

§ 333.120 Permitted combinations of active ingredients.

The following combinations are permitted provided each active ingredient is present within the established concentration and in the specified dosage form, and the product is labeled in accordance with § 333.160.

(a) *Combinations of antibiotic active ingredients.* (1) Bacitracin-neomycin sulfate ointment containing, in each gram, 500 units of bacitracin and 3.5 milligrams of neomycin in a suitable ointment base.

(2) Bacitracin-neomycin sulfate-polymyxin B sulfate ointment containing, in each gram, in a suitable ointment base the following:

(i) 500 units of bacitracin, 3.5 milligrams of neomycin, and 5,000 units of polymyxin B; or

(ii) 400 units of bacitracin, 3.5 milligrams of neomycin, and 5,000 units of polymyxin B;

(3) Bacitracin-polymyxin B sulfate topical aerosol containing, in each gram, 500 units of bacitracin and 5,000 units of polymyxin B in a suitable vehicle, packaged in a pressurized container with suitable inert gases.

(4) Bacitracin zinc-neomycin sulfate ointment containing, in each gram, 500 units of bacitracin and 3.5 milligrams of neomycin in a suitable ointment base.

(5) Bacitracin zinc-neomycin sulfate-polymyxin B sulfate ointment containing, in each gram, in a suitable ointment base the following:

(i) 400 units of bacitracin, 3 milligrams of neomycin, and 8,000 units of polymyxin B; or

(ii) 400 units of bacitracin, 3.5 milligrams of neomycin, and 5,000 units of polymyxin B; or

(iii) 500 units of bacitracin, 3.5 milligrams of neomycin, and 5,000 units of polymyxin B; or

(iv) 500 units of bacitracin, 3.5 milligrams of neomycin, and 10,000 units of polymyxin B;

(6) Bacitracin zinc-polymyxin B sulfate ointment containing, in each gram, 500 units of bacitracin and 10,000 units of polymyxin B in a suitable ointment base.

(7) Bacitracin zinc-polymyxin B sulfate topical aerosol containing, in each gram, 120 units of bacitracin and 2,350

units of polymyxin B in a suitable vehicle, packaged in a pressurized container with suitable inert gases.

(8) Bacitracin zinc-polymyxin B sulfate topical powder containing, in each gram, 500 units of bacitracin and 10,000 units of polymyxin B in a suitable base.

(9) Neomycin sulfate-polymyxin B sulfate ointment containing, in each gram, 3.5 milligrams of neomycin and 5,000 units of polymyxin B in a suitable water miscible base.

(10) Neomycin sulfate-polymyxin B sulfate cream containing, in each gram, 3.5 milligrams of neomycin and 10,000 units of polymyxin B in a suitable vehicle.

(11) Oxytetracycline hydrochloride-polymyxin B sulfate ointment containing, in each gram, 30 milligrams of oxytetracycline and 10,000 units of polymyxin B in a suitable ointment base.

(12) Oxytetracycline hydrochloride-polymyxin B sulfate topical powder containing, in each gram, 30 milligrams of oxytetracycline and 10,000 units of polymyxin B with a suitable filler.

(b) *Combinations of first aid antibiotic active ingredients and local anesthetic active ingredients.*

(1) Bacitracin ointment containing, in each gram, 500 units of bacitracin and any single generally recognized as safe and effective amine or "caine"-type local anesthetic active ingredient in a suitable ointment base.

(2) Bacitracin-neomycin sulfate-polymyxin B sulfate ointment containing, in each gram, in a suitable ointment base the following:

(i) 500 units of bacitracin, 3.5 milligrams of neomycin, 5,000 units of polymyxin B, and any single generally recognized as safe and effective amine or "caine"-type local anesthetic active ingredient; or

(ii) 400 units of bacitracin, 3.5 milligrams of neomycin, 5,000 units of polymyxin B, and any single generally recognized as safe and effective amine or "caine"-type local anesthetic active ingredient.

