

MINOXIDIL FOAM- minoxidil aerosol, foam
Publix Super Markets Inc

Publix Super Markets, Inc. Minoxidil Foam Drug Facts

Active ingredient

Minoxidil 5% w/w (without propellant)

Purpose

Hair regrowth treatment for men

Use

to regrow hair on the top of the scalp (vertex only, see pictures on side of this carton)

Warnings

For external use only. For use by men only.

Extremely Flammable: Avoid fire, flame, or smoking during and immediately following application.

Do not use if

- you are a woman
- your amount of hair loss is different than that shown on side of this carton or your hair loss is on the front of the scalp. Minoxidil Topical Aerosol, 5% (Foam) is not intended for frontal baldness or receding hairline.
- you have no family history of hair loss
- your hair loss is sudden and/or patchy
- you do not know the reason for your hair loss
- you are under 18 years of age. Do not use on babies and children.
- your scalp is red, inflamed, infected, irritated, or painful
- you use other medicines on the scalp

Ask a doctor before use if you have

heart disease

When using this product

- do not apply on other parts of the body
- avoid contact with the eyes. In case of accidental contact, rinse eyes with large amounts of cool tap water.
- some people have experienced changes in hair color and/or texture
- it takes time to regrow hair. Results may occur at 2 months with twice a day usage.

For some men, you may need to use this product for at least 4 months before you see results.

- the amount of hair regrowth is different for each person. This product will not work for all men.

Stop use and ask a doctor if

- chest pain, rapid heartbeat, faintness, or dizziness occurs
- sudden, unexplained weight gain occurs
- your hands or feet swell
- scalp irritation or redness occurs
- unwanted facial hair growth occurs
- you do not see hair regrowth in 4 months

May be harmful if used when pregnant or breast-feeding.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

- apply half a capful 2 times a day to the scalp in the hair loss area
- massage into scalp with fingers, then wash hands well
- see enclosed leaflet for complete directions on how to use
- using more or more often will not improve results
- continued use is necessary to increase and keep your hair regrowth or hair loss will begin again

Other information

- hair growth has been shown in a clinical study of men (mostly white) aged 18-49 years who used it for 4 months
- see hair loss pictures on side of this carton
- before use, read all information on package and enclosed leaflet
- keep the package. It contains important information.
- store at controlled room temperature 68-77°F (20-25°C)
- contents under pressure. Do not puncture or incinerate container. Do not expose to heat or store at temperatures above 120°F (49°C).

Inactive ingredients

butane, butylated hydroxytoluene, cetyl alcohol, citric acid, dehydrated alcohol, isobutane, lactic acid, polysorbate 60, propane, purified water, stearyl alcohol

Consumer Information

IMPORTANT INFORMATION ABOUT

Minoxidil Topical Aerosol, 5% (Foam)

Hair Regrowth Treatment

UNSCENTED

For Men

- Reactivates Hair Follicles To Stimulate Regrowth
- Easy-To-Use Foam
- Clinically Proven to Help Regrow Hair

Not For Use By Women

SAVE THIS LEAFLET FOR FUTURE REFERENCE

It takes time to regrow hair. Results may occur at 2 months with twice a day usage. For some men, you may need to use this product for at least 4 months before you see results.

Please read this leaflet carefully. It will help you understand how to use Minoxidil Topical Aerosol, 5% and what to expect from its use. If you have any questions after reading this leaflet, or anytime while using Minoxidil Topical Aerosol, 5%, you should ask your healthcare professional or call us at 1-800-719-9260.

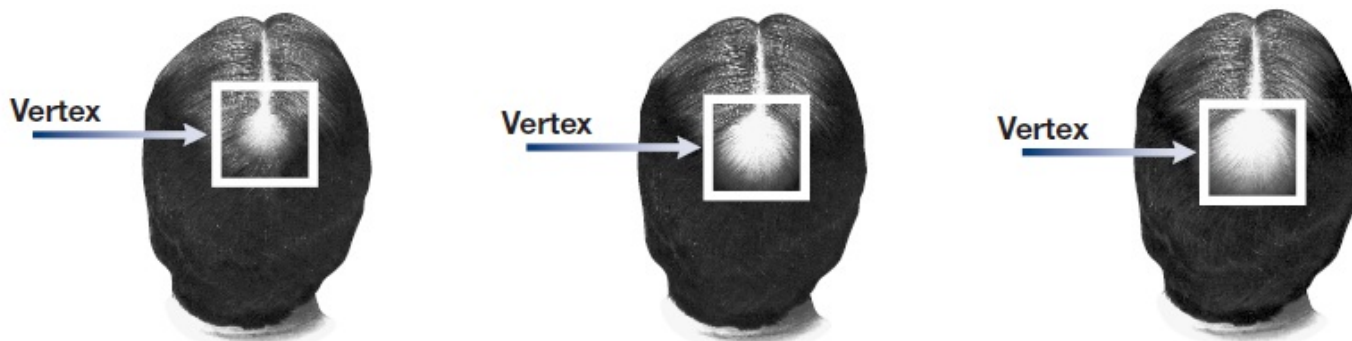
What is Minoxidil Topical Aerosol, 5%?

