Product Monograph

Including Patient Medication Information

[Pr] NDUVRA®

tapinarof cream

Cream, 1% w/w for topical use

Other antipsoriatics for topical use

Aryl hydrocarbon receptor agonist

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Date of Authorization:
2025-09-03

Submission Control Number: 297579

Recent Major Label Changes

None at time of authorization.

Table of Contents

Certain sections or subsections that are not applicable at time of the preparation of the most recent authorized product monograph are not listed.

Part 1: Healthcare Professional Information

1 Indications

NDUVRA® (tapinarof cream) is indicated for the topical treatment of plaque psoriasis in adults.

1.1 Pediatrics

Pediatrics (<18 years of age):

No data are available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use (7 Warnings and Precautions, 7.1 Special Populations, 7.1.3 Pediatrics).

1.2 Geriatrics

Geriatrics (≥65 years of age):

No overall differences in efficacy, safety or tolerability were observed between geriatric patients and younger adult patients in clinical trials (7 Warnings and Precautions, 7.1 Special Populations, 7.1.4 Geriatrics).

2 Contraindications

NDUVRA is contraindicated in patients who are hypersensitive to this drug or to any ingredients in the formulation, including any non-medicinal ingredients, or component of the container. For a complete listing, see 6 Dosage Forms, Strengths, Composition and Packaging.

4 Dosage and Administration

4.1 Dosing Considerations

NDUVRA is for external topical use only. NDUVRA is not for oral, ophthalmic or intravaginal use (see 7 Warning and Precautions, General).

4.2 Recommended Dose and Dosage Adjustment

Apply a thin layer of NDUVRA cream to affected areas once daily. NDUVRA may be used on all skin surfaces, including the head, neck, and intertriginous areas.

Health Canada has not authorized an indication for pediatric use (see 1 Indications, 1.1 Pediatrics).

4.4 Administration

Apply NDUVRA to dry, clean skin. Wash hands after application unless treating lesions on the hands or fingernails. Avoid swimming, bathing, showering, or strenuous activities for at least 2 hours after application of NDUVRA. Avoid applying NDUVRA to unaffected areas.

4.5 Missed Dose

Advise patients if they forget to use NDUVRA as directed, to apply it as soon as possible within the same day, then go back to their regular schedule the following day. Patients should be instructed not to apply NDUVRA more than once daily to make up for a missed daily dose on the previous day. Dosing can be continued on the next day.

5 Overdosage

There are no data from clinical trials regarding signs and symptoms of overdose of NDUVRA. Overdosage with NDUVRA is not anticipated with dermal application. If surplus NDUVRA has been applied, the excess should be wiped off.

For the most recent information in the management of a suspected drug overdose, contact your regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669).

6 Dosage Forms, Strengths, Composition and Packaging

Table 1 – Dosage Forms, Strengths, Composition and Packaging

Route of Administration	Dosage Form / Strength/Composition	Non-medicinal Ingredients
Topical	Cream/tapinarof (1% w/w) Each gram of NDUVRA cream contains 10 mg of tapinarof.	Benzoic acid, butylated hydroxytoluene, citric acid monohydrate, diethylene glycol monoethyl ether, disodium edetate, emulsifying wax, medium-chain triglycerides, polyoxyl 2 stearyl ether, polyoxyl 20 stearyl ether, polysorbate 80, propylene glycol, purified water, and sodium citrate dihydrate.

NDUVRA (tapinarof, cream) is a white to off-white cream with no visible signs of phase separation and is available in:

- 2 g (sample) Aluminum tube with a sealed membrane and membrane-piercing white high density polyethylene (HDPE) closure.
- 60 g Aluminum barrier laminate (ABL) tube with high density polyethylene (HDPE) shoulder, a peelable sealed membrane, and a white polypropylene (PP) closure.

7 Warnings and Precautions

General

NDUVRA is for external use only. NDUVRA cream is not for oral, ophthalmic, or intravaginal use.

7.1 Special Populations

7.1.1 Pregnancy

The available data on NDUVRA 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 (16 Non-Clinical , Reproductive and Developmental Toxicology).

