



Information for the user

Anti – Dandruff Ketoconazole 2% w/w Shampoo

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription to treat and prevent dandruff. However, you still need to use it carefully to get the best results from it.

- Keep this leaflet, you may need to read it again
- Ask your pharmacist if you need more information or advice
- You must contact a pharmacist or doctor if your symptoms worsen or do not improve after 4 weeks of treatment

What this medicine is for

This medicine contains Ketoconazole which belongs to a group of medicines called anti-fungals, which act to treat fungal infections.

It can be used to treat and prevent dandruff, which you may notice as visible flaking of dry skin from the scalp.

Dandruff is associated with the presence of a yeast (fungus) called *Pityrosporum Ovale*. This yeast lives naturally on the skin of everyone, but people with dandruff appear to have more than usual. Ketoconazole works by destroying the yeast associated with dandruff.

Before you use this medicine

This medicine can be used by adults and adolescents. However, some people should not use this medicine or should seek the advice of their pharmacist or doctor first.

Do not use:

- If you are allergic to any of the ingredients

Talk to your pharmacist or doctor:

- If you are using a steroid product (e.g. betamethasone or hydrocortisone) on your scalp (see "Other important information")
- If you are pregnant or breastfeeding

Other important information

Avoid contact with the eyes.

! If shampoo accidentally comes into contact with the eyes use cold water to gently bathe the eyes.

If you are using a steroid product on your scalp, when you stop using the steroid product your dandruff may worsen. Reducing the steroid over a period of 2 to 3 weeks whilst using the shampoo will reduce the chance of the dandruff becoming worse.

Ketoconazole Shampoo contains

- Benzyl alcohol - This medicine contains 5.00 mg benzyl alcohol in each gram which is equivalent to 0.50 % w/w. Benzyl alcohol may cause allergic reactions and mild local irritation.

How to use this medicine

Shake the bottle well before use.

Age	How much to use	How often to use
Adults and adolescents	Wet hair and scalp and apply enough shampoo to cover the scalp and produce a foam (lather). Leave for 3-5 minutes before rinsing.	Use twice a week, at least three days apart, for the first 2 to 4 weeks

After 2 to 4 weeks you can use the shampoo once every 1 to 2 weeks to keep dandruff under control.

For use on the hair and scalp only.

Do not use more than the amount recommended above. If your symptoms do not improve after 4 weeks talk to your pharmacist or doctor.

If symptoms do not go away within 4 weeks talk to your pharmacist or doctor.

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If you accidentally swallow some of the shampoo:

Swallowing this shampoo is normally harmless.

Talk to a doctor if you are concerned and take this shampoo with you.

Do not make yourself sick.

Possible side effects

Most people will not have problems, but some may get some, which are usually mild.

! If you get any of these serious side effects, stop using the shampoo.

See a doctor at once:

- Difficulty in breathing, swelling of the face, neck, tongue or throat (severe allergic reactions)

If you get any of the following side effects see your pharmacist or doctor:

Uncommon side effects (less than 1 in every 100 people are affected):

- Localised reactions including redness, irritation and itching of the skin
- Dry skin, skin rash or a burning sensation of the skin
- Swelling of the hair follicles, hair loss or changes in the hair texture
- An increase in tear production

Rare side effects (less than 1 in every 1000 people are affected):

- Changes in taste of food
- Eye irritation
- Other skin reactions such as flaky skin, acne, contact dermatitis (redness and swelling of the skin)
- Other localised allergic reactions including small blisters on the surface of your skin
- Other side effects (It is unknown how often these may occur):
- Changes in hair colour
- Raised, red itchy skin (symptoms of urticaria, which is often known as hives or nettle rash)

If any side effect becomes severe, or you notice any side effect not listed here, please tell your pharmacist or doctor.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

How to store this medicine

Do not store above 25°C. Store in the original container. Keep the container tightly closed.

Keep this medicine in a safe place out of the sight and reach of children, preferably in a locked cupboard.

Use by the date on the end flap of the carton.

What is in this medicine

Each gram of shampoo contains Ketoconazole 20 mg, which is the active ingredient.

