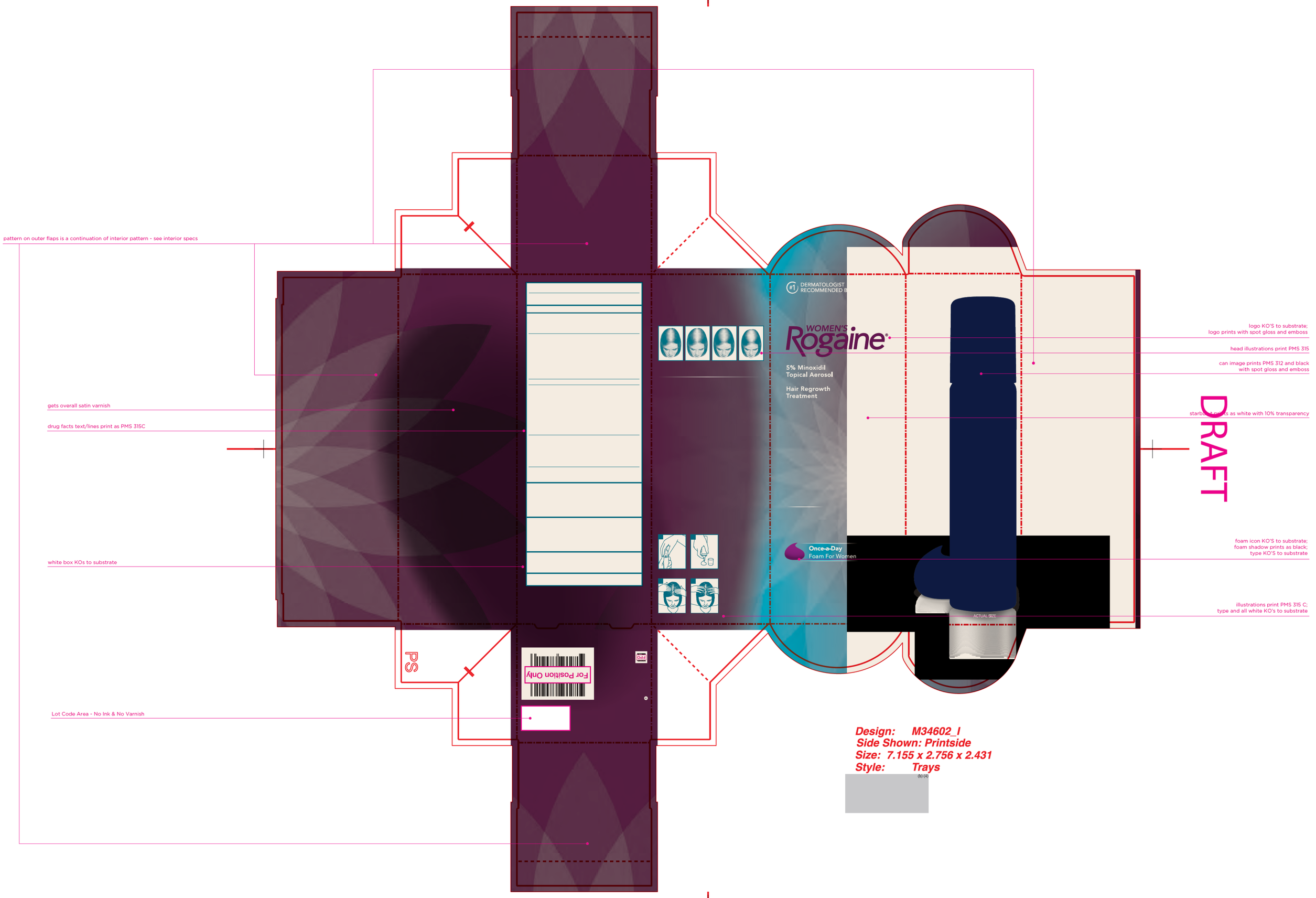


Design: M34602_I
Side Shown: Printside
Size: 7.155 x 2.756 x 2.431
Style: Trays

(b) (4)

