

## 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	
<b>Nasopharyngitis:</b> pain or swelling in the nose and throat	✓		
<b>Contact Dermatitis:</b> skin rash or irritation including itching and redness, peeling, burning, or stinging	✓		
<b>Headache</b>	✓		
<b>Influenza (flu):</b> fever, cough, muscle and body aches, headache, runny or stuffy nose, sore throat, sinus congestion, sneezing, generally feeling unwell	✓		
<b>Pruritus(itching)</b>	✓		
<b>RARE</b>			
<b>Urticaria:</b> 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](http://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.Dermavant.com](http://www.Dermavant.com), or by calling 1-8-DERMAVANT/1-833-762-8268.

This leaflet was prepared by Dermavant Sciences GmbH.

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