

NO7 REBALANCING DAY FLUID SUNSCREEN SPF 15 - octinoxate and avobenzone and ensulizole lotion

Boots Retail USA Inc

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.

Carton and bottle labelling

Active ingredients

Octinoxate (6.0%)

Avobenzone (2.0%)

Ensulizole (2.0%)

Purpose

Sunscreens

Uses

- Provides moderate protection against the adverse effects of the sun
- Higher SPF gives more protection

Warnings

For external use only

When using this product

- Keep out of eyes. If contact occurs, rinse thoroughly with cold water.
- Avoid direct contact with fabrics.

Stop use and ask a doctor if rash or irritation develops and lasts.

Keep out of reach of children. If swallowed, get medical help.

Directions

- After cleansing, massage over your face and neck, avoiding contact with your eyes.
- Apply evenly at least 15 minutes before sun exposure.
- Reapply as required.
- Not intended for children under the age of 12.
- Not intended for protection while sunbathing.

Other information

Do not store above 30⁰C or 86⁰F

Inactive ingredients

Aqua (Water), Glycerin, Cyclopentasiloxane, Alcohol denat., Cyclohexasiloxane, C12-15 alkyl benzoate, Triethanolamine, Dimethicone, Acrylamide/ammonium acrylate copolymer, Cetyl alcohol, Myristyl myristate, C18-36 acid glycol ester, Phenoxyethanol, Lauryl methacrylate/glycol dimethacrylate cross polymer, Polyisobutene, Glyceryl stearate, PEG-100 stearate, Betaine, Parfum (Fragrance), Dimethiconol, Methylparaben, Sodium 2-pyrrolidone-5-carboxylate, Xanthan gum, Ethylparaben, Sodium hyaluronate, Polysorbate 20, Dipropylene glycol, Sorbitol, Tetrasodium EDTA, Serine, Glycine, Glutamic acid, Lysine, BHT, Alanine, Arginine, Threonine, Propylparaben.

USA/Canada: Questions? 1-866-75-BOOTS

Balanced Hydration...

Treat your skin to a long cool drink with this deliciously light lotion, created to work in harmony with oily to combination skin without blocking pores.

The revolutionary water-based formula vanishes in to give your skin just the amount of moisture it needs. At the same time, the oil-absorbing micro-sponges work to reduce skin oiliness so you look youthfully radiant, not shiny.

With hyaluronic acid to keep skin hydrated for 24 hours, plus our ultra-light SPF 15 to care and protect. After 2 weeks 68% of our testers said their skin looked healthier and more radiant.

A little facial everyday...

After cleansing, massage over your face and neck. Apply prior to sun exposure. Avoid direct contact with eyes.

Dermatologically tested.

Made in the UK

The Boots Company PLC Nottingham England NG2 3AA

Dist in the USA by Boots Retail USA Inc. Stamford CT06901

www.boots.com

Bottle label

Balanced Hydration...

Treat your skin to a long cool drink with this light fluid, created for oily to combination skin without blocking pores.

The water-based formula gives your skin just the amount of moisture it needs. At the same time, the oil-absorbing micro-sponges work to reduce skin oiliness so you look youthfully radiant, not shiny.

With hyaluronic acid to keep skin hydrated for 24 hours.

