Actinic keratosis on the face or scalp in adults with a normal immune system

1.4 Limitations of Use

Imiquimod Cream USP, 5% is indicated for the treatment of external genital and perianal warts/cum contagiosum and these studies failed to demonstrate efficacy of Imiquimod Cream in the treatment of anal warts/cum contagiosum in children aged 2-12 (1.4, 8.4).

1.5 Unevaluated Populations

• Children younger than 2 years of age: the safety and efficacy of Imiquimod Cream have not been established in children younger than 2 years of age.

• Males: 19 (12%) 9 (8%) 3 (1%) 3 (1%) 19 (9%) 3 (3%) 3 (1%) 1 (<1%)

• Females: 21 (21%) 8 (8%) 1 (1%)

2.1 Actinic Keratosis

Imiquimod cream (im i´ kwi mod) is a prescription medicine for use on the skin only (topical) to treat:

• external genital warts/cum contagiosum

• actinic keratoses on the face or scalp in adults with a normal immune system

• actinic keratoses on the face or scalp in adults with a normal immune system

2.2 Malignant Warts

The safety and efficacy of Imiquimod Cream, USP, in immunocompromised patients has not been established.

2.3 Other Warts

Imiquimod Cream is for topical treatment of internal genital and perianal warts/cum contagiosum in adults with a normal immune system.
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11. DOSAGE AND ADMINISTRATION

11.1 General Information: Indications

Imiquimod Cream is indicated for the treatment of external genital warts, including perianal warts and external genital warts in adults and adolescents 12 years of age and older.

Imiquimod Cream is intended for topical application only. The solution should not be used systemically.

The recommended dosage for external genital warts is 1.25 mg/g.

11.2 External Genital Warts

The use of Imiquimod Cream is initiated on the day following the last scheduled application of study cream. Efficacy was assessed by the complete clearance of the external genital warts.

11.3 Actinic Keratosis

The mechanism of action of Imiquimod Cream in treating AK lesions is unknown.

The recommended dosage for AK is 1 mg/g.

11.4 Molluscum Contagiosum

The mechanism of action of Imiquimod Cream in treating MC is unknown.

The recommended dosage for MC is 1 mg/g.

11.5 Basal Cell Carcinoma

The mechanism of action of Imiquimod Cream in treating BCC is unknown.

The recommended dosage for BCC is 1 mg/g.

11.6 External Genital Warts

The mechanism of action of Imiquimod Cream in treating external genital warts is unknown.

The recommended dosage for external genital warts is 1.25 mg/g.

11.7 Treatment Parameters

The mechanism of action of Imiquimod Cream in treating treatment-resistant warts is unknown.

The recommended dosage for treatment-resistant warts is 1 mg/g.

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