Minoxidil Topical Aerosol, 5% is a white foam containing 5% minoxidil for use only on the scalp to help regrow hair in men.

Who may use Minoxidil Topical Aerosol, 5%?

Minoxidil Topical Aerosol, 5% is for use only by men. Minoxidil Topical Aerosol, 5% may be appropriate for you if you are a male at least 18 years old and experiencing gradually thinning hair or gradual hair loss on the top of the scalp (vertex only, as shown below). It is not intended for frontal baldness or a receding hairline. The common inherited thinning or hair loss process begins slowly and may become noticeable only after years of gradual loss.

Minoxidil Topical Aerosol, 5% is for men with hair loss or thinning hair that begins on the vertex of the scalp. Minoxidil Topical Aerosol, 5% is more likely to regrow hair in men with hair loss in the range shown below. If men have more hair loss than shown, Minoxidil Topical Aerosol, 5% may not work.



Many of those experiencing hair loss have other family members with gradually thinning hair or hair loss. **If you have no family history of gradually thinning hair or of gradual hair loss, or your hair loss is patchy, see your doctor.**

Who should NOT use Minoxidil Topical Aerosol, 5%?

- Women should not use Minoxidil Topical Aerosol, 5%.
- Minoxidil Topical Aerosol, 5% should not be used on babies or children under 18 years old.
- Minoxidil Topical Aerosol, 5% will not prevent or improve hair loss which may occur with the use of some prescription and non-prescription medications, certain severe nutritional problems (very low body iron; too much vitamin A intake), low thyroid states (hypothyroidism), chemotherapy, or diseases which cause scarring of the scalp.

Also, Minoxidil Topical Aerosol, 5% will not improve hair loss due to:

- damage from the use of hair care products which cause scarring or deep burns of the scalp.
- hair grooming methods such as cornrowing or ponytails which require pulling the hair tightly back from the scalp.

Do not use if you are not sure of the reason for your hair loss.

Will Minoxidil Topical Aerosol, 5% work for me?

The amount of hair regrowth is different for each person. Not everyone will respond to Minoxidil Topical Aerosol, 5%. The response to Minoxidil Topical Aerosol, 5% cannot be predicted. It is unlikely anyone will be able to grow back all their hair.

However, to see your best results with Minoxidil Topical Aerosol, 5% make sure you get the medicine directly to the scalp and apply it twice a day, every day.

You may get better results if you have been losing your hair for a short period of time or have little hair loss. However, for some men Minoxidil Topical Aerosol, 5% may not work.

How soon can I expect results from using Minoxidil Topical Aerosol, 5%?

Since normal hair usually grows only 1/2 to 1 inch per month, hair regrowth with Minoxidil Topical Aerosol, 5% also takes time.

Results may be seen as early as 2 months with twice daily use. For some men, it may take at least 4 months for results to be seen. If you do not see any results after 4 months, stop using Minoxidil Topical Aerosol, 5% and seek the advice of your physician.

When you **first** begin to use Minoxidil Topical Aerosol, 5%, your hair loss may increase temporarily for up to 2 weeks. This is likely a sign that you are getting rid of old hairs in order to regrow more new hairs. This temporary increase in hair loss is expected and is part of the process for how Minoxidil Topical Aerosol, 5% regrows hair. Remember, this increased hair loss is temporary. However, if it continues after two weeks, see your physician.

If Minoxidil Topical Aerosol, 5% is working, what will the hair look like?

At first, hair growth is usually soft, downy, colorless hairs (like peach fuzz). After further use, the new hairs should be the same color and thickness as the other hairs on your scalp.

How long do I need to use Minoxidil Topical Aerosol, 5%?

If you experience hair regrowth, continued use of Minoxidil Topical Aerosol, 5% is necessary or the hair loss will begin again.

What happens if I completely stop using Minoxidil Topical Aerosol, 5%?

Continuous use of Minoxidil Topical Aerosol, 5% is needed to maintain hair regrowth. If you stop using Minoxidil Topical Aerosol, 5%, you will lose your newly regrown hair in 3 to 4 months.