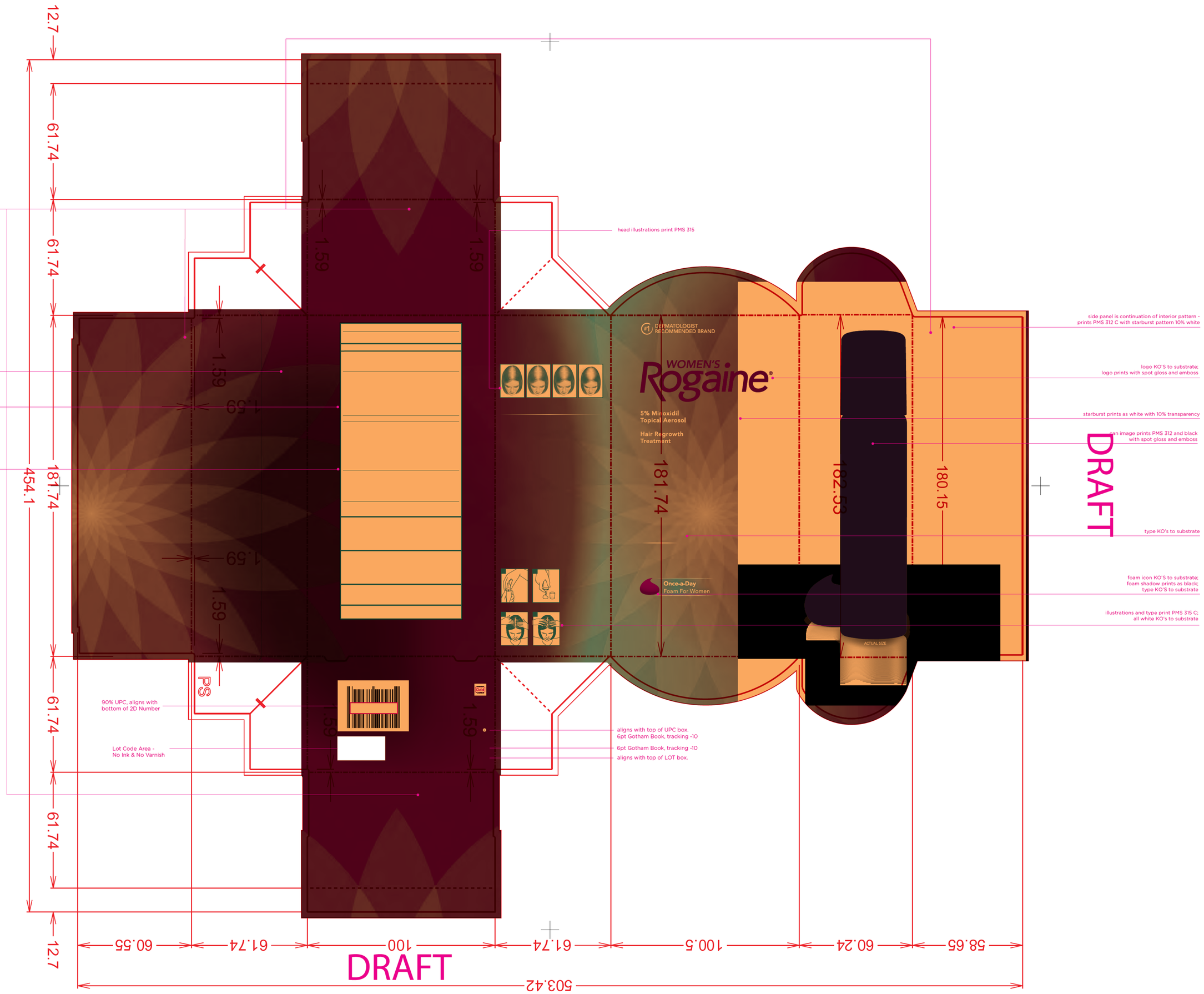
DRAFT

FDA STANDARD FORMAT COPY
Drug Facts 9 Pt: Helvetica Neue Bold Condensed Oblique
Headings 8 Pt: Helvetica Neue Bold Condensed Oblique
Sub Heads 6 Pt Helvetica Neue Bold Condensed
Text 6 Pt Helvetica Neue Condensed
Outline Box/Barline 1.5 Pt
Hairline Rule 0.5 Pt
Horizontal Scale 100%
Bullets 5 Pt
3/64" - Gap (Border - Type)
MM

