

POLICY & PRACTICE

Boost in SCHIP Funds

Help is on the way for states facing empty children's health care budgets. The Department of Health and Human Services is redistributing \$643 million in unspent 2002 funds for the State Children's Health Insurance Program. "I am very pleased that we can take action to prevent any loss or break in coverage because program funds weren't being used by states that need them the most," said Mark McClellan, M.D., administrator of the Centers for Medicare and Medicaid Services. Twenty-eight states will be getting supplemental

funds under this action. Without it, five states—Arizona, Minnesota, Mississippi, New Jersey, and Rhode Island—would have run out of federal funding for their SCHIP programs, according to HHS. Even with the redistribution, Dr. McClellan said he expected to complete fiscal year 2005 with more than \$5 billion in unspent federal matching funds.

Compensation for Vaccine Injuries

The National Vaccine Injury Compensation program (VICP) will now cover injuries related to the hepatitis A vaccine. He-

patitis A is the most common type of hepatitis reported in the United States, and causes an estimated 125,000-200,000 cases per year. The vaccine is recommended for children in certain states and high-incidence communities, in addition to people with chronic diseases or for those traveling to countries where the disease is common. Most people who receive the hepatitis A vaccine don't experience serious problems. However, those who believe they've been injured by the vaccine must file a claim within 3 years of the first symptom of the vaccine injury or within 2 years of the vaccine-related death, but not more than 4 years after the start of the

first symptom of the vaccine-related injury from which the death occurred. Administered by the Health Resources and Services Administration, the VICP program provides financial compensation to eligible individuals thought to be injured by vaccines.

Responsible Food Marketing

The Center for Science in the Public Interest wants supermarkets, media outlets, and schools to change the way "junk food" is marketed to children. The public interest group has issued guidelines calling on companies not to market low-nutrition drinks like sodas, sports drinks, and sweetened iced teas to children. Further, foods marketed to children should have reasonable portion sizes, and provide some basic nutrients. "What we're really asking is that marketers act responsibly and not urge kids to eat foods that could harm their health," said Margo G. Wootan, CSPI's nutrition policy director. CSPI's guidelines were sent to supermarkets, major food companies, chain restaurants, television networks and stations, movie studios, and children's magazines. Meanwhile, the National Automatic Merchandising Association released its own initiative to fight childhood obesity, promoting a color-coded snack food rating system in school vending machines.

Secondhand Smoke Campaign

In another campaign to improve children's health, the American Legacy Foundation is asking parents to create smoke-free environments for their families. According to the Foundation's research, more than 13 million children in the United States are breathing secondhand smoke in their homes, resulting in serious health implications. In 82% of the cases where a young person lives with a smoker, that smoker is a parent. In television and radio public service announcements, the campaign urges parents to keep their homes and cars smoke-free and refrain from smoking around children. The foundation is based in Washington and develops programs that address the health effects of tobacco use. A previous foundation report found that a small reduction in tobacco smoke exposure would result in fewer low-birth-weight babies and fewer cases of asthma and ear infections.

Medicaid's Benefits to the States

An annual fiscal survey of the states failed to examine the benefit of Medicaid to the states' economies, according to Families USA. The report released by the National Governors Association (NGA) and the National Association of State Budget Officers indicated that state spending for Medicaid, including federal funds, has surpassed state spending on primary and secondary education. Yet in examining state general fund expenditures, states spent more than twice as much on education than they did on Medicaid. "When analyzing the NGA survey's findings on Medicaid, it is important to count the economic benefit that Medicaid holds for states," said Families USA Executive Director Ron Pollack. "A recent Families USA study found that on average every \$1 million invested in Medicaid by states generates nearly 34 jobs, \$1.2 million in wages, and \$3.3 million in business activity," he added.

—Jennifer Silverman

Grifulvin V®

(griseofulvin tablets) microsize and (griseofulvin oral suspension) microsize Tablets/Suspension

BRIEF SUMMARY**Description**

Griseofulvin is an antibiotic derived from a species of *Penicillium*. Each GRIFULVIN V Tablet contains either 250 mg or 500 mg of griseofulvin microsize, and also contains calcium stearate, colloidal silicon dioxide, starch, and wheat gluten. Additionally, the 250 mg tablet also contains dibasic calcium phosphate. Each 5 mL of GRIFULVIN V Suspension contains 125 mg of griseofulvin microsize and also contains alcohol 0.2%, docusate sodium, FD&C Red No. 40, FD&C Yellow No. 6, flavors, magnesium aluminum silicate, menthol, methylparaben, propylene glycol, propylparaben, saccharin sodium, simethicone emulsion, sodium alginate, sucrose, and purified water.

IMPORTANT NOTE: This information is a BRIEF SUMMARY of the complete prescribing information provided with the product and therefore should not be used as the basis for prescribing the product. This summary has been prepared by deleting information from the complete prescribing information such as certain text, tables and references. The physician should be thoroughly familiar with the complete prescribing information before prescribing the product.

