

**WHITE GLO 2IN1 TOOTH W MOUTHWASH- sodium monofluorophosphate paste, dentifrice
BARROS LABORATORIES PTY LIMITED**

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.

White Glo 2in1 ToothPaste w Mouthwash

Drug Facts

Active ingredient

Sodium monofluorophosphate 0.76% (0.1% w/v fluoride ion).

Purpose

Anticavity toothpaste

Use

helps protect against cavities

Warnings

Keep out of reach of children under 6 years of age.

If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

Adults and children 2 years of age & older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor.

Children under 6 years of age: Instruct in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision.

Children under 2 years of age: Consult a dentist or doctor.

Other information

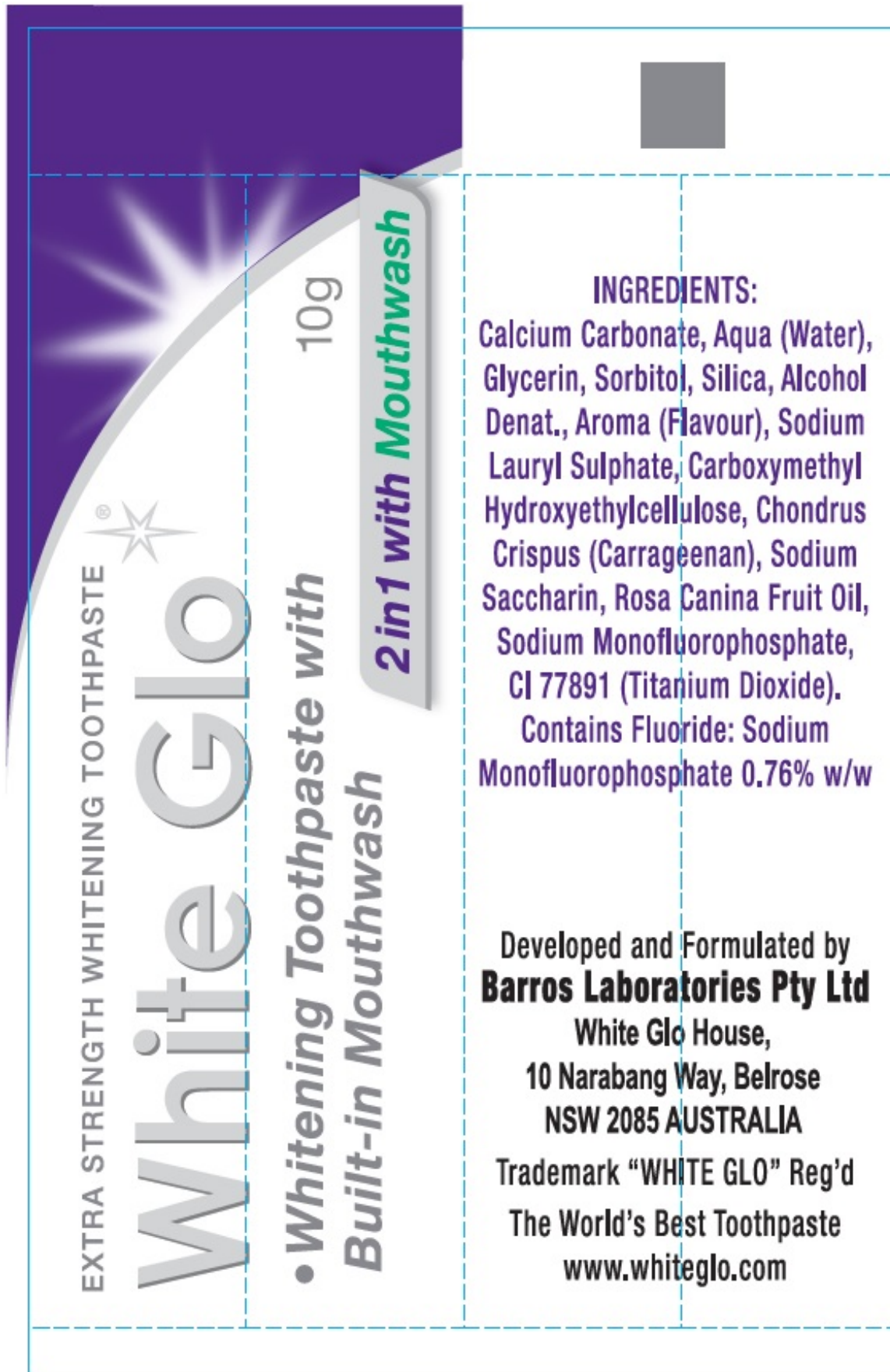
- Store in a cool place, below 86°F, away from heat
- Do not use if quality seal is broken or missing