Johnson&Johnson GLOBAL STRATEGIC DESIGN OFFICE

(b) (4)

Reference ID: 3699435



FDA STANDARD FORMAT COPY
Drug Facts 9 Pt Helvetica Neue Bold Condensed Oblique
Headings 8 Pt Helvetica Neue Bold Condensed Oblique
Sub Heads 6 Pt Helvetica Neue Bold Condensed
Text 6 Pt Helvetica Neue Condensed
Outline Box/Barline 1.5 Pt
Hairline Rule 0.5 Pt
Horizontal Scale 100%
Bullets 5 Pt
3/64" - Gap (Border - Type)
MM

Johnson&Johnson GLOBAL STRATEGIC DESIGN OFFICE

(b) (4)

Customer: JOHNSON & JOHNSON
Design: M34619_F
Size: 181.74 x 100.00 x 61.74
Style: Simplex Tray

Material: SBS .020
Description: (b) (4) 2ct.
Side Shown: Printside
Date: 02/24/2014

(b) (4)

Reference ID: 3699435

Reference ID: 3699435

DRAFT

580.74

69.92 | 71.5 | 111 | 73 | 116.5 | 73 | 71.81 | 12.7

73 | 73 | 73 | 73 | 12.7

501.41

184 | 184

182.41 | 184.79

johnson&johnson GLOBAL STRATEGIC DESIGN OFFICE

FDA STANDARD FORMAT COPY
Drug Facts 9 Pt Helvetica Neue Bold Condensed Oblique
Headings 8 Pt Helvetica Neue Bold Condensed Oblique
Sub Header 6 Pt Helvetica Neue Bold Condensed
Text 6 Pt Helvetica Neue Condensed
Outline Bar/Scriber 1.5 Pt
Hairline Rule 0.5 Pt
Ruling 5 Pt
Horizontal Scale 97%
3/64" - Grip (Exeter - Type)
HH HH

Customer: JOHNSON & JOHNSON
Design: M35521_A
Size: 184.00 x 110.50 x 73.00
Style: Simplex Tray
Material: SBS .020
Description: 3ct
Side Shown: Printside
Date: 03/26/2014

For Position Only

PS

LOT Code Area - No Ink & No Varnish

pattern on outer flaps is a continuation of interior pattern - see interior specs

drug facts text/all print PMS 315C

gets overall satin varnish

white base

ACTUAL SIZE

Once-a-Day
Foam For Women

5% Minoxidil
Topical Aerosol
Hair Regrowth
Treatment

WOMEN'S Rogaine

DERMATOLOGIST RECOMMENDED BRAND

#1

illustrations print PMS 315 C:
type and all white KO'S to substrate

foam icon KO'S to substrate;
foam shadow prints as black;
type KO'S to substrate

stars and prints as white with 10% transparency

can image prints PMS 312 and black with spot gloss and emboss

head illustrations print PMS 315

logo KO'S to substrate;
logo prints with spot gloss and emboss

type prints PMS 315;
background prints gradated values of black;
spot gloss over entire flag

DRAFT

DRAFT

Reference ID: 3699435

WOMEN'S Rogaine®

5% Minoxidil
Topical Aerosol

Hair Regrowth
Treatment

DRAFT

Save this booklet for future reference.

DRAFT

Reference ID: 3699435

Please read this booklet carefully. It will help you understand how to use WOMEN'S ROGAINE® Foam and what to expect from its use. It takes time to regrow hair. Results may occur at 3 months with **once daily** usage. For some women, you may need to use this product for at least 6 months before you see results. If you have any questions after reading this booklet, or anytime while using WOMEN'S ROGAINE® Foam, you should ask your health care professional or call us toll-free **800-ROGAINE** or **215-273-8755** (collect).

