§ 358.710  Active ingredients for the control of dandruff, seborrheic dermatitis, or psoriasis.

The active ingredient of the product consists of any of the following within the specified concentration established for each ingredient:

(a) Active ingredients for the control of dandruff.
   (1) Coal tar, 0.5 to 5 percent. When a coal tar solution, derivative, or fraction is used as the source of the coal tar, the labeling shall specify the identity and concentration of the coal tar source used and the concentration of the coal tar present in the final product.
   (2) Pyrithione zinc, 0.3 to 2 percent when formulated to be applied and then washed off after brief exposure.
   (3) Pyrithione zinc, 0.1 to 0.25 percent when formulated to be applied and left on the skin or scalp.
   (4) Salicylic acid, 1.8 to 3 percent.
   (5) Selenium sulfide, 1 percent.
   (6) Selenium sulfide, micronized, 0.6 percent.
   (7) Sulfur, 2 to 5 percent.

(b) Active ingredients for the control of seborrheic dermatitis.
   (1) Coal tar, 0.5 to 5 percent. When a coal tar solution, derivative, or fraction is used as the source of the coal tar, the labeling shall specify the identity and concentration of the coal tar source used and the concentration of the coal tar present in the final product.
   (2) Pyrithione zinc, 0.95 to 2 percent when formulated to be applied and then washed off after brief exposure.
   (3) Pyrithione zinc, 0.1 to 0.25 percent when formulated to be applied and left on the skin or scalp.
   (4) Salicylic acid, 1.8 to 3 percent.
   (5) Selenium sulfide, 1 percent.

(c) Active ingredients for the control of psoriasis.
   (1) Coal tar, 0.5 to 5 percent. When a coal tar solution, derivative, or fraction is used as the source of the coal tar, the labeling shall specify the identity and concentration of the coal tar source used and the concentration of the coal tar present in the final product.
   (2) Salicylic acid, 1.8 to 3 percent.


§ 358.720  Permitted combinations of active ingredients.

(a) Combination of active ingredients for the control of dandruff. Salicylic acid identified in § 358.710(a)(4) may be combined with sulfur identified in § 358.710(a)(7) provided each ingredient is present within the established concentration and the product is labeled according to § 358.750.

(b) Combination of control of dandruff and external analgesic active ingredients. Coal tar identified in § 358.710(a)(1) may be used at a concentration of 1.8 percent coal tar solution, on a weight to volume basis, in combination with menthol, 1.5 percent, in a shampoo formulation provided the product is labeled according to § 358.760.

[72 FR 9852, Mar. 6, 2007]

§ 358.750  Labeling of drug products for the control of dandruff, seborrheic dermatitis, or psoriasis.

(a) Statement of identity. The labeling of the product contains the established name of the drug, if any, and identifies the product with one or more of the following, as appropriate:
   (1) “For relief of” or “Controls” “the symptoms of” (select one or more

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