Health Disparities Support Need for Reform

BY MARY ELLEN SCHNEIDER

Racial and ethnic minorities have higher rates of disease and reduced access to health care compared with the general population, according to a new report from the Department of Health and Human Services.

African Americans, for example, suffer from chronic diseases such as diabetes nearly twice the rate of whites. About 15% of African Americans, 14% of Hispanics, and 18% of American Indians have type 2 diabetes, compared with 8% of whites, according to the report. Racial and ethnic minorities and low income individuals also have reduced access to health care. The report found that Hispanics are only half as likely as whites to have a usual source of medical care. Racial and ethnic minorities were also less likely to lack health insurance.

These disparities highlight the need for larger health reform that invests in prevention and wellness and ensures access to affordable health care, the report concluded. HHS Secretary Kathleen Sebelius repeated the message during a round table discussion at the White House. “Certainly the kind of disparities we’ve seen too often in the health care system are disproportionately represented by low income Americans and minority Americans,” she said. “Health care reform is key to helping us address these challenges.”

But new health reform legislation will be one only part of the administration’s push to reduce health disparities. Ms. Sebelius said she pledged to do whatever possible under the current authority given to HHS to close the gap on disparities.

Needs include a greater investment in prevention, more data collection to identify disparities, and access to more culturally competent care. An overview of the IMPACT Act was included with the report. The roundtable included representatives from various minority and public health groups who offered their suggestions for how health reform legislation could help to close the gap on disparities.

While nearly all expressed their eagerness to help get a health reform bill passed this year, many cautioned the administration that health coverage alone does not equal meaningful access. Other critical elements that are needed to help improve the equity of health care include a greater investment in prevention, more data collection to identify disparities, and access to more culturally competent care, the representatives said.

**Alldara® (imiquimod) Cream, 5%**

**Brief Summary of External Genital Wart Prescribing Information**

See Package Insert for Full Prescribing Information

**INDICATIONS AND USAGE:**

External genital Warts: Alldara Cream is indicated for the treatment of external genital warts caused by human papillomavirus (HPV) types 6 and 11 in patients 12 years of age and older. The safety and efficacy of Alldara Cream in immuno-compromised patients and in patients with concurrent infections is not established.

**CONTRAINDICATIONS:**

None.

**WARNINGS/ PRECAUTIONS:**

Local Infammatory Reactions: Infiammation, including skin swelling and pain of the injection site, may occur after Alldara Cream applications and may persist for several weeks. The risk of these reactions appears to be increased when using Alldara Cream on lesions including chronic graft versus host disease. Administration of Alldara Cream is not recommended until a skin test has been performed.

**ADVERSE REACTIONS:**

Systemic Reactions: Overall, 1.2% (4/327) of the subjects discontinued due to local skin/application site adverse reactions. Some of these reactions can result in a dermatologic reaction following multiple oral imiquimod doses of >200 mg (equivalent to imiquimod content of >16 packets) was demonstrated. These reactions include local skin or genital reactions and are most frequently reported during the first 3 months of treatment. The median absolute neutrophil count decreased by 1.42*10⁹/L.

**CLINICAL STUDIES:**

In patients with external genital/perianal warts below the age of 12 years have not been established. Alldara Cream has also not been evaluated for the treatment of anal, interdigital, oral, rectal, subungal, or in situ human papillomavirus disease.

**USE IN SPECIFIC POPULATIONS:**

Pregnancy: Pregnancy Category D. Oral doses of 1.5 and 5 mg/kg/day to pregnant rats resulted in an increase in fetal resorptions, and a decrease in fetal weight and ossification. No adverse effect on reproductive performance or fetal weights was noted in rats dosed at 5 mg/kg/day (164X MRHD based on AUC comparisons). In pregnant rabbits, oral doses of 6.5, 20, and 65 mg/kg/day produced a decrease in maternal weight gain and/or maternal toxicity. No teratogenic effect was noted in the high dose studied in the rat, 1 mg/kg/day (42X MRHD based on AUC comparisons). A combined fertility and post-partum development study was conducted in rats. Oral doses of 1.5, 5, and 6 mg/kg/day were biologically equivalent in rats for 70 days prior to mating through the mating period and for 14 days prior to breeding through pregnancy. No effects on fertility or post-partum were noted at doses of 1.5 mg/kg/day (164X MRHD based on AUC comparisons). The enhancement of ultraviolet carcinogenicity is not necessarily dependent on photodynamic mechanisms; therefore, patients should continue to avoid sun or artificial sources of ultraviolet exposure.

**APPLICATION SITE REACTIONS:**

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**EDUCATIONAL MATERIALS:**

Educational materials about the importance of routine screening and follow-up through the year 15 after treatment has not been established.

**PROVIDER INSTRUCTIONS:**

Topical Treatment of External Warts: Topical treatment with Alldara Cream is effective in the treatment of external genital warts caused by human papillomavirus types 6 and 11. The most frequently reported adverse reactions associated with the use of Alldara Cream are burning, 30% (31/107), and pain, 12% (13/107) in the treatment area in the studies conducted in adults and also included erythema, 14% (15/107), and pruritus, 12% (13/107). In studies conducted in children, 3% (9/283) of subjects reported a burning reaction. All subjects reported a burning reaction in studies conducted in children and adults. The most frequently reported adverse reactions associated with the use of Alldara Cream are burning, 30% (31/107), and pain, 12% (13/107) in the treatment area in the studies conducted in adults and also included erythema, 14% (15/107), and pruritus, 12% (13/107). In studies conducted in children, 3% (9/283) of subjects reported a burning reaction. All subjects reported a burning reaction in studies conducted in children and adults.

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