

Tapina®

Tapinarof 1%
Cream

Description

Tapinarof is a novel, first-in-class, small-molecule AhR agonist that is indicated for the treatment of adult psoriasis. It is available as a topical cream. Tapinarof was first discovered as a metabolite (3,5-dihydroxy-4-isopropylstilbene) produced in *Photobacterium luminescens*, a gram-negative bacillus that lives symbiotically with the *Heterorhabditis* nematodes.

Indications

Tapina® is indicated for the topical treatment of plaque psoriasis in adults.

Dosage And Applications

Apply a thin layer of Tapina® cream to affected areas once daily. Wash hands after application, unless Tapina® cream is for treatment of the hands. Tapina® cream is not for oral, ophthalmic, or intravaginal use.

Contraindications

Hypersensitive to any of its components.

Warning and Precautions

Before using Tapina® cream, it's important to consider all the medical conditions, including if the patient is pregnant or plan to become pregnant as there are no significant data about drug interaction during pregnancy or the patient is breastfeeding or plan to breastfeed.

Side Effects

The most common side effects of Tapina® cream include: Folliculitis, nasopharyngitis, skin rash or irritation including itching and redness, peeling, burning, or stinging, headache and flu.

Use in Specific Population

Pregnancy

The available data on Tapina® cream use in pregnant women are insufficient to evaluate for a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes.

In animal reproduction studies, subcutaneous administration of tapinarof to pregnant rats and rabbits during the period of organogenesis resulted in no significant adverse effects at doses 268 and 16 times, respectively, the maximum recommended human dose (MRHD). The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of major birth defects, loss, and other adverse outcomes.

Lactation

No data are available regarding the presence of tapinarof in human milk or the effects of tapinarof on the breastfed infant, or on milk production. Tapinarof was detected in rat offspring following subcutaneous administration to pregnant female rats which suggests that tapinarof was transferred into the milk of lactating rats. When a drug is present in animal milk, it is likely that the drug will be present in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Tapina® cream and any potential adverse effects on the breast-fed infant from Tapina® cream or from the underlying maternal condition.

Pediatric Use

Safety and efficacy of Tapina® cream have not been established in pediatric subjects with psoriasis under 18 years of age.

Geriatric Use

683 subjects exposed to Tapinarof cream in the PSOARING 1 or PSOARING 2 clinical trials, 99 (14.5%) were 65 years of age and older, including 8 (1.2%) subjects who were 75 years of age and older. No overall differences in efficacy, safety, or tolerability were observed between elderly subjects and younger adult subjects in clinical trials.

Drug Interaction

There is no specific drug interaction information about Tapinarof till now.

Pharmaceutical Precautions

Do not store above 30° C. Keep in a dry place. Protect from light and keep out of the reach of children.

Commercial Pack

Tapina® cream: Tube containing 30 g cream. Each gram contains Tapinarof INN 10 mg.



Manufactured by

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