Inactive ingredients

Calcium Carbonate, Aqua (Water), Glycerin, Sorbitol, Silica, Alcohol Denat., Aroma (Flavour), Sodium Lauryl Sulphate, Carboxymethyl Hydroxyethylcellulose, Chondrus Crispus (Carrageenan), Sodium Saccharin, Rosa Canina Fruit Oil, CI 77891 (Titanium Dioxide)

Questions or comments

Package Labeling: 68368-001-10



The image shows a packaging design for White Glo toothpaste and mouthwash. The design features a purple and white color scheme. On the left, there is a curved graphic with a starburst effect. The text 'EXTRA STRENGTH WHITENING TOOTHPASTE' is written vertically in a small font. The brand name 'White Glo' is prominently displayed in a large, stylized font. Below the brand name, it says '•Whitening Toothpaste with Built-in Mouthwash'. To the right of this, '10g' is written vertically. Further right, a banner says '2 in 1 with Mouthwash'. The ingredients list is on the right side, followed by the manufacturer's name 'Barros Laboratories Pty Ltd' and their address in Australia. The website 'www.whiteglo.com' is at the bottom.

EXTRA STRENGTH WHITENING TOOTHPASTE

White Glo

•Whitening Toothpaste with
Built-in Mouthwash

10g

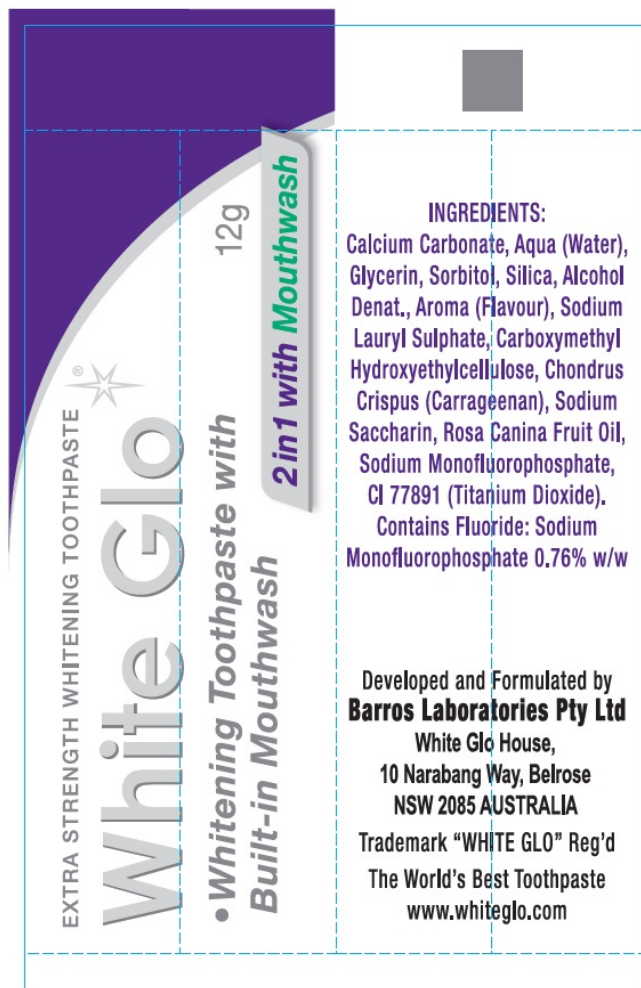
2 in 1 with Mouthwash

INGREDIENTS:
Calcium Carbonate, Aqua (Water),
Glycerin, Sorbitol, Silica, Alcohol
Denat., Aroma (Flavour), Sodium
Lauryl Sulphate, Carboxymethyl
Hydroxyethylcellulose, Chondrus
Crispus (Carrageenan), Sodium
Saccharin, Rosa Canina Fruit Oil,
Sodium Monofluorophosphate,
CI 77891 (Titanium Dioxide).
Contains Fluoride: Sodium
Monofluorophosphate 0.76% w/w

Developed and Formulated by
Barros Laboratories Pty Ltd
White Glo House,
10 Narabang Way, Belrose
NSW 2085 AUSTRALIA
Trademark "WHITE GLO" Reg'd
The World's Best Toothpaste
www.whiteglo.com