Indications and Usage

Major indications for GRIFULVIN V are:

- Tinea capitis (ringworm of the scalp)
- Tinea corporis (ringworm of the body)
- Tinea pedis (athlete's foot)
- Tinea unguium (onychomycosis; ringworm of the nails)
- Tinea cruris (ringworm of the thigh)
- Tinea barbae (barber's itch)

GRIFULVIN V inhibits the growth of those genera of fungi that commonly cause ringworm infections of the hair, skin, and nails, such as:

<i>Trichophyton rubrum</i>	<i>Microsporum audouinii</i>
<i>Trichophyton tonsurans</i>	<i>Microsporum canis</i>
<i>Trichophyton mentagrophytes</i>	<i>Microsporum gypseum</i>
<i>Trichophyton interdigitalis</i>	<i>Epidermophyton floccosum</i>
<i>Trichophyton verrucosum</i>	<i>Trichophyton megnini</i>
<i>Trichophyton sulphureum</i>	<i>Trichophyton gallinae</i>
<i>Trichophyton schoenleinii</i>	<i>Trichophyton crateriform</i>

Note: Prior to therapy, the type of fungi responsible for the infection should be identified. The use of the drug is not justified in minor or trivial infections which will respond to topical anti-fungal agents alone.

It is **not** effective in:

Bacterial infections	Coccidioidomycosis
Candidiasis (Moniliasis)	North American Blastomycosis
Histoplasmosis	Cryptococcosis (Torulosis)
Actinomycosis	Tinea versicolor
Sporotrichosis	Nocardiosis
Chromoblastomycosis	

Contraindications

This drug is contraindicated in patients with porphyria, hepatocellular failure, and in individuals with a history of hypersensitivity to griseofulvin.

Two cases of conjoined twins have been reported in patients taking griseofulvin during the first trimester of pregnancy. Griseofulvin should not be prescribed to pregnant patients.

Warnings

Prophylactic Usage: Safety and efficacy of prophylactic use of this drug has not been established.

Chronic feeding of griseofulvin, at levels ranging from 0.5-2.5% of the diet, resulted in the development of liver tumors in several strains of mice, particularly in males. Smaller particle sizes result in an enhanced effect. Lower oral dosage levels have not been tested. Subcutaneous administration of relatively small doses of griseofulvin once a week during the first three weeks of life has also been reported to induce hepatomata in mice. Although studies in other animal species have not yielded evidence of tumorigenicity, these studies were not of adequate design to form a basis for conclusions in this regard.

In subacute toxicity studies, orally administered griseofulvin produced hepatocellular necrosis in mice, but this has not been seen in other species. Disturbances in porphyrin metabolism have been reported in griseofulvin-treated laboratory animals. Griseofulvin has been reported to have a colchicine-like effect on mitosis and cocarcinogenicity with methylcholanthrene in cutaneous tumor induction in laboratory animals.

Reports of animal studies in the Soviet literature state that a griseofulvin preparation was found to be embryotoxic and teratogenic on oral administration to pregnant Wistar rats. Rat reproduction studies done in the United States and Great Britain were inconclusive in this regard. Pups with abnormalities have been reported in the litters of a few bitches treated with griseofulvin. Because the potential for adverse effects on the human fetus cannot be ruled out, additional contraceptive precautions should be taken during treatment with griseofulvin and for a month after termination of treatment. GRIFULVIN V should not be prescribed to women intending to become pregnant within one month following cessation of therapy.

Suppression of spermatogenesis has been reported to occur in rats but investigation in man failed to confirm this. Griseofulvin interferes with chromosomal distribution during cell division, causing aneuploidy in plant and mammalian cells. These effects have been demonstrated *in vitro* at concentrations that may be achieved in the serum with the recommended therapeutic dosage.

Since griseofulvin has demonstrated harmful effects *in vitro* on the genotype in bacteria, plants, and fungi, males should wait at least six months after completing griseofulvin therapy before fathering a child.

Precautions

Patients on prolonged therapy with any potent medication should be under close observation. Periodic monitoring of organ system function, including renal, hepatic and hemopoietic, should be done.

Since griseofulvin is derived from species of penicillin, the possibility of cross sensitivity with penicillin exists; however, known penicillin-sensitive patients have been treated without difficulty.

Since a photosensitivity reaction is occasionally associated with griseofulvin therapy, patients should be warned to avoid exposure to intense natural or artificial sunlight. Should a photosensitivity reaction occur, lupus erythematosus may be aggravated.

Drug Interactions: Patients on warfarin-type anticoagulant therapy may require dosage adjustment of the anticoagulant during and after griseofulvin therapy. Concomitant use of barbiturates usually depresses griseofulvin activity and may necessitate raising the dosage.

The concomitant administration of griseofulvin has been reported to reduce the efficacy of oral contraceptives and to increase the incidence of breakthrough bleeding.

Adverse Reactions

When adverse reactions occur, they are most commonly of the hypersensitivity type such as skin rashes, urticaria and rarely, angioneurotic edema or erythema multiforme-like drug reaction, and may necessitate withdrawal of therapy and appropriate countermeasures. Paresthesias of the hands and feet have been reported rarely after extended therapy. Other side effects reported occasionally are oral thrush, nausea, vomiting, epigastric distress, diarrhea, headache, fatigue, dizziness, insomnia, mental confusion and impairment of performance of routine activities.

Proteinuria and leukopenia have been reported rarely. Administration of the drug should be discontinued if granulocytopenia occurs.

When rare, serious reactions occur with griseofulvin, they are usually associated with high dosages, long periods of therapy, or both.

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