ADAPALENE- adapalene gel
Sun Pharmaceutical Industries, Inc.

Adapalene Gel USP, 0.1%

Drug Facts

Active ingredient

Adapalene USP, 0.1% (retinoid) [1]

---

1 read consumer information leaflet

Purpose

Acne treatment

Use

- For the treatment of acne

Warnings

For external use only

Do not use

- on damaged skin (cuts, abrasions, eczema, sunburn)
- if you are allergic to adapalene or any of the ingredients in this product.

If pregnant or breast-feeding, ask a doctor before use.

When using this product

- limit sun exposure, including light from tanning beds, and use sunscreen when going outdoors
- do not wax to remove hair in areas where the product has been applied
- during the early weeks of use, your acne may appear to worsen before it improves (this is normal); continue using as directed, unless you get irritation that becomes severe
- irritation (redness, itching, dryness, burning) is more likely to occur:
  - in the first few weeks of use
  - if using more than one topical acne medication at a time
  - but irritation usually lessens with continued use of this product
- it may take up to 3 months of once daily use to see results
- avoid product contact with eyes, lips, and mouth. If contact occurs, immediately flush the area with water.
- wash hands after use

Stop use and ask doctor if

- you become pregnant, or are planning to become pregnant, while using the product
- you have symptoms of an allergic reaction (such as itching, rash, hives, swelling of the lips, eyelids, and shortness of breath)
- irritation becomes severe
- you see no improvement after 3 months of once daily use

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Adults and children 12 years of age and older:

- use **once** daily
- clean the skin gently and pat dry before applying the product
- cover the entire affected area with a thin layer. For example, if your acne is on the face, apply the product to the entire face.
- do not use more than one time a day. Applying more than directed will not provide faster or better results, but may worsen skin irritation.

Children under 12 years of age: ask a doctor

Other information

- **TAMPER EVIDENT: DO NOT USE IF THE SEAL ON THE TUBE IS PUNCTURED OR NOT VISIBLE.**
- **store at 20° to 25°C (68° to 77°F)**[see USP Controlled Room Temperature].
- protect from freezing

Inactive ingredients

carbomer homopolymer type C, edetate disodium, phenoxyethanol, poloxamer 182, propylene glycol, purified water, sodium hydroxide.

Questions?

1-866-923-4914

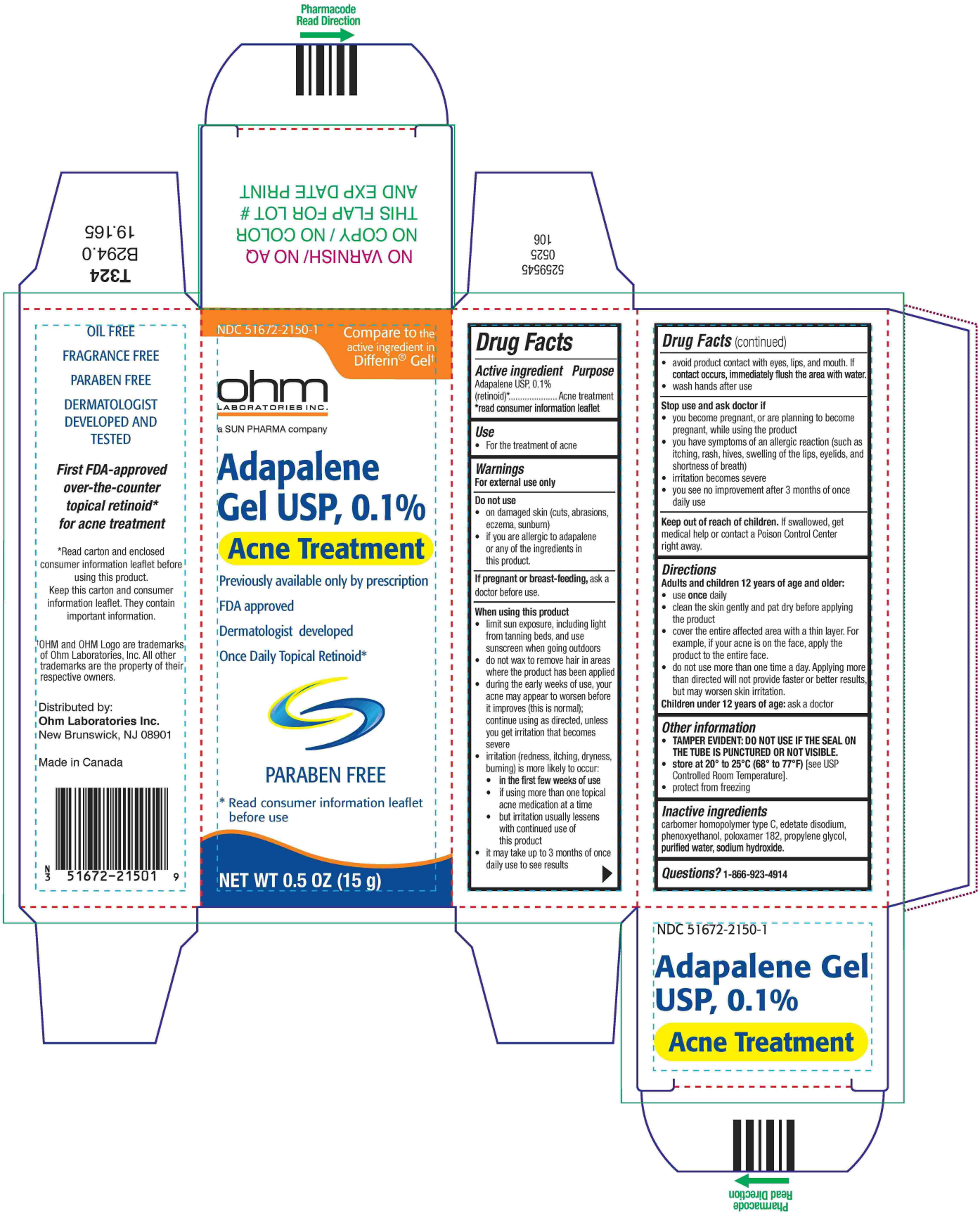
Distributed by:
Ohm Laboratories Inc.
New Brunswick, NJ 08901