7.1.2 Breastfeeding

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 (see 16 Non-Clinical). 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 NDUVRA cream and any potential adverse effects on the breastfed infant from NDUVRA cream or from the underlying maternal condition (16 Non-Clinical , Reproductive and Developmental Toxicology).

7.1.3 Pediatrics

Pediatrics (<18 years of age): No data are available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use.

7.1.4 Geriatrics

Geriatrics (≥65 years of age): Of the 1090 patients exposed to NDUVRA in clinical trials, 136 (12.5%) were 65 years of age and older, including 8 (0.7%) patients who were 75 years of age and older. No overall differences in efficacy, safety, or tolerability were observed between elderly patients and younger adult patients in clinical trials.

8 Adverse Reactions

8.1 Adverse Reaction Overview

The most frequently reported adverse reactions were local skin reactions, these included folliculitis (20%) and contact dermatitis (7%).

8.2 Clinical Trial Adverse Reactions

Clinical trials are conducted under very specific conditions. Therefore, the frequencies of adverse reaction rates observed in the clinical trials may not reflect frequencies observed in clinical practice and should not be compared to frequencies in clinical trials of another drug.

In two randomized, double-blind, multicenter, vehicle-controlled clinical trials (DMVT-505-3001 [PSOARING 1] and DMVT-505-3002 [PSOARING 2]), 1025 adults with plaque psoriasis were treated with NDUVRA cream or vehicle cream once daily for up to 12 weeks (see 14 Clinical Trials).

Patients ranged in age from 18 to 75 years, with an overall median age of 51 years. The majority of patients were white (85%) and male (57%); and 85% were non-Hispanic or Latino (see 14 Clinical Trials).

Table 2 presents adverse reactions that occurred in at least 1% of patients treated with NDUVRA cream, and for which the rate exceeded the rate for vehicle.

Table 2 - Adverse Reactions Occurring in ≥1% of the Patients in the 12-week PSOARING 1 and PSOARING 2 Clinical Trials

Adverse Reaction	Tapinarof cream N = 683 n (%)	Vehicle cream N = 342 n (%)
Infections and infestations		
Folliculitis[a]	140 (20)	3 (1)
Nasopharyngitis[b]	73 (11)	31 (9)
Influenza[c]	14 (2)	2 (1)
Nervous system disorders		
Headache[d]	26 (4)	5 (1)
Skin and subcutaneous tissue disorders		
Contact dermatitis[e]	45 (7)	2 (1)
Pruritus[f]	20 (3)	2 (1)

[a] Folliculitis includes application site folliculitis and folliculitis
[b] Nasopharyngitis includes nasopharyngitis, nasal congestion, pharyngitis, respiratory tract infection (RTI) viral, rhinorrhea, sinus congestion, upper RTI, and viral upper RTI
[c] Influenza includes influenza and influenza-like illness
[d] Headache includes headache, migraine, and tension headache
[e] Contact dermatitis includes dermatitis, contact dermatitis, hand dermatitis, and rash
[f] Pruritus includes application site pruritus, pruritus, generalized pruritus, and genital pruritus

Adverse reactions leading to treatment discontinuation in >1% of patients who received NDUVRA cream were contact dermatitis (2.9%) and folliculitis (2.8%). The incidence of follicular events was less in females (14.2%) compared to males (24.4%).

In an open label safety trial (DMVT-505-3003 [PSOARING 3]), 763 patients were treated for up to an additional 40 weeks after completing PSOARING 1 or PSOARING 2. In addition to the adverse reactions reported in the 12-week PSOARING 1 and PSOARING 2 clinical trials, the following adverse reactions were reported: urticaria (1.0%) and drug eruption (0.8%).

8.3 Less Common Clinical Trial Adverse Reactions

Skin disorders: Two (0.3%) patients using NDUVRA cream in the pivotal clinical trials developed urticaria.

9 Drug Interactions

9.2 Drug Interactions Overview

Based on in vitro data and minimal systemic exposure, no formal drug-drug interaction studies were conducted with NDUVRA.

9.3 Drug Behavioural Interactions

None have been established.

