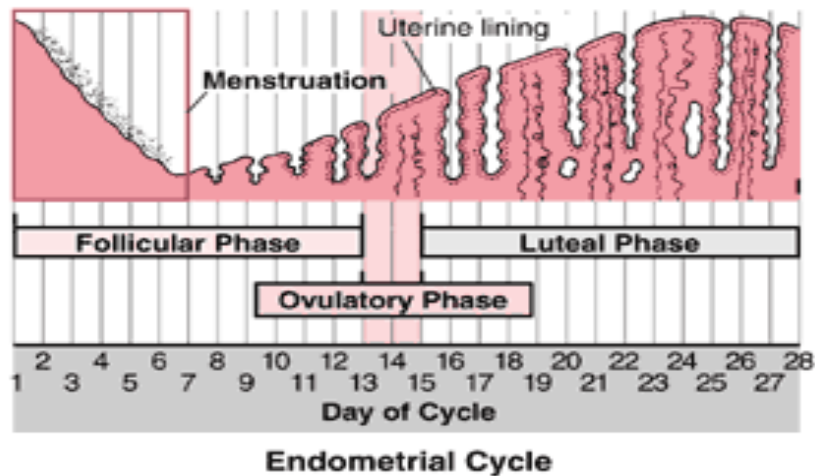
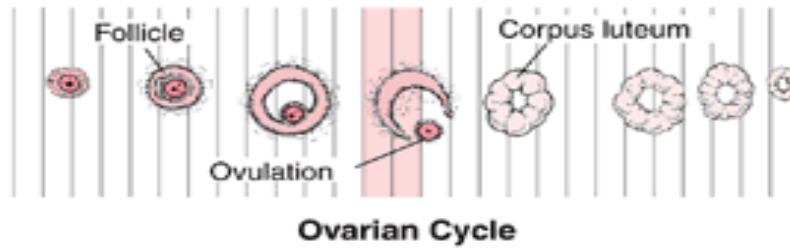
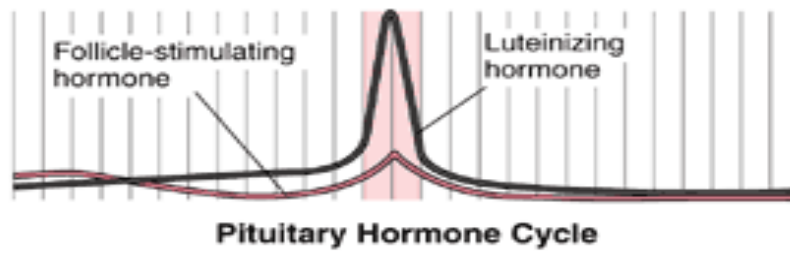
## *When is EC needed?*

- When any method of birth control fails
- No birth control is used
- A woman misses 2 or more birth control pills in a row or starts a pack 2 or more days late
- A woman is more than 2 weeks late for a Depo-provera injection
- A women is sexually assaulted