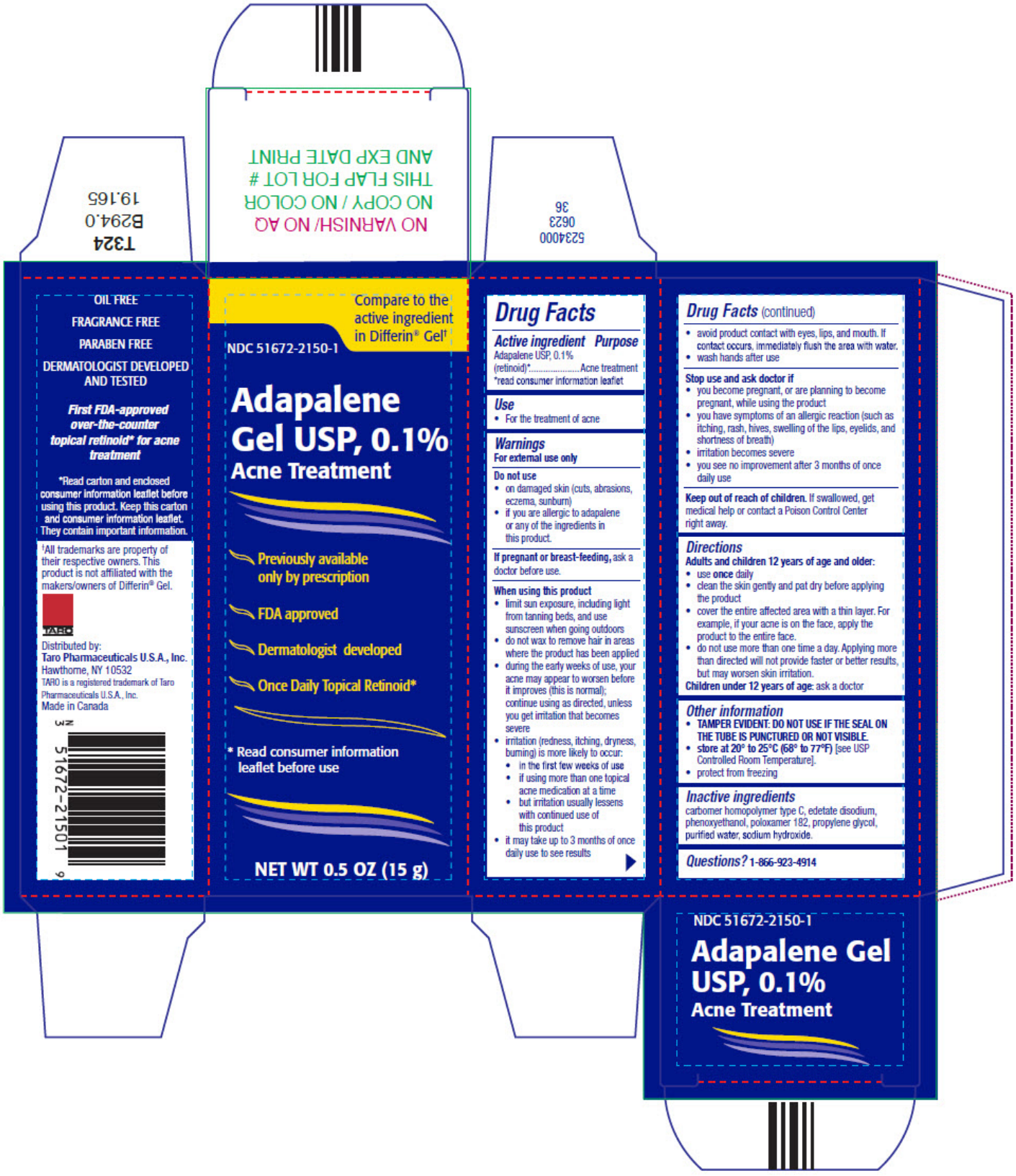
Made in Canada

PRINCIPAL DISPLAY PANEL - 15 g Tube Carton

NDC 51672-2150-1

Adapalene
Gel USP, 0.1%


Pharmacode
Read Direction
NO VARNISH/ NO AQ
NO COPY / NO COLOR
THIS FLAP FOR LOT #
AND EXP DATE PRINT
T324
B294.0
19.165
5259545
0525
106
OIL FREE
FRAGRANCE FREE
PARABEN FREE
DERMATOLOGIST DEVELOPED AND TESTED
First FDA-approved over-the-counter topical retinoid* for acne treatment
*Read carton and enclosed consumer information leaflet before using this product.
Keep this carton and consumer information leaflet. They contain important information.
OHM and OHM Logo are trademarks of Ohm Laboratories, Inc. All other trademarks are the property of their respective owners.
Distributed by:
Ohm Laboratories Inc.
New Brunswick, NJ 08901
Made in Canada
N 3 51672-21501 9
NDC 51672-2150-1
Compare to the active ingredient in Differin® Gel†
ohm LABORATORIES INC.
a SUN PHARMA company
Adapalene Gel USP, 0.1%
Acne Treatment
Previously available only by prescription
FDA approved
Dermatologist developed
Once Daily Topical Retinoid*
PARABEN FREE
* Read consumer information leaflet before use
NET WT 0.5 OZ (15 g)
Drug Facts
Active ingredient Purpose
Adapalene USP, 0.1% (retinoid)*..... Acne treatment
*read consumer information leaflet
Use
• For the treatment of acne
Warnings
For external use only
Do not use
• on damaged skin (cuts, abrasions, eczema, sunburn)
• if you are allergic to adapalene or any of the ingredients in this product.
If pregnant or breast-feeding, ask a doctor before use.
When using this product
• limit sun exposure, including light from tanning beds, and use sunscreen when going outdoors
• do not wax to remove hair in areas where the product has been applied
• during the early weeks of use, your acne may appear to worsen before it improves (this is normal); continue using as directed, unless you get irritation that becomes severe
• irritation (redness, itching, dryness, burning) is more likely to occur:
• in the first few weeks of use
• if using more than one topical acne medication at a time
• but irritation usually lessens with continued use of this product
• it may take up to 3 months of once daily use to see results