9.4 Drug-Drug Interactions

In Vitro Studies

Cytochrome P450 (CYP) Enzymes: Tapinarof is not expected to inhibit CYP2B6, CYP2C8, CYP2C9, CYP2C19, CRP2D6 or CYP3A4/5 nor induce CYP1A2, CYP2B6 or CYP3A4 under conditions of clinical use.

Transporter Systems: Tapinarof is not expected to inhibit BCRP, BSEP, MATE1, MATE-2K, OAT1, OAT3, OATP1B1, OATP1B3, OCT1, OCT2, or P-gp under conditions of clinical use. Tapinarof is not a substrate for BCRP, OATP1B1, OATP1B3, or P-gp.

9.5 Drug-Food Interactions

Interactions with food have not been evaluated, as not applicable for topical products.

9.6 Drug-Herb Interactions

Interactions with herbal products have not been evaluated, as not applicable for topical products.

9.7 Drug-Laboratory Test Interactions

Interactions with laboratory tests have not been evaluated.

10 Clinical Pharmacology

10.1 Mechanism of Action

Tapinarof is an aryl hydrocarbon receptor (AhR) agonist. The specific mechanisms by which tapinarof exerts its therapeutic action in psoriasis patients are unknown.

10.2 Pharmacodynamics

Pharmacodynamics of NDUVRA cream are unknown.

Cardiac Electrophysiology

At the approved dosage, NDUVRA does not prolong the QTc interval.

10.3 Pharmacokinetics

Table 3 - Summary of NDUVRA Pharmacokinetic Parameters in 27-73 year old patients with moderate to severe plaque psoriasis and treated body surface area (BSA) range from 21% - 46%

	C_{max} (ng/mL) N	T_{max} (h) N	$t_{½}$ (h)	$AUC_{0\text{-last}}$ (ng*h/mL) N
Day 1	0.898 ± 1.448 21	3.10 (1.1, 23.8) 18	NA	4.067 ± 6.331 17
Day 29	0.116 ± 0.148 19	3.17 (1.1, 12.2) 11	NA	0.609 ± 0.646 11

Data reported as mean ± SD except for T_{max} reported as median (range); NA = not applicable

Note: Of 21 patients with PK samples on Day 1, 18 patients had an estimable T_{max} and 4 patients had an estimable $AUC_{0\text{-t}}$. Of 19 patients with PK samples on Day 29, 11 patients had an estimable T_{max} and 1 patient had an estimable $AUC_{0\text{-t}}$.

Absorption

NDUVRA cream exhibits low systemic absorption following topical application with no accumulation upon repeat dosing. Systemic absorption was evaluated in 21 patients with moderate to severe plaque psoriasis affecting mean 27.2% (range 21 to 46%) body surface area. Plasma concentration of tapinarof was below the quantifiable limits (BQL) of the assay (lower limit of quantification was 50 pg/mL) in 68% of the pharmacokinetic samples. On Day 1, mean ± SD values of C_{max} and $AUC_{0\text{-last}}$ were 0.90 ± 1.4 ng/mL and 4.1 ± 6.3 ng.h/mL, respectively. On Day 29, plasma concentrations were lower and the mean ± SD C_{max} and $AUC_{0\text{-last}}$ were 0.12 ± 0.15 ng/mL and 0.61 ± 0.65 ng.h/mL, respectively. In Phase 3 trials in patients with mild to severe plaque psoriasis affecting 3 to 20% body surface area, ≥ 95% of PK samples were BQL.

Distribution:

Human plasma protein binding of tapinarof is approximately 99% *in vitro*.

Metabolism:

Tapinarof is metabolized in the liver by multiple pathways including oxidation, glucuronidation, and sulfation *in vitro*.

Elimination

The elimination half-life in humans could not be reliably determined due to the lack of detectable tapinarof plasma concentrations in the elimination phase.

Following a single dermal administration in minipigs, less than 1% of the administered material was recovered in excreta, suggesting minimal absorption.

11 Storage, Stability and Disposal

Store between 2°C and 25°C.

Do not freeze. Protect from exposure to excessive heat. Keep out of reach of children.