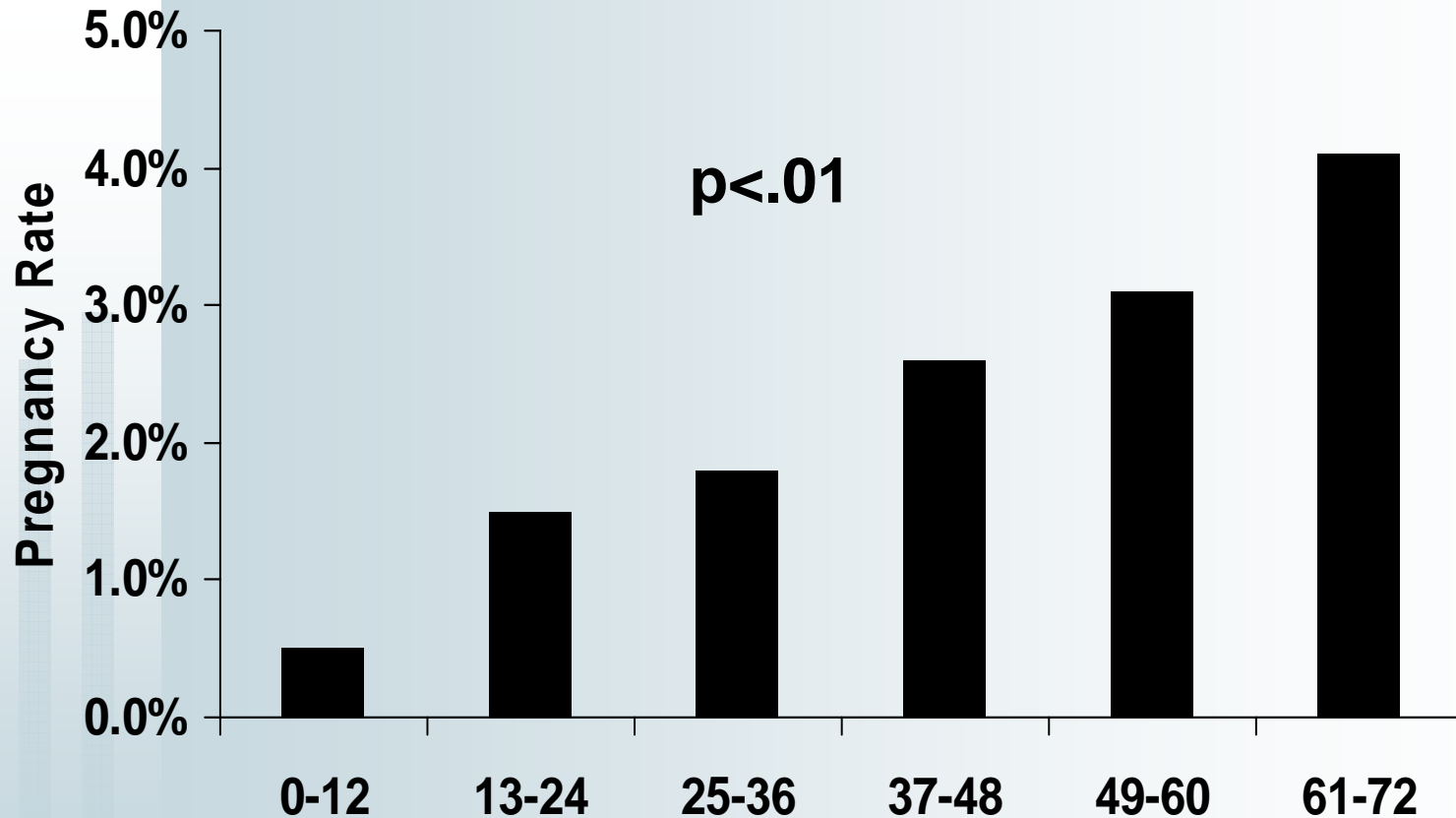
## *Newer Indications:*

- *Evra* Patch (transdermal patch)
  - Patch off for  $\geq 24$  hours during patch-on weeks
  - Left patch on more than 9 days straight
  - More than 2 days late putting patch back on
- *NuvaRing* (vaginal ring)
  - Taken out for  $> 3$  hours during ring-in weeks
  - Left in more than 5 weeks in a row
  - More than 2 days late putting ring back in





## *How Long After the Morning After? WHO Pooled Data (Yuzpe and LNg)*





# *International Consortium for Emergency Contraception*

July 2003

- Repeat Use
  - Women should use ECPs as often as needed.
  - However, counseling should include:
    - ECPs less effective at preventing pregnancy than other hormonal contraceptive methods;
    - Women choosing to take ECPs should start the method as early as possible after unprotected sex,
    - ECPs don't protect against STIs and that barrier methods should be used if at risk



## *Safety of ECP*

- Combination and Progestin only ECP
  - No evidence-based contraindications
- Combination ECP only
  - Acute classical migraine ?
  - History of thrombotic disease ?
    - No effect on clotting factors



# *Eligibility*

- Normal menstrual period in the last 4 weeks
- First act of unprotected intercourse within the last 120 hours



# *Additional Patient Assessment Information*

- Allergies
- Current contraceptive method
- Satisfaction with current method
- STD screening referral
- Victim of violence?
- Consider referral for any of above & know phone # and address of services



## *When to Expect Menses after ECP Use*

- Time to resumption of menses similar for combined and progestin-only regimens
- Compared with anticipated onset of next menses
  - 13% have a delay of 8+ days
  - 15% have a delay of 4-7 days
  - 61% have menses within  $\pm 3$  days
  - 11% have early onset ( $>3$  days early)
- A follow-up visit is warranted if menses do not return within three weeks following treatment



## *Key Messages in Counseling:*

- 72-hour (120hr) time frame for ECPs (but sooner is better)
- Safe and effective
- Mechanism of action (informed choice)
- Will not harm or interrupt an established pregnancy
- Do not cause abortion (Not like RU-486)
- Side effects: nausea, tiredness



## *Key Messages in Counseling:*

- Not as effective as other contraceptives for regular use
- Does not protect against STDs
- No future impact on childbearing
- Expense of ECP (covered in many cases)
- Confidentiality
- Need for on-going contraception
- Need to use EVERY time a contraceptive method fails or is not used



## *OTC Plan B<sup>TM</sup> Dilemmas*

- Will insurance cover OTC product? If Rx'd?
- What I.D. is necessary?
- What if consumer looks obviously over 18 but has no I.D.?
- How many can be purchased at a time?
- Is it legal to sell to one person knowing that it will be used by someone else?



## *OTC Plan B™ Dilemmas*

- Can a man buy it?
- Do I need to keep a signature registry like pseudoephedrine products and photo I.D.?
- What if store/pharmacy have differential hrs?
- How will patients get the information they need about EC, on-going HC, needed resources?
- Can I use current Plan B™ as OTC product?



# *Patient Education Materials Available for Download:*

- **www.path.org**
  - Patient Education Materials in 13 Languages
- **www.GO2ec.org** (for providers)
- **Not-2-Late website and phone** (for consumers)
  - **http://ec.princeton.edu/** or **www.not-2-late.com**
  - **888-NOT-2-LATE**



# *Human Papilloma Virus (HPV)*

- HPV is the most commonly diagnosed sexually transmitted infection in the United States.
- 6.2 million new infections
- 20% of 15-49 year-old Americans are infected
- 50% lifetime risk for sexually active males and females



## *HPV Cancer Risk*

- Persistent infection with high-risk HPV is responsible for 99.7% of cervical cancers.



# *Preventing Cervical Cancer*

## Secondary prevention

- Screening

- Primary prevention

- Behavioral changes

- Condom use

- Vaccination



# *HPV Vaccine*

- Gardasil™
  - Quadrivalent vaccine
  - Merck
  - Licensed 6/06
  - 3 injected doses: Start, 2 months from start and 6 months from start
  - Prevents almost all cervical cancers!