

**JUST FOR MEN CONTROL GX ANTI-DANDRUFF- pyrithione zinc shampoo
Combe Incorporated**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Just For Men Control GX Anti-Dandruff Shampoo

JUST FOR MEN[®] Control GX[®] Anti-Dandruff Shampoo

Drug Facts

Active ingredient

Pyrithione Zinc 1%

Purpose

Anti-Dandruff

Use

Helps prevent recurrence of flaking and itching associated with dandruff.

Warnings

For external use only

Allergy Alert

Do not use if you have known sensitivity to haircolouring products. **This product contains hair dye.** Read thoroughly Safety Warnings and Caution Statements on carton and enclosed leaflet.

When using this product

avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.

Stop use and ask doctor if

condition worsens, or does not improve after regular use of this product as directed.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- This product contains hair dye. Read thoroughly Usage Instructions on enclosed leaflet
- Before using this product, you must perform a 48-Hour Skin Allergy Test according to enclosed leaflet
- Wet hair
- Apply shampoo and work into a lather
- Leave on for about 1 minute
- Rinse thoroughly
- For best anti-dandruff results, use at least twice a week or as directed by a doctor.

Other Information

Not for use on children under the age of 16

Inactive ingredients

Water, Disodium Lauryl Sulfosuccinate, Decyl Glucoside, Cetearyl Alcohol, Glycol Stearate, Ethanolamine, Cocamidopropyl Hydroxysultaine, Guar Hydroxypropyltrimonium Chloride, Sodium Cocoyl Isethionate, N,N-Bis(2-Hydroxyethyl)-P-Phenylenediamine Sulfate, Acetic Acid, Aloe Barbadensis Leaf Juice, Chamomilla Recutita (Matricaria) Flower Extract, 1,2,4-Trihydroxybenzene, Cetearyl Glucoside, Erythorbic Acid, Sodium Sulfite, Phenoxyethanol, Caprylyl Glycol, Stearamide Amp, P-Aminophenol, Panthenol, Sorbic Acid, Fragrance.

PACKAGE INSERT

48-HOUR SKIN ALLERGY TEST

YOU MUST PERFORM THIS SKIN ALLERGY TEST 48-HOURS BEFORE FIRST USE, AND WHENEVER YOU HAVE NOT USED THIS PRODUCT FOR 2 CONSECUTIVE WEEKS OR MORE, EVEN IF YOU HAVE ALREADY USED THIS OR ANOTHER HAIRCOLOUR PRODUCT WITHOUT ANY ADVERSE REACTION.

Allergic reactions (such as itching, burning, redness, swelling, skin abrasions, eruptions or irritation) to permanent haircolour, including this product, can occur and in rare instances be severe. If you have ever experienced any of these symptoms while using this product, stop using haircolouring products until you consult a doctor, as these are signs that you may have developed an allergy.

- **You MUST do this test 48 hours before first use and whenever you have not used this product for 2 consecutive weeks or more.** This test is not a guarantee of avoiding future allergic reactions.
- For some users, frequent use of haircolouring products can increase the risk of allergic reactions.
- This test represents an important precaution. However, be aware that even if a test has been carried out, you may still experience an allergic reaction when you use this product.

1) **WASH TEST AREA.** With mild soap and water, wash an area about the size of a coin on the inside bend of your elbow. Pat dry.

2) **APPLY PRODUCT.** Peel off freshness tab under cap. Do not use if missing or broken. Squeeze a small amount of product from the tube and spread it thinly with a cotton swab or tissue onto the test area. Place cap back on tube immediately and tightly so it doesn't lose effectiveness.

3) **DO NOT WASH OR COVER TEST AREA FOR 48 HOURS.** Examine the test area during this time. If at **ANY TIME** during the testing, you experience itching, burning, redness, swelling, eruptions, or any irritation, you may be allergic. **STOP!** Wash area immediately and keep it uncovered. **YOU MUST NOT USE** this product or **ANY OTHER** haircolouring product.