As well as the active ingredient, the shampoo also contains sodium laureth sulfate paste, disodium laureth sulfosuccinate, sodium chloride, citric acid monohydrate, benzyl alcohol, tetrasodium EDTA, imidurea, polyquaternium-7, dexpanthenol, laureth-2, sodium hydroxide, erythrosine (E127) and purified water.

The pack contains 60 ml or 100 ml of clear, pink to red/orange, thick shampoo.

Who makes this medicine

Manufactured for The Boots Company PLC Nottingham NG2 3AA by the Marketing Authorisation Holder Pinewood Laboratories Ltd., Ballymacarbry Clonmel Co. Tipperary Ireland

Leaflet prepared May 2021

If you would like any further information about this medicine, please contact The Boots Company PLC Nottingham NG2 3AA

Other formats

To request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information:

Product name: Boots Anti-Dandruff Ketoconazole 2% w/w Shampoo
Reference number: 04917/0063

This is a service provided by the Royal National Institute of Blind People.

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ARTWORK ONLY

Trident Reference No: **WBAG424260**
Zen Ref: TR1890425
Category: WBA Global
Sub-Category: Wellness
Brand: Boots Own Brand
Pack Type: Skin Care
Variant: Anti Dandruff Shampoo Leaflet

Action: **J**
Date: 14/01/22
Country: UK

Component Code: **23LF01750PW**
Item Code: **89-36-676**

CAD Ref No: 148x360mm
Printer: N/A
Substrate: White Paper

Barcode Type: N/A
Barcode Number: N/A
Magnification: N/A
Barcode Truncated By: N/A (smallest bar)
Edgemark Position: N/A
Pharmacode No/NE: N/A

Technical & Non Printing Items
Cutter Guides

Colours
PANTONE 285 C



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Please note that any low resolution paper Canon colour copies associated with this job should be referred to for content, layout and colour separation only.

UNDER NO CIRCUMSTANCES SHOULD THIS ARTWORK BE ALTERED WITHOUT PRIOR PERMISSION FROM TRIDENT.

STUDIO USE ONLY Ethan Farr v1.0
SmsArt check results: G=1, O=0, R=0, - EF - 14/01/22 09:33:34

TECHNICAL INFO: PRINTER PLEASE NOTE

Trident have created this artwork to a generic print process specification and repro has not been applied. Please call your Boots contact to discuss any amendments or if anything falls beneath your print tolerances.

PACK MOCK UP

Product Name: Anti-Dandruff Ketoconazole 2% w/w Shampoo
Product Licence No.: 04917/0063
Wording Ref: MHRA Approved 28/02/2021 TR18904251
Status: MHRA Approved
Pack Details: White high-density polyethylene (HDPE) multi dose bottles with polypropylene top closures
Pack Size: 60 or 100 ml

Version No.	Date Issued	Reason For Change
1	15/6/2021	Reformulation and new leaflet size. RFI

REGULATORY INFORMATION

FIC Application:	Yes		
Largest Surface Area:	532.80cm ²		
Statement of Identity:	Minimum	Artwork	x Height
Mandatory Font Size (x-height):	1.2 mm	N/A	N/A
Main Headings:	-	17.00pt	3.10mm
Sub Headings:	-	15.00pt	2.74mm
Body Copy:	-	13.00pt	2.37mm
Weight dec. text height:	-	N/A	N/A
The "e" Mark height:	-	N/A	N/A
Directions for Use:	-	N/A	N/A
Warnings:	-	N/A	N/A
Name and Address:	-	N/A	N/A
Distributor Address:	-	N/A	N/A
Country of Origin:	-	N/A	N/A
Ingredients:	-	N/A	N/A
PAO:	-	N/A	N/A
Recycle Now Logo Portrait:	9.5 mm	N/A	
Recycle Now Logo Landscape:	3.5 mm	N/A	
Green dot symbol size:	6 mm	N/A	
Mobius loop:	6 mm	N/A	
Hazard symbol size:	10 x 10 mm	N/A	