DRAFT

DRAFT

Reference ID: 3699435

WHAT IS WOMEN'S ROGAINE® FOAM?
WOMEN'S ROGAINE® Foam is a white foam containing 5% minoxidil for use only on the scalp to help regrow hair in women.

WHO MAY USE WOMEN'S ROGAINE® FOAM?
WOMEN'S ROGAINE® Foam may be appropriate for you if you are an adult who is at least 18 years old and experiencing gradually thinning hair or gradual hair loss on the top of your scalp. The common hereditary thinning or hair loss process begins slowly and may become noticeable only after years of gradual loss.

WOMEN'S ROGAINE® Foam is for general thinning of hair on the top of the scalp as shown on the next page. WOMEN'S ROGAINE® Foam has been shown to regrow hair in women with the degrees of hair loss shown. If women have more hair loss than shown, WOMEN'S ROGAINE® Foam may not work.

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

DRAFT

DRAFT

Reference ID: 3699435

DRAFT

DRAFT

Reference ID: 3699435

WHO SHOULD NOT USE WOMEN'S ROGAINE® FOAM?

WOMEN'S ROGAINE® Foam will not prevent or improve hair loss related to pregnancy, the use of some prescription and non-prescription medications, certain severe nutritional problems (very low body iron; excessive vitamin A intake), the recently discontinued use of birth control pills, low thyroid states (hypothyroidism), chemotherapy, or diseases which cause scarring of the scalp. Also, WOMEN'S ROGAINE® Foam 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 WOMEN'S ROGAINE® FOAM WORK FOR ME?

The amount of hair regrowth is different for each person. Not everyone will respond to WOMEN'S ROGAINE® Foam. The response to WOMEN'S ROGAINE® Foam cannot be predicted. No one will be able to grow back all their hair.

DRAFT

DRAFT

Reference ID: 3699435

To see your best results with WOMEN'S ROGAINE® Foam, make sure you apply the product directly to the scalp **once daily**. For some women, WOMEN'S ROGAINE® Foam may not work.

HOW SOON CAN I EXPECT RESULTS FROM USING WOMEN'S ROGAINE® FOAM?

Since normal hair usually grows only 1/2 to 1 inch per month, hair regrowth with WOMEN'S ROGAINE® Foam also takes time. Generally, new hair growth is slow for a WOMEN'S ROGAINE® Foam user. Results may be seen as early as 3 months with **once daily** use. For some women, it may take at least 6 months for results to be seen. If you do not see any results after 6 months, stop using WOMEN'S ROGAINE® Foam and seek the advice of your doctor.

When you first begin to use WOMEN'S ROGAINE® Foam, your hair loss may continue for up to 2 weeks. This increase in hair loss is expected and is temporary. However, if it continues after two weeks, see your physician.

DRAFT

DRAFT

Reference ID: 3699435

IF WOMEN'S ROGAINE® FOAM IS WORKING, WHAT WILL THE HAIR LOOK LIKE?
At first, hair growth may be soft, downy, and colorless hairs. 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 WOMEN'S ROGAINE® FOAM?
If you respond to WOMEN'S ROGAINE® Foam, you need to use it **once daily** to keep and continue the hair regrowth. Up to 3 months of usage may be needed to see your best results from WOMEN'S ROGAINE® Foam.

WHAT HAPPENS IF I COMPLETELY STOP USING WOMEN'S ROGAINE® FOAM? WILL I KEEP THE NEW HAIR?
Continuous use of WOMEN'S ROGAINE® Foam is needed to maintain hair regrowth. If you stop using WOMEN'S ROGAINE® Foam, the normal hair loss process will start again. You will probably lose your newly regrown hair in three to four months.

HOW DO I USE WOMEN'S ROGAINE® FOAM?
For best results, apply half a capful **once 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 two months, if used as

DRAFT

DRAFT

Reference ID: 3699435

directed. Never take this product by mouth or apply to other parts of the body. Please refer to the "Directions for Use" section of this booklet.