If you have **NO** reaction after 48 hours, you may use the product.

WHAT TO DO IF YOU HAVE A REACTION AT ANY TIME WHILE OR AFTER USING THIS PRODUCT:

- If you experience **ANY** itching, burning, redness, swelling, eruptions, or irritation, rinse immediately and thoroughly as this may be an indication of an allergic reaction. **DO NOT USE** this product again. If symptoms persist seek medical attention.
- **SEEK MEDICAL ATTENTION** if you experience a rapidly spreading rash, dizziness, faintness, difficulty breathing and shortness of breath, tightness of chest, hives, swelling of eyes/face, blistering of skin or scalp weeping.

SAFETY WARNINGS

- If you have ever experienced any allergic reaction (such as itching, burning, redness, swelling, skin abrasions, eruptions or irritation) following use of a haircolouring product, do not use this or any other haircolouring product.
- **Always do the 48-Hour Skin Allergy Test before first use, and whenever you have not used this product for 2 consecutive weeks or more.**
- Wait at least 24 hours after you have relaxed or straightened your hair before you use this product. Wait 2 weeks after you have used a permanent wave.
- Temporary black henna tattoos may increase your risk of allergy.
- Before use, carefully check the skin area(s) where this product is to be applied for irritations, cuts, scratches or other unusual conditions. Do not use this or any other permanent haircolouring product if you have a rash on your face or sensitive, irritated and damaged scalp. In case of a reaction while colouring your hair, such as stinging, rash or burning sensation on the skin, rinse out immediately and discontinue use.
- Do not use on hair that has been lightened, bleached, highlighted, coloured blond or has been coloured with henna.
- If your hair has been coloured with metal dyes consult manufacturer.
- Remove all metal objects and jewelry before colouring and keep them away during colouring.
- Do not mix this product with any other product.
- Keep the empty package for a few days, in case you experience a reaction.
- Contact the manufacturer and/or the relevant national authority if you have experienced an allergic reaction.
- For external use only.
- Do not use on body hair.
- Avoid prolonged skin contact.
- When possible, remove contact lenses before applying this product.
- Avoid contact with eyes. In case of contact, rinse immediately and thoroughly with cool water. If irritation persists, call a doctor.
- This product is not intended for use on persons under the age of 16.

IN RARE CASES, USE OF HAIR DYE HAS BEEN ASSOCIATED WITH SKIN DEPIGMENTATION (SKIN LIGHTENING OR LOSS OF SKIN COLOUR), WHICH MAY BE TEMPORARY OR PERMANENT. IF YOU NOTICE ANY SKIN DEPIGMENTATION, DISCONTINUE USE IMMEDIATELY.

DO NOT USE THIS PRODUCT AT ALL IF YOU HAVE SKIN DEPIGMENTATION PROBLEMS SUCH AS WHITE PATCHES ON YOUR SKIN (A CONDITION CALLED VITILIGO) OR IF YOU HAVE A FAMILY HISTORY OF SKIN DEPIGMENTATION PROBLEMS, AS AN ALLERGIC REACTION MAY CAUSE TEMPORARY OR PERMANENT LOSS OF SKIN PIGMENT.

Contains phenylenediamines.

DO NOT USE ON EYEBROWS OR EYELASHES; to do so may cause blindness.

KEEP ALL HAIRCOLOURING PRODUCTS OUT OF REACH OF CHILDREN. DO NOT INGEST. IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

JUST FOR MEN® CONTROL GX® Grey Reducing Anti-Dandruff Shampoo

1% pyrithione zinc

IMPORTANT: READ AND FOLLOW THE 48-HOUR SKIN ALLERGY TEST INSTRUCTIONS AND SAFETY WARNINGS BEFORE YOU USE THIS PRODUCT.

USAGE DIRECTIONS

You must perform the **48-Hour Skin Allergy Test** before first use and whenever you have not used this shampoo for 2 consecutive weeks or more. **DO NOT USE** on hair that has been lightened, bleached, highlighted, coloured blond or has been coloured with henna.