Drug Facts		Drug Facts (continued)	
Active ingredient Sodium monofluorophosphate 0.76% (0.1% fluoride ion).	Purpose Anticavity toothpaste	Other information <ul style="list-style-type: none"> • Store in a cool place, below 86°F, away from heat • Do not use if quality seal is broken or missing 	
Use helps protect against cavities		Inactive ingredients Calcium Carbonate, Aqua (Water), Glycerin, Sorbitol, Silica, Alcohol Denat., Aroma (Flavour), Sodium Lauryl Sulphate, Carboxymethyl Hydroxyethylcellulose, Chondrus Crispus (Carrageenan), Sodium Saccharin, Rosa Canina Fruit Oil.	
Warnings Keep out of reach of children under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.		Questions or comments For customer enquiries, please contact: customer.enquiry@whiteglo.com White Glo USA INC. 25 Suffolk Court, Hauppauge, NY, 11788 USA. www.whiteglo.com	
Directions Adults and children 2 years of age & older:	Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor.		
Children under 6 years of age:	Instruct in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision.		
Children under 2 years of age: Consult a dentist or doctor.			

Package Labeling: 68368-001-07



Package Labeling: 68368-001-05

EXTRA STRENGTH WHITENING
TOOTHPASTE

White Glo[®]

5g

2 in 1 with Mouthwash

INGREDIENTS:

Calcium Carbonate Aqua (Water),
Glycerin, Sorbitol, Silica, Alcohol
Denat., Aroma (Flavour), Sodium
Lauryl Sulphate, Carboxymethyl
Hydroxyethylcellulose, Chondrus
Crispus (Carrageenan), Sodium
Saccharin, Rosa Canina Fruit Oil,
Sodium Monofluorophosphate,
CI 77891 (Titanium Dioxide).

Contains Fluoride: Sodium
Monofluorophosphate 0.76% w/w

Developed and Formulated by
Barros Laboratories Pty Ltd

White Glo House
10 Narabang Way,
Belrose NSW, 2085
AUSTRALIA

www.whiteglo.com

2

2*5

1

EXTRA STRENGTH WHITENING
TOOTHPASTE

White Glo[®]

4g

2 in 1 with Mouthwash

6*3

3

INGREDIENTS:

Calcium Carbonate Aqua (Water),
Glycerin, Sorbitol, Silica, Alcohol
Denat., Aroma (Flavour), Sodium
Lauryl Sulphate, Carboxymethyl
Hydroxyethylcellulose, Chondrus
Crispus (Carrageenan), Sodium
Saccharin, Rosa Canina Fruit Oil,
Sodium Monofluorophosphate,
CI 77891 (Titanium Dioxide).

Contains Fluoride: Sodium
Monofluorophosphate 0.76% w/w

Developed and Formulated by
Barros Laboratories Pty Ltd

Made in China
White Glo House
10 Narabang Way,
Belrose NSW, 2085
AUSTRALIA

www.whiteglo.com



EXTRA STRENGTH WHITENING
TOOTHPASTE

White Glo® 3g

2in1 with Mouthwash

INGREDIENTS:
 Calcium Carbonate, Aqua (Water), Glycerin, Sorbitol, Silica, Alcohol Denat., Aroma (Flavour), Sodium Lauryl Sulphate, Carboxymethyl Hydroxyethylcellulose, Chondrus Crispus (Carrageenan), Sodium Saccharin, Rosa Canina Fruit Oil, Sodium Monofluorophosphate CI 77891 (Titanium Dioxide), Contains Fluoride: Sodium Monofluorophosphate 0.76% w/w.

Developed and Formulated by
Barros Laboratories Pty Ltd
 AUSTRALIA
 Trademark "WHITE GLO" Reg'd
 The World's Best Toothpaste
www.whiteglo.com

WHITE GLO 2IN1 TOOTH W MOUTHWASH

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68368-001
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	7.6 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITOL (UNII: 506T60A25R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ALCOHOL (UNII: 3K9958V90M)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CHONDRUS CRISPUS (UNII: OQS23HUA1X)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
ROSA CANINA FRUIT OIL (UNII: CR7307M3QZ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68368-001-10	1 in 1 BOX	01/01/2020	
1		10 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:68368-001-07	1 in 1 BOX	01/01/2020	
2		7 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:68368-001-05	1 in 1 BOX	01/01/2020	
3		5 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:68368-001-04	1 in 1 BOX	01/01/2020	
4		4 g in 1 TUBE; Type 0: Not a Combination Product		
5	NDC:68368-001-03	1 in 1 BOX	01/01/2020	
5		3 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
OTC monograph final	part355	01/01/2020	

Labeler - BARROS LABORATORIES PTY LIMITED (751813452)