Part 2: Scientific Information

13 Pharmaceutical Information

Drug Substance

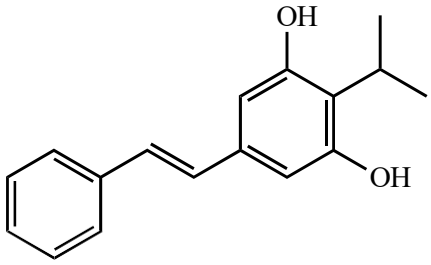
Proper/Common name: Tapinarof

Chemical name: 3, 5-Dihydroxy-4-isopropyl-*trans*-stilbene

(*E*)-2-isopropyl-5-styrylbenzene-1,3-diol

Molecular formula and molecular mass: $C_{17}H_{18}O_2$, 254.32

Structural formula:



Physicochemical properties:

Description: White to pale brown powder

Solubility: Practically insoluble in water, soluble in methanol.

14 Clinical Trials

14.1 Clinical Trials by Indication

Treatment of plaque psoriasis in adults

Table 4 - Summary of patient demographics for clinical trials in plaque psoriasis

Study #	Study design	Dosage, route of administration and duration	Study patients (n)	Mean age (Range)	Sex
PSOARING 1 (DMVT-505-3001)	A double-blind, randomized, vehicle-controlled, Phase 3, multicenter study to evaluate the efficacy and safety in adults with plaque psoriasis	Thin layer of tapinarof cream, 1% or vehicle cream, once daily applied to affected areas for 12 weeks.	Total enrolled: 510 Tapinarof cream, 1%: 340 Vehicle cream: 170	49.6 (18 to 75)	Tapinarof cream, 1%: Female: 127 Male: 213 Vehicle cream: Female: 84 Male: 86
PSOARING 2 (DMVT-505-3002)	A double-blind, randomized, vehicle-controlled, Phase 3, multicenter study to evaluate the efficacy and safety in adults with plaque psoriasis	Thin layer of tapinarof cream, 1% or vehicle cream, once daily applied to affected areas for 12 weeks.	Total enrolled: 515 Tapinarof cream, 1%: 343 Vehicle cream: 172	50.0 (18 to 75)	Tapinarof cream, 1%: Female: 155 Male: 188 Vehicle cream: Female: 70 Male: 102
PSOARING 3 (DMVT-505-3003)	A long-term, open-label, extension study to evaluate the safety and efficacy in adults with plaque psoriasis	Thin layer of tapinarof cream, 1%, once daily applied to affected areas for up to 40 weeks.	Total enrolled: 763	50.7 (18 to 75)	Female: 315 Male: 448

Two multicenter, randomized, double-blind, vehicle-controlled trials were conducted to evaluate the safety and efficacy of NDUVRA® cream for the treatment of adults with plaque psoriasis (PSOARING 1

and PSOARING 2). These trials were conducted in a total of 1025 patients randomized 2:1 to NDUVRA cream or vehicle cream applied once daily for 12 weeks to any lesion regardless of anatomic location.

The trials enrolled male and female patients aged 18 to 75 years old with a clinical diagnosis of chronic plaque psoriasis and stable disease for at least 6 months prior to the study. Patients had mean percent body surface area (%BSA) involvement of ≥3% and ≤20%, excluding scalp, palms, fingernails, toenails, and soles. Baseline disease severity was graded using the 5-point Physician Global Assessment (PGA). At baseline patients scored "Mild"(2), "Moderate"(3), or "Severe"(4). Patients with "Mild" and "Severe" psoriasis were limited to approximately 10% each of the total randomized population. Patients with psoriasis other than plaque variant and patients with current or chronic history of liver disease were excluded from the trials. Concurrent treatment for plaque psoriasis was not allowed.

At baseline, the majority of patients had "Moderate" disease (82%), while 10% had "Mild" disease, and 8% had "Severe" disease. The extent of disease involvement assessed by %BSA, was 7.8%. The mean baseline Psoriasis Area and Severity Index (PASI) score was 9.0 (range 2 to 25). The median age was 51 years. The majority of patients were male (57.5%), white (84.9%), and not Hispanic or Latino (84.6%).