Get the look you want: Use daily until you like what you see, then regularly to maintain the look you like.

Keep it that way: Once you've reached the level of grey reduction you like, you can reduce the frequency of use, alternating with another anti-dandruff shampoo (preferably a gentle shampoo, so you don't start losing your great look).

1) Peel off freshness tab under cap. Do not use if missing or broken. Do not leave tube open between uses.

2) Massage into wet hair using the palms of your hands, **NOT** your fingertips, to avoid nail staining. Wash hands thoroughly with soap and water. Leave on for about 1 minute before rinsing hair thoroughly.

3) Wash hands thoroughly again with soap and water, and dry hair with an old or dark towel.

4) **IMPORTANT:** Rinse off any product that has dripped or splattered. Failure to do so can result in staining of surfaces. Store tube facing cap down.

FREQUENTLY ASKED QUESTIONS

1) **Will the product stain my skin?** Some men with very dry skin may experience temporary staining of fingers and nails. This can be avoided by following these precautions:

- Moisturise hands with a hand or body moisturiser before using the product.
- Use the palms of your hands to apply, **not** your fingertips.
- Wash hands and nails thoroughly with soap immediately after using this product.
- Should you experience any nail staining, gently clean with toothpaste and a toothbrush.
- If you still experience skin or nail staining, use disposable gloves.

2) **Does the product rub off?** Control GX permanently reduces your grey and does not rub off if you **rinse your hair thoroughly**. To be on the safe side, use a dark or old towel to dry hair. Any stains on towels should come off by washing them as long as you don't wait too long.

3) **Will the product stain surfaces?** Control GX may stain surfaces if you don't rinse it off thoroughly. Check surfaces for any dripped or splattered product after use. Rinse off with water to avoid staining. If you see staining, use a non-abrasive cleaner with bleach. Always test in an inconspicuous area first.

4) **I see some dark spots in the product. Is that normal?** Control GX may develop dark spots in the tube over time. This is normal because Control GX is sensitive to oxygen. As the product is opened and closed for use, trace amounts of oxygen can enter the tube. Darkening in the tube does not affect the results of the product. Store the tube facing cap down.

5) **Can I use with another haircolour?** **DO NOT USE** Control GX on hair that has been lightened, bleached, highlighted, coloured blond or has been coloured with henna. You may use Control GX on hair that has been previously darkened, however the colour can become darker and change tone. If you have visible colour in your hair, for best results wait until it has grown out before using Control GX.

6) **Can I use on facial or body hair?** No, Control GX Anti-Dandruff was designed and tested only for use on head hair.

PRINCIPAL DISPLAY PANEL

REDUCES GREY WITH EACH SHAMPOO

JUST FOR MEN®

CONTROL GX® ANTI-DANDRUFF

GREY REDUCING ANTI-DANDRUFF SHAMPOO

1% pyrithione zinc

GRADUALLY REDUCES GREY

SUBTLE, NATURAL-LOOKING RESULTS

GENTLY CLEANS & CONTROLS DANDRUFF

FOR ANY SHADE OF HAIR. SEE BACK PANEL*

4 FL. OZ. (118 mL)

ANTI-DANDRUFF + HAIRCOLOUR SHAMPOO

IMPORTANT: Haircolour can cause allergic reactions. Follow Safety Warnings on side panel.

NEW

REDUCES GREY WITH EACH SHAMPOO

JUST FOR MEN
CONTROLGX
ANTI-DANDRUFF

GREY REDUCING
ANTI-DANDRUFF
SHAMPOO

1% pyrithione zinc

GRADUALLY REDUCES GREY

IMPORTANT: Haircolour can cause allergic reactions. Follow Safety Warnings on side panel.