How do I use Minoxidil Topical Aerosol, 5%?

For best results, apply half a capful **2 times a day directly** to the scalp in the hair loss area. Using more than the recommended amount will not improve results. Each can should last one month, if used as directed. Never take this product by mouth or apply to other parts of the body.

When do I use Minoxidil Topical Aerosol, 5%?

Apply Minoxidil Topical Aerosol, 5% once in the morning and once at night. Allow the nighttime application to dry completely before going to bed. Each can should last one month, if used as directed.

What if I miss a dose or forget to use Minoxidil Topical Aerosol, 5%?

If you miss one or two daily doses of Minoxidil Topical Aerosol, 5%, just continue with your next dose. You should not make up for missed doses.

Can I use Minoxidil Topical Aerosol, 5% more than twice a day? Will it work faster, better?

No. Minoxidil Topical Aerosol, 5% will not work faster or better if used more than two times a day. More frequent use or larger doses have not been shown to speed up hair growth and may increase your chance of side effects.

What kind of shampoo should I use with Minoxidil Topical Aerosol, 5%?

If you wash your scalp before applying Minoxidil Topical Aerosol, 5%, use a mild shampoo.

Can I use hair sprays, mousses, conditioners, gels, etc.?

Yes. Hair sprays, spritz, or styling aids may be used on your hair while using Minoxidil Topical Aerosol, 5%. For best results, Minoxidil Topical Aerosol, 5% should be allowed to soak into the scalp before using any styling products. Try to develop a good routine of applying Minoxidil Topical Aerosol, 5% first, and then applying styling products and style as usual. Keep in mind that your best results will be seen with proper application.

Can I have my hair colored or permed or use hair relaxers while using Minoxidil Topical Aerosol, 5%?

Yes. We have no evidence that coloring or perming your hair or that the use of relaxers change the effect of Minoxidil Topical Aerosol, 5%. However, because the use of a permanent wave and hair color can cause scalp irritation on certain people, we

recommend the following precautions:

1. To avoid possible scalp irritation, you should make sure all of the Minoxidil Topical Aerosol, 5% has been washed off the hair and scalp before using color or perm chemicals.
2. For best results, do not apply Minoxidil Topical Aerosol, 5% on the same day that you use a chemical treatment on your hair.
3. Do not use Minoxidil Topical Aerosol, 5% for 24 hours after using any chemicals to make sure your scalp has not been irritated by the perm or color treatment. If no irritation occurs, continue use of Minoxidil Topical Aerosol, 5% as usual.
4. Simply restart your normal Minoxidil Topical Aerosol, 5% routine. There is no need to use more Minoxidil Topical Aerosol, 5% to make up for missed applications.

Missing one day of Minoxidil Topical Aerosol, 5% will not affect your hair regrowth results.

Can I apply Minoxidil Topical Aerosol, 5% and wash my hair an hour later?

No. For Minoxidil Topical Aerosol, 5% to work best, you should allow it to stay on the scalp for about 4 hours before washing.

Using the product:

- Please familiarize yourself with the instructions below in order to help make your product application a success.
- This product should be used **TWICE DAILY**, EVERY DAY.
- To be effective, it is important to apply the product **DIRECTLY TO YOUR SCALP** and **NOT TO YOUR HAIR** so that it can easily get to your hair follicles to help regrow your hair.
- There is no need to shampoo your hair before using the product. If you wish to shampoo your hair before applying Minoxidil Topical Aerosol, 5%, towel dry your hair so that the skin on the scalp is dry.

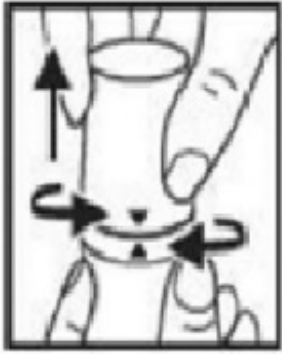
1: PREP HANDS WITH COLD WATER

Rinse your fingers in cold water and dry them. **Note:** Foam will melt on contact with warm surfaces.



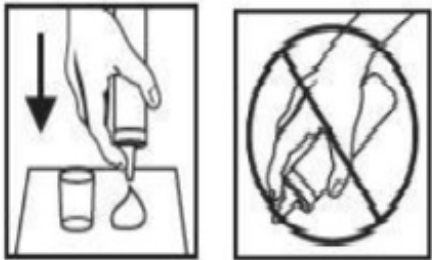
2: OPEN CHILD RESISTANT CAP

Be sure to align arrow on the cap with arrow on white ring. Tilt cap back and pull off.