Clinical Response at Week 12 in PSOARING 1 and PSOARING 2 in Adults with Plaque Psoriasis

The primary efficacy endpoint in both studies was the proportion of patients who achieved treatment success, defined as a PGA score of "Clear" (0) or "Almost Clear" (1) and at least a 2-grade improvement from baseline to Week 12. Secondary efficacy endpoints included PASI-75 (improvement of at least 75% in PASI score from baseline), change from baseline in %BSA, and PASI-90 (improvement of at least 90% in PASI score from baseline) at Week 12. Efficacy results from the two trials are summarized in Table 5.

Table 5 - Clinical Response at Week 12 in PSOARING 1 and PSOARING 2 in Adults with Plaque Psoriasis (Intent-to-Treat; Multiple Imputation)

Clinical Response	PSOARING 1		PSOARING 2	
	NDUVRA Cream N=340	Vehicle Cream N=170	NDUVRA Cream N=343	Vehicle Cream N=172
Primary Endpoint:				
PGA Treatment Success [a]	35.4%	6.0%	40.2%	6.3%
Difference (95% CI)	29.4% (22.7%, 36.2%)		33.9% (27.1%, 40.7%)	
P-value[b]	<0.0001		<0.0001	
Secondary Endpoints:				
PASI-75	36.1%	10.2%	47.6%	6.9%
Difference (95% CI)	25.9% (18.7%, 33.1%)		40.7% (33.9%, 47.5%)	
P-value[b]	<0.0001		<0.0001	
Change from baseline %BSA	-3.5	-0.2	-4.2	0.1
Difference (95% CI)	-3.3 (-4.4, -2.1)		-4.3 (-5.2, -3.5)	
P-value[c]	<0.0001		<0.0001	
PASI-90	18.8%	1.6%	20.9%	2.5%
Difference (95% CI)	17.2% (12.5%, 22.0%)		18.4% (13.4%, 23.5%)	
P-value[b]	0.0005		<0.0001	

[a] Treatment success was defined as a PGA score of "Clear" or "Almost Clear" and at least a 2-grade improvement from baseline.

[b] P-value based on Cochran-Mantel-Haenszel Analysis Stratified by Baseline PGA Score

[c] P-value based on Analysis of Covariance

Multiple comparisons of the secondary endpoints were controlled using the fixed-sequence method. Testing of the secondary endpoints were performed sequentially following the prespecified order.

Following 12 weeks of treatment in PSOARING 1 or PSOARING 2, eligible patients could receive an additional 40 weeks of treatment in an open-label extension trial (PSOARING 3) to evaluate NDUVRA cream for long-term safety and maintenance of response.

Patients entering with a PGA = 0 had treatment discontinued and were followed for durability of treatment (remittive response).

Of the 763 patients enrolled in PSOARING 3, 74 patients entered with a PGA score of 0 ("Clear") following treatment with NDUVRA cream for 12 weeks during PSOARING 1 or PSOARING 2, 57 patients (77%) experienced a PGA ≥2 at least one time during the study and median time off therapy before experiencing PGA ≥2 was 115 days (95% CI: 85, 162).

16 Non-Clinical Toxicology

Carcinogenicity: Long-term carcinogenicity studies were conducted in mice (daily topical administration at doses of 0.5, 1.5, and 3% tapinarof cream) and in rats (subcutaneous administration at doses of 0.1, 0.3, and 1 mg/kg/day tapinarof). No drug-related neoplasms were noted in mice after 98 (females) to 102 (males) weeks of daily topical administration at doses up to 3% tapinarof cream (44 times the maximum recommended human dose [MRHD] based on AUC comparisons). An increased incidence of benign squamous cell papilloma was observed in males treated with ≥ 1.5% and females treated with 3% tapinarof, which was considered secondary to tapinarof-related skin irritation. No drug-related neoplasms were noted in female rats after 83 weeks of daily subcutaneous administration at doses up to 1 mg/kg/day tapinarof (8 times the MRHD based on AUC comparisons).

Genotoxicity: Tapinarof revealed no evidence of mutagenicity or clastogenicity in a bacterial reverse mutation assay (Ames test), an in vitro mammalian chromosomal aberration assay, an in vitro mouse lymphoma assay, and an in vivo rat bone marrow micronucleus assay.

