



## Rx Focus

### Exanta versus Coumadin

There is currently a lot of interest in a new anticoagulant called Exanta (generic name ximelagatran). It is the first oral anticoagulant in a class called Direct Thrombin Inhibitors that are used to decrease the risk of clotting. Results from a major study called the SPORTIF V trial showed Exanta to be just as effective as Coumadin in the prevention of stroke in patients with a clotting associated heart dysfunction called atrial fibrillation. The results illustrated that 36 mg of Exanta given twice daily had only a 1.6% incidence of stroke compared to 1.2% in the Coumadin group. When comparing the risk of bleeds, Exanta proved to have a lower risk in relation to Coumadin. One of the disadvantages of Exanta is that it causes a short term liver impairment, which normally subsides within 2-3 months.

The major advantages of Exanta are its rapid onset of action (2 hours versus 72 hours with Coumadin), lack of food or drug interactions, and lack of need for continuous coagulation monitoring as with Coumadin. Typically, treatment with Coumadin, due to its delayed onset, requires a bridge therapy with Heparin or Low Molecular Weight Heparin, which are only available as injectables. Exanta, however, due to its fast onset does not require a

bridging therapy. Coumadin interacts with many foods and drugs such as antibiotics, anticonvulsants, and grapefruit juice. Exanta lacks such interactions. This makes Exanta a safer medication. The biggest advantage of Exanta is that it doesn't require the continued blood tests to check coagulation levels called INR as does Coumadin. Exanta exhibits a predictable action in the body that allows for use of fixed doses thus eliminating the need for coagulation monitoring. This will decrease the costs associated with anticoagulation therapy, thereby altering the current structure of such clinics.

Currently, Exanta has been approved for use in France for the prevention of clots in major hip or knee replacement surgery. The manufacturer plans to file for U.S. approval and expects to receive authorization for distribution in late 2004.

#### References:

1. Francis CW, Berkowitz SD, Comp PC, et al. Comparison of ximelagatran with warfarin for the prevention of venous thromboembolism after total knee replacement. *N Engl J Med* 2003;349:1703-12.
2. Pharmacist's Letter: December 2003; Vol:19, No.12

### Emergency Contraceptive Available OTC?

The Food and Drug Administrations (FDA) Advisory Committee has recently recommended that the emergency contraceptive called Plan B be switched to over-the-counter (OTC) status. Plan B was approved in 1999 for emergency contraception following unprotected sex. It is 89% effective, if used within the first 72 hours after intercourse, in preventing a fertilized egg from implanting and even more effective if used within 24 hours. Plan B comes as two 0.75mg doses of levonorgestrel taken 12 hours apart, which makes for ease of usage. It has been estimated that Plan B could prevent 1.7 million unintended pregnancies and 800,000 abortions per year in the United States. Currently, Canada and many European countries offer this product OTC. Through collaborative practices with physicians, pharmacists in Alaska, California, Washington and New Mexico can sell Plan B without a prescription. The most common adverse side effects of Plan B include nausea, vomiting, dizziness, headache, fatigue, breast tenderness, abdominal pain, and menstrual irregularities.

In order to be approved for OTC status in the U.S., the product must have low toxicity, no potential for overdose or addiction, no fetal effects, no medical screening, uniform dose requirements, and lack drug interactions. Supporters of

### March Health Observances

**National Colorectal Cancer Awareness Month** – sponsored by Cancer Research and Prevention Foundation, [www.preventcancer.org/colorectal](http://www.preventcancer.org/colorectal)

**Save Your Vision Month** – sponsored by American Optometric Association, [www.aoa.org](http://www.aoa.org)

**National Kidney Month** – sponsored by National Kidney Foundation, [www.kidney.org](http://www.kidney.org)

**National Multiple Sclerosis Education and Awareness Month** - sponsored by Multiple Sclerosis Foundation, [www.msfocus.org/programs\\_events/prog\\_edumth.html](http://www.msfocus.org/programs_events/prog_edumth.html)

Plan B OTC argue that Plan B fulfills all the above requirements and believe it will be approved by next year. The OTC version of Plan B will be kept behind the pharmacy counter and cost \$30-\$40, which should discourage women from using it as a regular contraceptive.

References:

1. Barr, Plan B Emergency Contraceptive OTC CARE Program Adequate, Cmte. <http://www.fdaadvisorycommittee.com>
2. Pharmacist's Letter: January 2004; Vol:20, No.1



## Industry Report

### DNA and Medication Selection

Within the next 3 years, the FDA will be requiring all drug manufacturers to conduct pharmacogenomic tests on new medications. Pharmacogenomics involves the small genetic (DNA) differences that explain why people respond differently to medications. This will allow individualization of drug choice by predicting which people have a greater chance of risk or benefit in order to maximize effectiveness and safety. Pharmacogenomics may also be used to help track down the cause of certain rare, serious drug side effects.

References:

1. New Along the Pike, Dec. 3, 2003.  
<http://www.fda.gov/cder>



## New Drug Approvals

### Avastin™

**Approved 2/26/2004**

*Chemical Name:* Bevacizumab

*Manufacturer:* Genentech, Inc.

*Therapeutic Class:* Angiogenesis Inhibitor

*Approved Indications:* Treatment of metastatic colorectal cancer

*Other Drugs in Class:* none

### Plenaxis™

**Approved 11/25/2003**

*Chemical Name:* Abarelix

*Manufacturer:* Praecis Pharmaceuticals

*Therapeutic Class:* Anti-Androgen

*Approved Indications:* Treatment of Advanced Prostate Cancer

*Other Drugs in Class:* Lupron and Zoladex

### Ertaczo™

**Approved 12-10-03**

*Chemical Name:* Sertaconazole

*Manufacturer:* Mylan Laboratories

*Therapeutic Class:* Anti-Fungal

*Approved Indication:* Tinea Pedis

*Other Drugs in Class:* Ketoconazole and clotrimazole



## New Generic Approvals

### Hydrocortisone Butyrate Solution Approved 9/18/03

*Brand Name Equivalent:* Locoid

*Manufacturer:* Taro

*Therapeutic Class:* Topical Steroid

*Approved Indication:* Dermatoses



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