Drug Facts (continued)
• avoid product contact with eyes, lips, and mouth. If contact occurs, immediately flush the area with water.
• wash hands after use
Stop use and ask doctor if
• you become pregnant, or are planning to become pregnant, while using the product
• you have symptoms of an allergic reaction (such as itching, rash, hives, swelling of the lips, eyelids, and shortness of breath)
• irritation becomes severe
• you see no improvement after 3 months of once daily use
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
Directions
Adults and children 12 years of age and older:
• use once daily
• clean the skin gently and pat dry before applying the product
• cover the entire affected area with a thin layer. For example, if your acne is on the face, apply the product to the entire face.
• do not use more than one time a day. Applying more than directed will not provide faster or better results, but may worsen skin irritation.
Children under 12 years of age: ask a doctor
Other information
• TAMPER EVIDENT: DO NOT USE IF THE SEAL ON THE TUBE IS PUNCTURED OR NOT VISIBLE.
• store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].
• protect from freezing
Inactive ingredients
carbomer homopolymer type C, edetate disodium, phenoxyethanol, poloxamer 182, propylene glycol, purified water, sodium hydroxide.
Questions? 1-866-923-4914
NDC 51672-2150-1
Adapalene Gel USP, 0.1%
Acne Treatment
Pharmacode
Read Direction



ADAPALENE

adapalene gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51672-2150

Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ADAPALENE (UNII: 1L4806J2QF) (ADAPALENE - UNII:1L4806J2QF)	ADAPALENE	1 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLOXAMER 182 (UNII: JX0HIX6OAG)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51672-2150-1	1 in 1 CARTON	01/14/2022	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:51672-2150-6	1 in 1 CARTON	01/14/2022	
2		45 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA215940	01/14/2022	

Labeler - Sun Pharmaceutical Industries, Inc. (146974886)

Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharma Canada Inc.		243339023	manufacture(51672-2150)

Revised: 5/2025 Sun Pharmaceutical Industries, Inc.