Reproductive and Developmental Toxicology: In an embryofetal development study in rats, tapinarof was administered by subcutaneous injection to pregnant animals at doses of 1.2, 6.9 and 34 mg/kg/day during the period of organogenesis. Tapinarof was not associated with embryofetal lethality or fetal malformations. Tapinarof increased the incidence of skeletal variations (incomplete ossification of nasal bones) at the dose of 34 mg/kg/day (268 times the MRHD based on AUC comparisons).

In an embryofetal development study in rabbits, tapinarof was administered by subcutaneous injection to pregnant animals twice daily at doses of 0.3, 1, and 3 mg/kg/day during the period of organogenesis. Maternal toxicity as evidenced by decreased maternal body weight gain and associated increased post-implantation loss (embryolethality) was observed at 3 mg/kg/day. In addition, fetal skeletal variations were observed at 3 mg/kg/day. Tapinarof was not associated with embryofetal lethality or fetal malformations at doses up to 1 mg/kg/day (16 times the MRHD based on AUC comparison) or fetal malformations at doses up to 3 mg/kg/day (30 times the MRHD based on AUC comparison).

In a second embryofetal development study in rabbits, tapinarof was administered by continuous subcutaneous infusion to pregnant animals at doses of 1, 2 and 3 mg/kg/day during the period of organogenesis. Tapinarof was not associated with embryofetal lethality or fetal malformations at doses up to 3 mg/kg/day (20 times the MRHD based on AUC comparison).

In a prenatal and postnatal development study, tapinarof was administered by subcutaneous injection to pregnant rats at doses of 1, 6 and 30 mg/kg/day beginning on gestation day 6 through lactation day 20. Maternal toxicity associated with decreases in body weight gain and food consumption was noted at 30 mg/kg/day (268 times the MRHD based on AUC comparisons). Tapinarof decreased fetal survival and viability that resulted in reduced litter sizes and decreased fetal weights at doses greater than or equal to 6 mg/kg/day (45 times the MRHD based on AUC comparisons). No tapinarof-related effects on fetal survival and viability were noted at a dose of 1 mg/kg/day (6 times the MRHD based on AUC comparisons). No tapinarof-related effects on postnatal development, neurobehavioral or reproductive performance of offspring were noted at doses up to 30 mg/kg/day (268 times the MRHD based on AUC comparison).

Tapinarof was quantifiable in offspring plasma samples on postnatal day 10 at doses of 6 and 30 mg/kg/day, suggesting that tapinarof is present in animal milk.

Local Tolerance and Phototoxicity

Following single-dose dermal administration, tapinarof cream concentrations of up to 8% were not associated with irritation (in rats or rabbits) or sensitization (in guinea pigs) or phototoxicity (in hairless mice). Tapinarof cream concentrations up to 4% were not associated with sensitization in mice. Tapinarof cream at a concentration of 8% was found to be practically nonirritating upon application to the rabbit eye. These studies were conducted with earlier formulations which are not the final commercial formulation.

Juvenile Toxicity: In a juvenile animal toxicity study, tapinarof was administered by subcutaneous injection to juvenile rats at doses of 1, 10 and 20 mg/kg/day from postnatal day (PND) 7 to 21 and at doses of 1.5, 15, and 30 mg/kg/day from PND 22 to 77. The dose escalation conducted at PND 22 was implemented to maintain consistent systemic exposure across the duration of the dosing period. Renal pelvic dilatation was observed at doses greater than or equal to 15 mg/kg/day (165 times the MRHD based on AUC comparisons). No adverse effects in juvenile animals were noted at 1.5 mg/kg/day (11 times the MRHD based on AUC comparisons).

Animal:Human Exposure Ratios

At the proposed dose to treat up to 50% BSA for the clinical studies, the systemic exposure (AUC) ratios of tapinarof at the animal NOAELs were up to 64-fold in mice and up to 13-fold in minipigs (gender averaged at the highest doses tested due to the maximum feasible concentration and area tested for dermal administration) and up to 410-fold (subcutaneous administration in rats, gender averaged) above the averaged observed human $AUC_{0\text{-}24}$ of 8.0 ng·h/mL. The systemic exposure C_{max} ratios were up to 30-fold and 1.5-fold (gender averaged at the highest doses tested for dermal administration to mice and minipigs, respectively) and up to 278-fold (subcutaneous administration in rats, gender averaged) above the maximum observed clinical human C_{max} of 5 ng/mL.