(3) Bacitracin-polymyxin B sulfate topical aerosol containing, in each gram, 500 units of bacitracin and 5,000 units of polymyxin B and any single

generally recognized as safe and effective amine or "caine"-type local anesthetic active ingredient in a suitable vehicle, packaged in a pressurized container with suitable inert gases.

(4) Bacitracin zinc-neomycin sulfate-polymyxin B sulfate ointment containing, in each gram, in a suitable ointment base the following:

(i) 400 units of bacitracin, 3 milligrams of neomycin, 8,000 units of polymyxin B, and any single generally recognized as safe and effective amine or "caine"-type local anesthetic active ingredient; or

(ii) 400 units of bacitracin, 3.5 milligrams of neomycin, 5,000 units of polymyxin B, and any single generally recognized as safe and effective amine or "caine"-type local anesthetic active ingredient; or

(iii) 500 units of bacitracin, 3.5 milligrams of neomycin, 5,000 units of polymyxin B, and any single generally recognized as safe and effective amine or "caine"-type local anesthetic active ingredient; or

(iv) 500 units of bacitracin, 3.5 milligrams of neomycin, 10,000 units of polymyxin B, and any single generally recognized as safe and effective amine or "caine"-type local anesthetic active ingredient;

(5) Bacitracin zinc-polymyxin B sulfate ointment containing, in each gram, 500 units of bacitracin, 10,000 units of polymyxin B, and any single generally recognized as safe and effective amine or "caine"-type local anesthetic active ingredient in a suitable ointment base.

(6) Neomycin sulfate-polymyxin B sulfate cream containing, in each gram, 3.5 milligrams of neomycin, 10,000 units of polymyxin B, and any single generally recognized as safe and effective amine or "caine"-type local anesthetic active ingredient in a suitable vehicle.

[52 FR 47322, Dec. 11, 1987; 52 FR 48792, Dec. 24, 1987, as amended at 53 FR 18838, May 25, 1988; 55 FR 9722, Mar. 15, 1990; 55 FR 40381, Oct. 3, 1990; 55 FR 50172, Dec. 5, 1990; 64 FR 403, Jan. 5, 1999]

§ 333.150 Labeling of first aid antibiotic drug products.

(a) *Statement of identity.* The labeling of the product contains the established

name of the drug, if any, and identifies the product as a "first aid antibiotic."

(b) *Indications.* The labeling of the product states, under the heading "Indications," the following: "First aid to help" [select one of the following: "prevent," ("decrease" ("the risk of" or "the chance of")), ("reduce" ("the risk of" or "the chance of")), "guard against," or "protect against"] [select one of the following: "infection," "bacterial contamination," or "skin infection"] "in minor cuts, scrapes, and burns." Other truthful and nonmisleading statements describing only the indications for use that have been established and listed in this paragraph (b), may also be used, as provided in § 330.1(c)(2), subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(c) *Warnings.* The labeling of the product contains the following warnings under the heading "Warnings":

(1) "For external use only. Do not use in the eyes or apply over large areas of the body. In case of deep or puncture wounds, animal bites, or serious burns, consult a doctor."

(2) *For products containing chlortetracycline hydrochloride or tetracycline hydrochloride.* "Stop use and consult a doctor if the condition persists or gets worse. Do not use longer than 1 week unless directed by doctor."

(3) *For any product containing bacitracin, bacitracin zinc, neomycin, neomycin sulfate, polymyxin B, and/or polymyxin B sulfate.* "Stop use and consult a doctor if the condition persists or gets worse, or if a rash or other allergic reaction develops. Do not use if you are allergic to any of the ingredients. Do not use longer than 1 week unless directed by a doctor."

(d) *Directions.* The labeling of the product contains the following statements under the heading "Directions":

(1) *For ointment and cream products.* "Clean the affected area. Apply a small amount of this product (an amount equal to the surface area of the tip of a finger) on the area 1 to 3 times daily.