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Rx Focus

West Nile Virus Infection

Due to higher rainfall and increased temperatures across the United States this summer, experts believe this will be the worst year yet for West Nile Virus (WNV) infection. WNV is transmitted to humans by infected mosquito bites. (Mosquitoes acquire the virus by feeding off the blood of infected birds.)

Infections typically occur in late summer and early fall. It takes anywhere from 3 to 14 days to develop symptoms with symptoms lasting approximately 3 to 6 days. It is estimated that only 20% of infected individuals develop mild symptoms: fever, headache, swollen lymph nodes, and body aches. More severe symptoms are experienced by about 1% of infected individuals: muscle weakness, altered mental status, brain inflammation, seizures, coma, and rarely, death. (Last year, over 4,000 people in the United States were infected with the virus with 284 reported deaths.)

It appears that people over 50 years of age and those with low immunity are at greatest risk for developing severe symptoms. WNV is not contagious; however, it is known that the virus may be spread through blood transfusions, organ transplants, breastfeeding and even from mother to baby during pregnancy.

Because there is not specific treatment for WNV other than symptom relief, it is best to prevent infection. Limit outdoor activities at dusk and dawn when mosquitoes are most active. Wear long sleeves and pants outside, and avoid wearing tight clothes as mosquitoes can bite through them. Use insect repellent containing DEET (N,N-diethyl-3-methylbenamide) while outdoors.

Adults are advised to use products containing anywhere from 10% to 50% DEET. Generally, the higher the concentration of DEET, the longer the duration of protection. The current recommendation from the American Academy of Pediatrics is not to exceed 30% DEET in insect repellent products for infants and children. DEET-containing products are NOT recommended for use in infants less than two months of age. (If using sunscreen as well, the sunscreen should be applied first.)

The CDC recommends against the use of combination sunscreen/insect repellent products because the sunscreen generally has to be applied more frequently than the repellent.



Industry Report

Counterfeit Medications

In an effort to stop medication counterfeiting, the Pharmaceutical Research and Manufacturers of America (PhRMA) organization joined forces with the FDA, back in June, to encourage all pharmaceutical companies to notify the FDA of suspected counterfeit products. On July 16th, the FDA announced the start of a task force to prevent the distribution of counterfeit medications.

Although the incidence of medication counterfeiting in the United States (US) is not widespread, there has been an increase in recent years – at least ten counterfeit products have reached pharmacy shelves and have been dispensed to patients. These products include Epogen®, Neupogen®, Procrit®, Combivir®, Lipitor®, Viagra®, and Zyprexa®. Typically, the drugs chosen for counterfeiting are very expensive, netting large profits for the forgers, and the actual counterfeiting involves product mislabeling, dilution of active ingredients, or substitution with cheaper ingredients.

The factors that are contributing to the increased incidence of counterfeit medications reaching US consumers include the on-line sale of drugs by unlicensed pharmacies and/or foreign websites, US wholesalers acquiring medications from unreliable secondary sources, and very sophisticated counterfeiting technology. Consumers can protect themselves by purchasing their medications solely from domestic licensed pharmacies. In addition, any unusual packaging, odor, unusual appearance or unfamiliar side effects should be reported immediately to their physician or pharmacist.

More ➔



State & Federal Updates

On September 3, 2003, the Food and Drug Administration (FDA) announced new progress toward "21st Century" regulation of pharmaceutical manufacturing. This initiative was launched one year ago and is expected to take two years to implement. Its aim is to ensure that regulatory review, compliance and inspection policies are based on state-of-the-art pharmaceutical science and do not delay rapid adoption of new pharmaceutical technologies. In addition, it aims to produce more precise safe and effective medications and to assure their quality while increasing efficiencies.

Four major steps have been taken:

- ➔ New guidances have been issued by the FDA to enhance the consistency and coordination of its drug quality regulatory programs.
- ➔ The FDA has collaborated with academia, industry and other government organizations to promote cutting edge approaches to drug development and regulation.
- ➔ The agency has taken steps to streamline its internal processes.
- ➔ The FDA is actively seeking to improve international standards for drugs by collaborating with its public health counterparts in other nations.



New Drug Approvals

Aloxi Approved 7/28/2003

Chemical Name: Palonosetron

Manufacturer: Cardinal Health and Helsinn Birex Pharmaceuticals

Therapeutic Class: Antiemetic and Antinauseant

Approved Indications: Treatment of acute and delayed nausea and vomiting associated with cancer chemotherapy.

Other Drugs in Class: Anzemet, Kytril, Zofran

Average Wholesale Price: \$64.80 per vial

Special Notes: IV Injection

FluMist Approved 6/17/2003

(Influenza Virus Vaccine Live, Intranasal)

Manufacturer: MedImmune Vaccines Inc. (Wyeth will share marketing responsibilities.)

Therapeutic Class: Influenza Vaccine

Approved Indication: Prevention of influenza illness in healthy individuals ages 5 to 49 years of age.

Average Wholesale Price: \$57.50 per unit

Special Notes: FluMist is both the first nasally administered vaccine and first live virus vaccine to be marketed in the United States.

Levitra Approved 8/19/2003

Chemical Name: Vardenafil

Manufacturer: Bayer and GlaxoSmithKline

Approved Indication: Treatment of Erectile Dysfunction

Other Drugs in Class: Viagra

Average Wholesale Price: \$9.63 per tablet (all strengths)

Seasonale Approved 9/8/2003

Chemical Name: Ethinyl Estradiol and Levonorgestrel

Manufacturer: Barr Laboratories

Therapeutic Class: Oral Contraceptive

Approved Indications: Prevention of pregnancy

Average Wholesale Price: Unavailable at present

Special Notes: First 91-day regimen to be approved in the United States. Active tablets are taken for 12 weeks followed by one week of placebo (inactive) tablets.



New Generic Approvals

Cefuroxime Axetil Tablets

250mg and 500mg: 7/25/2003

Brand Name Equivalent: Ceftin®

Manufacturer: Watson Pharmaceuticals, Inc.

Oxycodone/Acetaminophen Tablets

7.5mg/325mg and 10mg/325mg: 9/8/2003

Brand Name Equivalent: Percocet® Tablets

Manufacturer: Watson Pharmaceuticals, Inc.



675 Foxon Road, Suite 204

East Haven CT 06513

Phone: (800) 936-1193

Fax: (203) 468-8416

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