3: DISPENSE VERTICALLY ONTO A COLD SURFACE

Hold the can straight upside down. If you hold the can at an angle, foam may not dispense properly. Press nozzle to dispense half a capful of foam onto cold surface (e.g. dish, or cold hands).



4: APPLY TO SCALP, NOT HAIR

Part your hair to expose hair loss area. Massage foam into **scalp**, not hair. **Repeat** until all hair loss areas have been covered.



5: CLOSE CAP AND WASH HANDS

Snap cap back into place. Be sure arrows do not line up, so cap remains child resistant. Wash hands and any surface thoroughly after use.



Warnings:

For external use only

For use by men only

Extremely Flammable: Avoid fire, flame, or smoking during and immediately following application.

Do not use if

- you are a woman
- your amount of hair loss is different than that shown on the other side of this leaflet or your hair loss is on the front of the scalp. Minoxidil Topical Aerosol, 5% is not intended for frontal baldness or receding hairline.
- you have no family history of hair loss
- your hair loss is sudden and/or patchy
- you do not know the reason for your hair loss
- you are under 18 years of age. Do not use on babies and children.
- your scalp is red, inflamed, infected, irritated, or painful
- you use other medicines on the scalp

Ask a doctor before use if you have heart disease.

When using this product

- do not apply on other parts of the body
- avoid contact with the eyes. In case of accidental contact, rinse eyes with large amounts of cool tap water.
- some people may experience changes in hair color and/or texture
- it takes time to regrow hair. Results may occur at 2 months with twice a day usage. For some men, you may need to use this product for at least 4 months before you see results.
- the amount of hair regrowth is different for each person. This product will not work for all men.

Stop use and ask a doctor if

- chest pain, rapid heartbeat, faintness, or dizziness occurs
- sudden, unexplained weight gain occurs
- your hands or feet swell
- scalp irritation or redness occurs
- unwanted facial hair growth occurs

- you do not see hair regrowth in 4 months

Not for use by women.

May be harmful if used when pregnant or breast-feeding.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away (1-800-222-1222).

What are the most common side effects with Minoxidil Topical Aerosol, 5%?

The most common side effects are itching and skin irritation of the treated area of the scalp. If scalp irritation continues, stop use and see a doctor. Minoxidil Topical Aerosol, 5% contains alcohol, which will cause burning or irritation of the eyes. If Minoxidil Topical Aerosol, 5% accidentally gets into eyes, rinse with large amounts of cool tap water.

Can Minoxidil Topical Aerosol, 5% produce unwanted hair growth?

Unwanted hair growth on the face and other parts of the body has been reported in women. But it is rare and reversible. If you develop unwanted hair, stop using Minoxidil Topical Aerosol, 5%. Over time, the unwanted hair growth caused by Minoxidil Topical Aerosol, 5% will go away. You can take the following steps to decrease the chances of unwanted hair growth:

- 1) limit the application of Minoxidil Topical Aerosol, 5% only to the scalp;
- 2) if you use your hands to apply Minoxidil Topical Aerosol, 5%, wash your hands well immediately afterwards.

Can I use Minoxidil Topical Aerosol, 5% for baldness or hair loss in babies or children?

No. Minoxidil Topical Aerosol, 5% must not be used to treat baldness or hair loss in babies and children.

If you have any other questions, ask your healthcare professional or call us at 1-800-719-9260.

Store at Controlled Room Temperature 20°C to 25°C (68°F to 77°F).

Contents under pressure. Do not puncture or incinerate container. Do not expose to heat or store at temperature above 120°F (49°C).

Save this leaflet for future reference.

To Open:

1. Be sure to align arrow on the cap with the arrow on the white ring.
2. Tilt cap back and pull off.



To Close:

1. Place **CAP** on container and snap into place.
2. Be sure arrows **DO NOT** line up so **CAP** remains child resistant.

Made in Israel

Distributed By

Perrigo®

Allegan, MI 49010

Rev 07-21

: 29400 00 J4

Package/Label Principal Display Panel

P

minoxidil foam

MINOXIDIL TOPICAL AEROSOL, 5% (FOAM)