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Rebalancing Day Fluid

Oily/Combination

Moisturises, mattifies and balances your skin

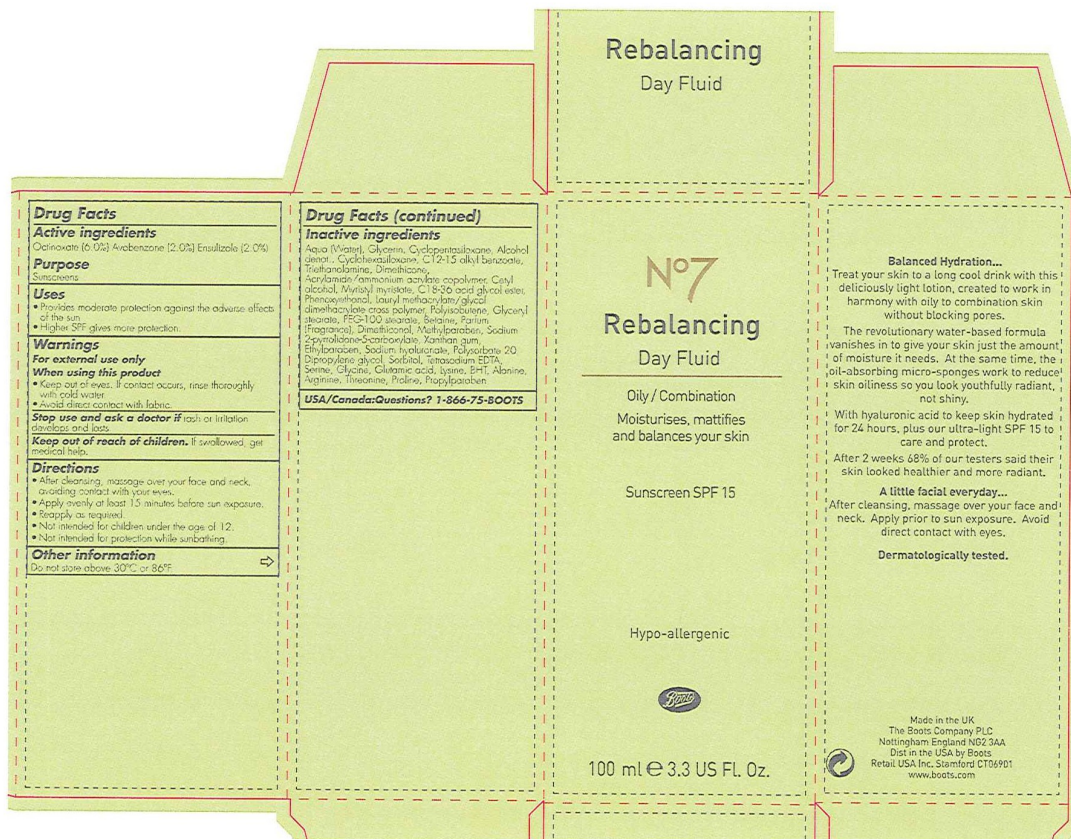
Sunscreen SPF 15

Hypo-allergenic

Boots

100ml e 3.3 US Fl. Oz

Rebalancing Day Fluid carton.jpg



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Rebalancing Day Fluid bottle.jpg



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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68472-102
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	6 mL in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2 mL in 100 mL
ENSULIZOLE (UNII: 9YQ9D1I1W42) (ENSULIZOLE - UNII:9YQ9D1I1W42)	ENSULIZOLE	2 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CYCLOMETHICONE 5 (UNII: 0TH5PC10R)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	

TROLAMINE (UNII: 9O3K93S3TK)
DIMETHICONE (UNII: 92RU3N3Y1O)
CETYL ALCOHOL (UNII: 936JST6JCN)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
BETAINE (UNII: 3SCV180C9W)
METHYLPARABEN (UNII: A2I8C7HI9T)
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)
XANTHAN GUM (UNII: TTV12P4NEE)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
ETHYLPARABEN (UNII: 14255EXE39)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
SORBITOL (UNII: 506T60A25R)
SERINE (UNII: 452VLY9402)
GLYCINE (UNII: TE7660XO1C)
GLUTAMIC ACID (UNII: 3KX376GY7L)
LYSINE (UNII: K3Z4F929H6)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
ALANINE (UNII: OF5P57N2ZX)
ARGININE (UNII: 94ZLA3W45F)
THREONINE (UNII: 2ZD004190S)
PROLINE (UNII: 9DLQ4CIU6V)
PROPYLPARABEN (UNII: Z8IX2SC1OH)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68472-102-01	1 in 1 CARTON		
1		100 mL in 1 BOTTLE, PUMP		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/04/2009	

Labeler - Boots Retail USA Inc (143151533)

Registrant - The Boots Company PLC (218622660)

Establishment			
Name	Address	ID/FEI	Business Operations
BCMLtd		230780322	manufacture, analysis