REDUCES GREY WITH EACH SHAMPOO

NEW

JUST FOR MEN
CONTROLGX
ANTI-DANDRUFF

GREY REDUCING
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1% pyrithione zinc

GRADUALLY REDUCES GREY

- SUBTLE, NATURAL-LOOKING RESULTS
- GENTLY CLEANS & CONTROLS DANDRUFF
- FOR ANY SHADE OF HAIR SEE BACK PANEL*

4 FL. OZ. (118 mL)

ANTI-DANDRUFF + HAIRCOLOUR SHAMPOO

IMPORTANT: Haircolour can cause allergic reactions. Follow Safety Warnings on the panel.



Consumer Survey of Product Innovation
2018*

JUST FOR MEN
CONTROLGX

GREY REDUCING
ANTI-DANDRUFF
SHAMPOO

1% pyrithione zinc

GRADUALLY REDUCES GREY

SAFETY WARNINGS

HAIR COLOURANTS CAN CAUSE SEVERE ALLERGIC REACTIONS. BEFORE USING THIS PRODUCT, YOU MUST PERFORM A PRELIMINARY 48-HOUR SKIN ALLERGY TEST ACCORDING TO ACCOMPANYING DIRECTIONS. THIS PRODUCT IS NOT INTENDED FOR USE ON PERSONS UNDER THE AGE OF 16. TEMPORARY "BLACK HENNA" TATTOOS MAY INCREASE YOUR RISK OF ALLERGY.

DO NOT USE THIS PRODUCT IF:

- You have already experienced any reaction to this or any other haircolour product.
- You have a rash on your face, an irritated, sensitive or damaged scalp.
- You have experienced a reaction to a temporary "black henna" tattoo in the past.

REMEMBER TO PERFORM THE 48-HOUR SKIN ALLERGY TEST BEFORE EACH USE EVEN IF YOU HAVE PREVIOUSLY USED THIS OR OTHER HAIRCOLOURING PRODUCTS. FOR THIS REASON, BUY THIS PRODUCT TWO DAYS BEFORE YOU INTEND TO USE IT.

READ AND FOLLOW DIRECTIONS ON ENCLOSED LEAFLET.

In rare cases, use of haircolour has been associated with skin depigmentation (skin lightening or loss of skin colour), which may be temporary or permanent. If you notice any skin depigmentation or other allergic reaction such as discomfort or severe itching, discontinue use immediately. Do not use this product at all if you have skin depigmentation problems such as white patches on your skin (a condition called vitiligo) or if you have a family history of skin depigmentation problems, as an allergic reaction may cause temporary or permanent loss of skin pigment.

CAUTION

THIS PRODUCT CONTAINS INGREDIENTS WHICH MAY CAUSE SKIN IRRITATION ON CERTAIN INDIVIDUALS AND A PRELIMINARY 48-HOUR SKIN ALLERGY TEST ACCORDING TO ACCOMPANYING DIRECTIONS SHOULD BE DONE FIRST. THIS PRODUCT MUST NOT BE USED FOR DYEING THE EYELASHES OR EYEBROWS - TO DO SO MAY CAUSE BLINDNESS. CONTAINS PHENYLENEDIAMINES.

KEEP PRODUCT OUT OF REACH OF CHILDREN
FOR EXTERNAL USE ONLY
AVOID CONTACT WITH EYES.
IN CASE OF CONTACT, RINSE IMMEDIATELY.

JUST FOR MEN
CONTROLGX

BREAKTHROUGH PATENTED† TECHNOLOGY REDUCES GREY A LITTLE BIT WITH EACH SHAMPOO



Reduces grey a little bit with each shampoo for subtle, gradual results. Use daily until you like what you see, then regularly to maintain the look you like.

NATURAL-LOOKING RESULTS



How much grey you get rid of depends on how often you use it.

*Best for all shades from light brown to black hair. Results may vary on naturally blond and red hair, or hair that has been previously coloured. **DO NOT USE** on hair that has been lightened, bleached, highlighted or coloured blond or with henna.