WHEN DO I USE WOMEN'S ROGAINE® FOAM?
Apply WOMEN'S ROGAINE® Foam **once daily**. If you apply at night, allow application to dry completely before going to bed.

WHAT IF I FORGET TO USE WOMEN'S ROGAINE® FOAM OR MISS A DOSE?
If you miss one daily dose of WOMEN'S ROGAINE® Foam, just continue with your next dose. You should not make up for missed doses.

CAN I USE WOMEN'S ROGAINE® FOAM MORE THAN ONCE A DAY? WILL IT WORK FASTER, BETTER?
No. WOMEN'S ROGAINE® Foam will not work faster or better if used more than **once a day**. More frequent use or larger doses have not been shown to speed up hair growth and may increase your chances of side effects.

WHAT KIND OF SHAMPOO SHOULD I USE WITH WOMEN'S ROGAINE® FOAM?
If you wash your scalp before applying WOMEN'S ROGAINE® Foam, use a mild shampoo.

DRAFT

DRAFT

Reference ID: 3699435

CAN I USE HAIR SPRAYS, MOUSSES, CONDITIONERS, GELS, ETC.?
Yes. There is no reason to change your usual hair care routine when using WOMEN'S ROGAINE® Foam. However, you should apply WOMEN'S ROGAINE® Foam first and wait for it to dry before applying your styling aids.

CAN I HAVE MY HAIR COLORED OR PERMED OR USE HAIR RELAXERS WHILE USING WOMEN'S ROGAINE® FOAM?
Yes. We have no evidence that coloring, perming, or using relaxers on your hair change the effect of WOMEN'S ROGAINE® Foam. 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 WOMEN'S ROGAINE® Foam has been washed off the hair and scalp before using color or perm chemicals.
2. For best results, do not apply WOMEN'S ROGAINE® Foam on the same day that you use a chemical treatment on your hair.
3. Do not use WOMEN'S ROGAINE® Foam for 24 hours after using any chemicals to make sure your scalp

DRAFT

DRAFT

Reference ID: 3699435

has not been irritated by the perm or color treatment. If no irritation occurs, continue use of WOMEN'S ROGAINE® Foam as usual.

4. Simply restart your normal WOMEN'S ROGAINE® Foam routine. There is no need to use more WOMEN'S ROGAINE® Foam to make up for missed applications.

Missing one day of WOMEN'S ROGAINE® Foam will not affect your hair regrowth results.

CAN I APPLY WOMEN'S ROGAINE® FOAM AND WASH MY HAIR AN HOUR LATER?

No. For WOMEN'S ROGAINE® Foam to work best, you should allow WOMEN'S ROGAINE® Foam to remain on the scalp for about 4 hours before washing.

DRAFT

DRAFT

Reference ID: 3699435

DIRECTIONS FOR USE

- Please familiarize yourself with the instructions below in order to help make your product application a success.
- This product should be used **ONCE 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 WOMEN'S ROGAINE® Foam, towel dry your hair so that the skin on the scalp is dry.
- **TO OPEN** the container: Hold ring. While holding ring, twist cap to line up the arrow on the ring with the arrow on the cap. (Figure 1 below) Tilt cap back and pull off cap.
- **The foam may begin to melt on contact if your fingers are warm. Rinse your fingers in cold water first before dispensing. Be sure to dry them thoroughly before handling the foam.**
- Hold the can straight upside down, press nozzle to dispense half a capful of the foam onto a non-absorbent surface (Figure 2 below). The total amount of foam applied should not exceed half a capful.

DRAFT

DRAFT

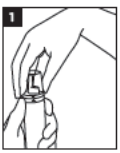
Reference ID: 3699435

- Within your hair thinning areas, make a center part to help maximize scalp exposure. Part your hair at least 2 more times on each side of the center part (Figure 3 below).
- Using your fingertips, spread just enough foam over the hair loss areas and gently massage the foam into the scalp starting from the back to front (forehead) direction (Figure 4 below). Use until all the foam is gone.
- After each use, thoroughly clean and dry the dish or saucer if used.
- Wash your hands well with soap and water after applying.
- **TO CLOSE** the container: place cap on container and snap into place. Be sure arrows do not line up so cap remains child resistant.