HAIR REGROWTH TREATMENT FOR MEN

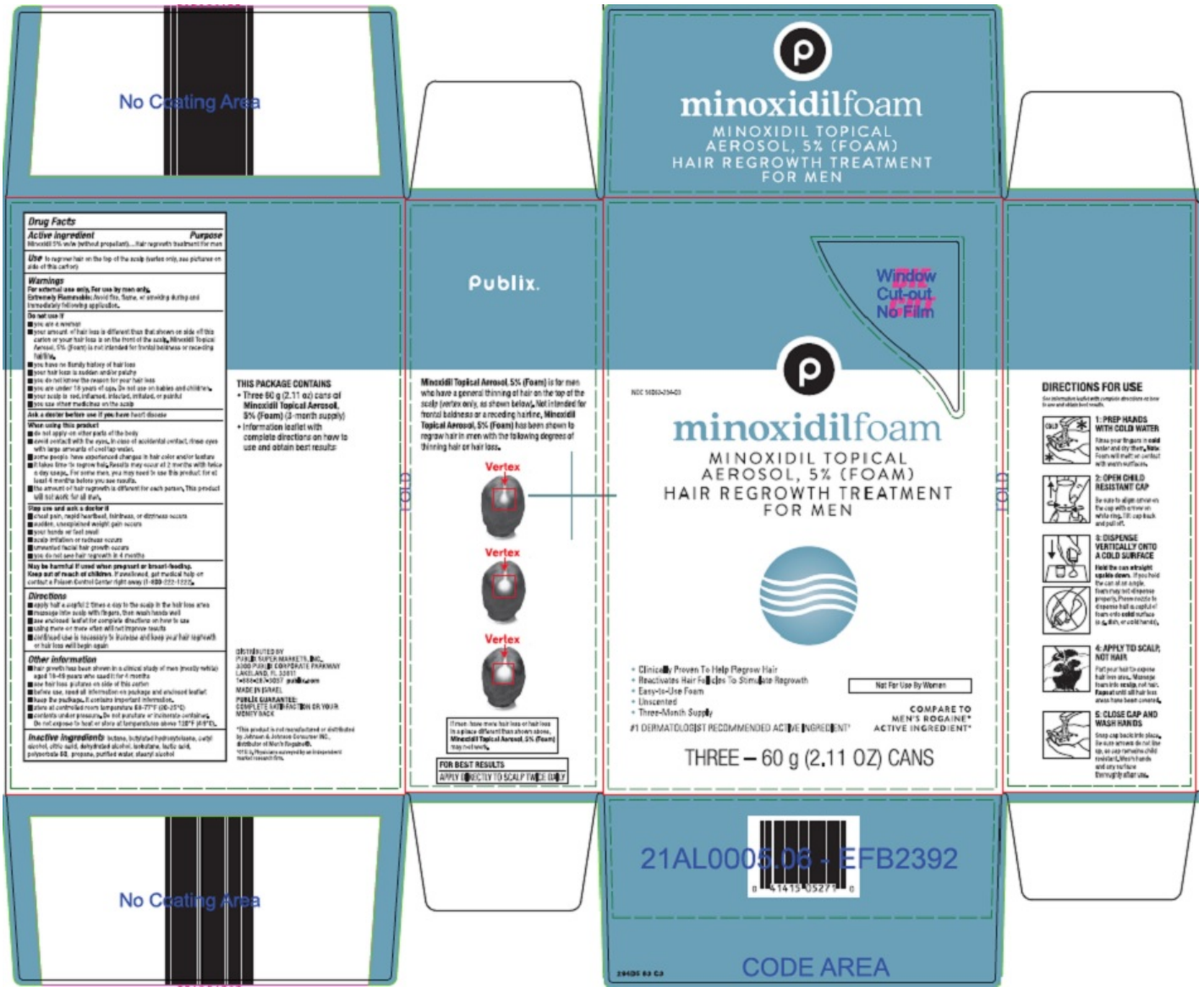
- Clinically Proven To Help Regrow Hair
- Reactivates Hair Follicles To Stimulate Regrowth
- Easy-to-Use Foam
- Unscented
- Three-Month Supply

Not For Use By Women

COMPARE TO MEN'S ROGAINE® ACTIVE INGREDIENT

#1 DERMATOLOGIST RECOMMENDED ACTIVE INGREDIENT

THREE - 60 g (2.11 OZ) CANS



MINOXIDIL FOAM			
minoxidil aerosol, foam			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56062-294
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
MINOXIDIL (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1)		MINOXIDIL	5 g in 100 g
Inactive Ingredients			
Ingredient Name			Strength
BUTANE (UNII: 6LV4FOR43R)			

BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
ALCOHOL (UNII: 3K9958V90M)	
ISOBUTANE (UNII: BXR49TP611)	
LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
PROPANE (UNII: T75W9911L6)	
WATER (UNII: 059QF0K00R)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56062-294-01	1 in 1 CARTON	06/17/2013	06/01/2019
1		60 g in 1 CAN; Type 0: Not a Combination Product		
2	NDC:56062-294-03	3 in 1 CARTON	08/30/2017	
2		60 g in 1 CAN; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091344	06/17/2013	

Labeler - Publix Super Markets Inc (006922009)