GENTLY CLEANS & CONTROLS DANDRUFF

It's a shampoo that gently and thoroughly cleans hair. Relieves scalp itch, dryness, irritation and helps prevent flakes, while it cleans. Increases volume for a thicker, fuller look.

Visit ControlGX.com for more information.

Combe Incorporated, 1101 Westchester Avenue, White Plains, NY 10604
1-800-431-2610, justformen.com

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† US Pat. Nos. 9237993 and 9474704

Drug Facts

Active ingredients	Purpose
Pyrrithione Zinc 1%	Anti-dandruff

Use
Helps prevent recurrence of flaking and itching associated with dandruff.

Warnings
For external use only

Allergy alert
Do not use if you have a known sensitivity to haircolouring products. **This product contains hair dye.** Read thoroughly Safety Warnings and Caution Statements on carton and enclosed leaflet.

When using this product, avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.

Stop use and ask doctor if condition worsens, or does not improve after regular use of this product as directed.

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

Directions ■ This product contains hair dye. Read thoroughly Usage Instructions on enclosed leaflet ■ before using this product, you must perform a 48-Hour Skin Allergy Test according to enclosed leaflet ■ wet hair ■ apply shampoo and work into a lather ■ leave on for about 1 minute ■ rinse thoroughly ■ for best anti-dandruff results, use at least twice a week or as directed by a doctor.

Other information
Not for use on children under the age of 16

Inactive ingredients Water, Disodium Lauryl Sulfosuccinate, Decyl Glucoside, Cetearyl Alcohol, Glycol Stearate, Ethanolamine, Cocamidopropyl Hydroxysultaine, Guar Hydroxypropyltrimonium Chloride, Sodium Cocoyl Isethionate, N,N-Bis(2-Hydroxyethyl)-P-Phenylenediamine Sulfate, Acetic Acid, Aloe Barbardensis Leaf Juice, Chamomilla Recutita (Matricaria) Flower Extract, 1,2,4-Trihydroxybenzene, Cetearyl Glucoside, Erythorbic Acid, Sodium Sulfite, Phenoxyethanol, Caprylyl Glycol, Stearamide Amp, P-Aminophenol, Panthenol, Sorbic Acid, Fragrance. (RD-005225)

THE FIRST SHAMPOO WITH A BRAIN®

*So smart, ControlGX® Grey Reducing Shampoo was voted 2018 Product of the Year winner Men's Hair Care category. Survey conducted by Kantar TNS.

JUST FOR MEN CONTROL GX ANTI-DANDRUFF

pyrrithione zinc shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11509-5225
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	10 mg in 1 mL
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Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
DISODIUM LAURYL SULFO SUCCINATE (UNII: P160Q81342)	
Decyl Glucoside (UNII: Z17H97EA6Y)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCOL STEARATE (UNII: 0324G66D0E)	
MONOETHANOLAMINE (UNII: 5KV86114PT)	
CO CAMIDO PROPYL HYDRO XYSUL TAINÉ (UNII: 62V75NI93W)	
GUAR HYDRO XYPROPYL TRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)	
SODIUM CO COYL ISETHIONATE (UNII: 518XTE8493)	
N,N-BIS(2-HYDRO XYETHYL)-P-PHENYLENEDIAMINE SULFATE (UNII: 3X5A8DP6HC)	
ACETIC ACID (UNII: Q40Q9N063P)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
1,2,4-TRIHYDRO XYBENZENE (UNII: 173O8B04RD)	
CETEARYL GLUCO SIDE (UNII: 09FUA47KNA)	
ERYTHORBIC ACID (UNII: 311332OIII)	
SODIUM SULFITE (UNII: VTK01UQK3G)	
PHENO XYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
STEARAMIDE AMP (UNII: U3K8640346)	
P-AMINO PHENOL (UNII: R7P8FRP05V)	
PANTHENOL (UNII: WV9CM0O67Z)	
SORBIC ACID (UNII: X045WJ989B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11509-5225-1	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part358H	01/01/2019	

Labeler - Combe Incorporated (002406502)