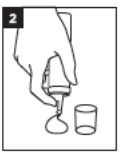
DRAFT

DRAFT

Reference ID: 3699435



OPEN CONTAINER



HOLD CAN STRAIGHT UPSIDE DOWN

PART THE HAIR

USE YOUR FINGERS

DRAFT

ARE THERE ANY SPECIAL WARNINGS ABOUT THE USE OF WOMEN'S ROGAINE® FOAM?

For external use only.

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

DO NOT USE IF

- your degree of hair loss is more than that shown on page 5 of this booklet, because this product may not work for you
- you have no family history of hair loss
- your hair loss is sudden and/or patchy

DRAFT

Reference ID: 3699435

- your hair loss is associated with childbirth
- 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 use more than directed
- 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 in 3 months with **once daily** use. For some women you may need to use this product **once daily** for at least 6 months before you see results.
- the amount of hair regrowth is different for each person. This product will not work for everyone.

DRAFT

DRAFT

Reference ID: 3699435

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 6 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.

WHAT ARE THE MOST COMMON SIDE EFFECTS WITH WOMEN'S ROGAINE® FOAM?
The most common side effects are itching and other skin irritations of the treated area of the scalp. WOMEN'S ROGAINE® Foam contains alcohol, which would cause burning or irritation of the eyes or sensitive skin areas. If WOMEN'S ROGAINE® Foam accidentally gets into these areas, rinse with large amounts of cool tap water. Stop using WOMEN'S ROGAINE® Foam and contact your doctor if irritation persists.

DRAFT

DRAFT

Reference ID: 3699435

CAN WOMEN'S ROGAINE® FOAM PRODUCE UNWANTED HAIR?

Unwanted hair growth has been reported on the face and on other parts of the body with ROGAINE® use. The unwanted hair growth may be caused by the transfer of WOMEN'S ROGAINE® Foam to areas other than the scalp, or by absorption into the circulatory system of low levels of the active ingredient, or by a medical condition not related to the use of WOMEN'S ROGAINE® Foam.

If you experience unwanted hair, discontinue using WOMEN'S ROGAINE® Foam and see your doctor for recommendations about appropriate treatment. After stopping use of WOMEN'S ROGAINE® Foam, the unwanted hair, if caused by the use of WOMEN'S ROGAINE® Foam, should go away over time. You can take steps to decrease the chances for unwanted hair growth:

1. Limit the application of WOMEN'S ROGAINE® Foam only to the scalp,

2. If you use the hands to apply WOMEN'S ROGAINE® Foam, wash your hands thoroughly afterwards, and

DRAFT

DRAFT

Reference ID: 3699435

3. Allow sufficient drying time before going to bed (usually 2 to 4 hours before going to bed after applying WOMEN'S ROGAINE® Foam).

CAN I USE WOMEN'S ROGAINE® FOAM FOR BALDNESS OR HAIR LOSS IN BABIES AND CHILDREN?
No. WOMEN'S ROGAINE® Foam must not be used to treat baldness or hair loss in babies or children.

WHAT FACTORS MAY INCREASE THE RISK OF SERIOUS SIDE EFFECTS WITH WOMEN'S ROGAINE® FOAM?
WOMEN'S ROGAINE® Foam should be applied only to the scalp. The risk of side effects may be greater when WOMEN'S ROGAINE® Foam is applied to other parts of the body.

DRAFT

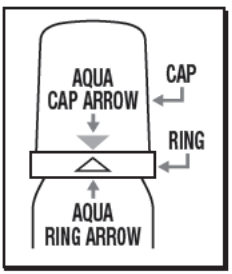
DRAFT

Reference ID: 3699435

If you have any other questions, ask your health care professional or call us toll-free **800-ROGAINE** or **215-273-8755** (collect).