Patient Medication Information

Read this for Safe and Effective use of Your Medication

PrNDUVRA®

Tapinarof cream

This patient medication information is written for the person who will be taking **NDUVRA®**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This patient medication information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **NDUVRA**, talk to a healthcare professional.

What NDUVRA is used for:

- NDUVRA is a cream used on the skin to treat adults with a skin condition called plaque psoriasis.

How NDUVRA works:

NDUVRA contains the medicine, tapinarof, that works to control plaque psoriasis.

Psoriasis causes areas of inflamed skin where skin cells grow too fast. This creates red, scaly, thick patches (plaques) of skin.

NDUVRA works on your skin to control your psoriasis by reducing inflammation (redness, swelling, itching, thickness, flaking).

The ingredients in NDUVRA are:

Medicinal ingredients: tapinarof

Non-medicinal ingredients: benzoic acid, butylated hydroxytoluene, citric acid monohydrate, diethylene glycol monoethyl ether, disodium edetate, emulsifying wax, medium-chain triglycerides, polyoxyl 2 stearyl ether, polyoxyl 20 stearyl ether, polysorbate 80, propylene glycol, purified water, and sodium citrate dihydrate.

NDUVRA comes in the following dosage forms:

Cream; tapinarof 1% w/w

Do not use NDUVRA if:

- If you are allergic to tapinarof or any of the other ingredients found in NDUVRA, or any parts of the container (see **What are the ingredients in NDUVRA?**).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you apply NDUVRA. Talk about any health conditions or problems you may have, including if you:

- are pregnant or plan to become pregnant. It is not known if NDUVRA will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if NDUVRA passes into your breast milk.
    - Talk to your healthcare professional about the best way to feed your baby during treatment with NDUVRA.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Drug interactions have not been studied for NDUVRA.

How to apply NDUVRA:

- Use NDUVRA exactly as your healthcare professional tells you to use it.
- NDUVRA is for external use only. **NDUVRA is NOT for oral, ophthalmic, or intravaginal use**.
- Apply NDUVRA to dry, clean skin.
- Wash your hands after applying NDUVRA unless you are using it to treat your hands.
- Avoid swimming, bathing, showering, or difficult activities for at least 2 hours after applying NDUVRA.
- If someone else applies NDUVRA for you, they should wash their hands after applying NDUVRA on you.

Usual dose:

Apply a thin layer of NDUVRA, only to parts of your skin with psoriasis, once a day.

Avoid applying NDUVRA on areas of your skin without psoriasis.

If you apply too much NDUVRA, wipe some of it off.

Overdose:

If you think you, or a person you are caring for, have taken any NDUVRA orally, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed Dose:

If you forget to use NDUVRA use it as soon as you remember. Do NOT use NDUVRA more than once a day.

Possible side effects from using NDUVRA:

These are not all the possible side effects you may have when using NDUVRA. If you experience any side effects not listed here, tell your healthcare professional.

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop using drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Folliculitis: red raised bumps around hair pores	✓		
COMMON			

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop using drug and get immediate medical help
	Only if severe	In all cases	
Nasopharyngitis: pain or swelling in the nose and throat	✓		
Contact Dermatitis: skin rash or irritation including itching and redness, peeling, burning, or stinging	✓		
Headache	✓		
Influenza (flu): fever, cough, muscle and body aches, headache, runny or stuffy nose, sore throat, sinus congestion, sneezing, generally feeling unwell	✓		
Pruritus(Itching)	✓		
RARE			
Urticaria: hives	✓		

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store between 2°C and 25°C.

Do not freeze.

Protect from exposure to excessive heat.

Keep out of reach and sight of children.

If you want more information about NDUVRA:

- Talk to your healthcare professional.

- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada Drug Product Database website: (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html; the manufacturer's website www.organon.ca, or by calling 1-844-820-5468.

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