



Tapinarof INN 1%



50118

Description

VTAPA™ Cream, 1% is a steroid free preparation of Tapinarof as an active ingredient. Tapinarof is an aryl hydrocarbon receptor (AhR) agonist.

Indication

VTAPA™ Cream, 1% is indicated for the topical treatment of plaque psoriasis in adults.

Dosage and Application

- Apply a thin layer of VTAPA™ cream to affected areas once daily.
- Wash hands after application, unless VTAPA™ cream is for treatment of the hands.

Side Effect

- Folliculitis
- Nasopharyngitis
- Contact dermatitis
- Headache

Contraindications

None

Warning and Precaution

- External use only. VTAPA™ cream is not for oral, ophthalmic, or intravaginal use.
- If there is any hypersensitivity issue with the use of VTAPA™, treatment should be discontinued.

Use in Specific Population

Pregnancy:

Available data in pregnant women are insufficient to evaluate for a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal 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.

Drug interactions

In Vitro Studies confirmed that Tapinarof is not an inhibitor of Cytochrome P450 (CYP) Enzymes. Tapinarof is not an inhibitor of BCRP, MATE1, MATE-2K, OAT1, OAT3, OATP1B1, OATP1B3, OCT1, OCT2, or P-gp.

Pharmaceuticals Precaution

- Do not store above 25° C.
- Do not freeze.
- Protect from exposure to excessive heat.
- Keep out of reach of children.

Commercial Pack

VTAPA™ Cream 30g: Each pack has a tube containing 30g cream. Each gram of VTAPA™ cream contains 10 mg of tapinarof in a white to off-white cream.

Manufactured by:



Synovia Pharma PLC., Station Road, Tongi, Gazipur.

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Direction Slip Artwork Legend

Name of Printed D/S	VTAPA Cream D/S	
Oracle Code	3021000291	
Synovia Version No	01	
Artwork generation date	21.06.2023	
Dimensions	L-100 mm X W-240 mm	
Minimum font size	8 pt	
Color Ref	Pantone process black ■ Pantone 2347 C ■	
Artwork Prepared By	In House (Anowar Hossain)	
Change Control Ref No	MOC-2023-0197	
Artwork Checked By	Quality Control	
	Change Control Coordinator	
	Market Regulatory	
	Marketing	