Store at controlled room temperature 20° to 25°C (68° to 77°F).

Save this booklet for future reference.



TO OPEN:

1. Hold **RING**. (See diagram)
2. While holding **RING** twist **CAP** to line up white arrow on **RING** with gray arrow on **CAP**.
3. Tilt **CAP** back and pull

TO CLOSE:

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

DRAFT

DRAFT

Reference ID: 3699435

DRAFT

Dist: Johnson & Johnson Healthcare Products
Division of McNEIL-PPC, Inc.
Skillman, NJ 08558 USA
©McNEIL-PPC, Inc. 2014

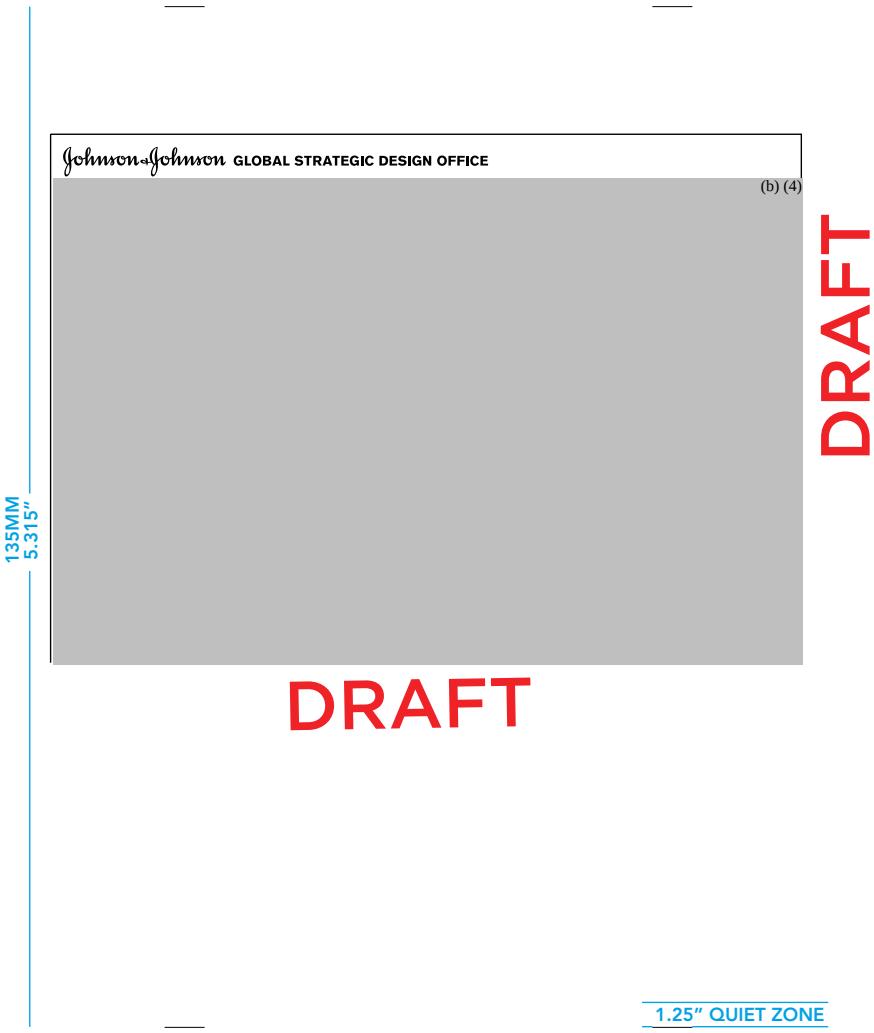
U.S. Patent No. 6,946,120

Product incorporates technology licensed from Stiefel Laboratories
The WOMEN'S ROGAINE® Foam name and the design of this packaging is subject to trademark protection.

Questions? Call toll-free **800-ROGAINE** or **215-273-8755** (collect).

30029317

DRAFT



Reference ID: 3699435

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

THERESA M MICHELE
02/10/2015