§ 369.10 Conspicuousness of warning statements.

Necessary warning statements should appear in the labeling prominently and conspicuously as compared to other words, statements, designs, and devices, and in bold type on clearly contrasting background, in order to comply with the provisions of section 502(c) and (f)(2) of the act. The warning statements should be placed in the labeling in juxtaposition with the directions for use and, in any case, should appear on the label when there is sufficient label space in addition to mandatory label information.

Subpart B—Warning and Caution Statements for Drugs

§ 369.20 Drugs; recommended warning and caution statements.

ACETANILID.

Warning—Do not exceed recommended dosage. Overdosage or continued use may result in serious blood disturbances.

ACETOPHENETIDIN CONTAINING PREPARATIONS. (See § 201.309 of this chapter.)

Warning—This medication may damage the kidneys when used in large amounts or for a long period of time. Do not take more than the recommended dosage, nor take regularly for longer than 10 days without consulting your physician.

ANESTHETICS FOR EXTERNAL USE (LOCAL ANESTHETICS). (See also § 310.201(a)(19) and (23) of this chapter.)

Caution—Do not use in the eyes. Not for prolonged use. If the condition for which this preparation is used persists or if a rash or irritation develops, discontinue use and consult physician.

ANTIHISTAMINICS FOR EXTERNAL USE (EXCEPT PREPARATIONS FOR OPHTHALMIC USE).

Caution—Do not use in the eyes. If the condition for which this preparation is used persists or if a rash or irritation develops, discontinue use and consult physician.

ANTIHISTAMINICS, ORAL. (See also § 310.201(a)(4) and (a)(24) of this chapter.)

Caution—This preparation may cause drowsiness. Do not drive or operate machinery while taking this medication. Do not give to children under 6 years of age or exceed the recommended dosage unless directed by physician.

The reference to drowsiness is not required on preparations for the promotion of sleep or on preparations that are shown not to produce drowsiness.

ANTIPYRINE.

Warning—Do not exceed recommended dosage. If skin rash appears, discontinue use and consult physician.

ANTISEPTICS FOR EXTERNAL USE.

Caution—In case of deep or puncture wounds or serious burns, consult physician. If redness, irritation, swelling, or pain persists or increases or if infection occurs discontinue use and consult physician.

The reference to wounds and burns is not required on preparations intended solely for diaper rash.

ARSENIC PREPARATIONS.

Warning—Frequent or prolonged use may cause serious injury. Do not exceed recommended dosage. Keep out of the reach of children.

BELLADONNA PREPARATIONS AND PREPARATIONS OF ITS ALKALOIDS (ATROPINE, HYOSCYAMINE, AND SCOPOLAMINE (HYOSCINE); HYOSCYAMUS, STRamonium. THEIR DERIVATIVES, AND RELATED DRUG PREPARATIONS.

Warning—Not to be used by persons having glaucoma or excessive pressure within the eye, by elderly persons (where undiagnosed glaucoma or excessive pressure within the eye occurs most frequently), or by children under 6 years of age, unless directed by a physician. Discontinue use if blurring of vision, rapid pulse, or dizziness occurs. Do not exceed recommended dosage. Not for frequent or prolonged use. If dryness of the mouth occurs, decrease dosage. If eye pain occurs, discontinue use and see your physician immediately as this may indicate undiagnosed glaucoma.
In the case of scopolamine or scopolamine aminoxide preparations indicated for insomnia, the portion of the above warning that reads "children under 6 years of age" should read instead "children under 12 years of age".

BORIC ACID (POWDERED, CRYSTALLINE, OR GRANULAR).

Warning—Do not use as a dusting powder, especially on infants, or take internally. Use only as a solution. Do not apply to badly broken or raw skin, or to large areas of the body.

BROMIDES.

Caution—Use only as directed. Do not give to children or use in the presence of kidney disease. If skin rash appears or if nervous symptoms persist, recur frequently, or are unusual, discontinue use and consult physician.

CARBOLIC ACID (PHENOL) PREPARATIONS (MORE THAN 0.5 PERCENT) FOR EXTERNAL USE.

Warning—Use according to directions. Do not apply to large areas of the body. If applied to fingers or toes, do not bandage.

CATHARTICS AND LAXATIVES—IRRITANTS AND OTHER PERISTALTIC STIMULANTS.

Warning—Do not use when abdominal pain, nausea, or vomiting are present. Frequent or prolonged use of this preparation may result in dependence on laxatives.

Mercury preparations should have added to the "frequent use" statement, the words "and serious mercury poisoning".

Phenolphthalein preparations should bear, in addition to the general warning, the following statement:

Caution—If skin rash appears, do not use this or any other preparation containing phenolphthalein.

See also Mineral Oil Laxatives.

CHLORATES: MOUTH WASH OR GARGLE.

Avoid swallowing.

COBALT PREPARATIONS (See also §250.106 of this chapter.)

Warning—Do not exceed the recommended dosage. Do not administer to children under 12 years of age unless directed by physician. Do not use for more than 2 months unless directed by physician.

This warning is not required on articles containing not more than 0.5 milligram of cobalt as a cobalt salt per dosage unit and which recommend administration of not more than 0.5 milligram per dose and not more than 2 milligrams per 24-hour period.

"COUGH-DUE-TO-COLD" PREPARATIONS. (See also §310.201(a)(20) of this chapter.)

Warning—Persons with a high fever or persistent cough should not use this preparation unless directed by physician.

COUNTERIRRITANTS AND RUBEFACIENTS.

Caution—Do not apply to irritated skin or if excessive irritation develops. Avoid getting into the eyes or on mucous membranes.

If offered for use in arthritis or rheumatism, in juxtaposition therewith, the statement:

Caution—If pain persists for more than 10 days, or redness is present, or in conditions affecting children under 12 years of age consult a physician immediately.

See also "Salicylates" in this section for additional warnings for preparations containing methyl salicylate.

CREOSOTE, CRESOLS, GUAIACOL, AND SIMILAR SUBSTANCES IN PREPARATIONS FOR EXTERNAL USE.

Warning—The use of solutions stronger than those recommended may result in severe local irritation, burns, or serious poisoning. Mix as directed before pouring into douche bag. Do not use more often than twice weekly unless directed by physician.

CREOSOTE, CRESOLS, GUAIACOL, AND SIMILAR SUBSTANCES IN DOUCHE PREPARATIONS.

Warning—The use of solutions stronger than those recommended may result in severe local irritation, burns, or serious poisoning. Mix as directed before pouring into douche bag. Do not use more often than twice weekly unless directed by physician.

DENTURE RELINERS, PADS, AND CUSHIONS.

Warning—for temporary use only. Long-term use of this product may lead to faster bone loss, continuing irritation, sores, and tumors. For use only until a dentist can be seen.
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DENTURE REPAIR KITS.

Warning—For emergency repairs only.
Long-term use of home-repaired den-
tures may cause faster bone loss, con-
tinuing irritation, sores, and tumors.
This kit for emergency use only. See
Dentist Without Delay.

DOUCHE PREPARATIONS.

Warning—Do not use more often than
twice weekly unless directed by physi-
cian.
See also Creosote * * * Douche for
additional warnings.

DRESSINGS, PROTECTIVE SPRAY-
ON TYPE. (See also § 310.201(a) (11) and
(18) of this chapter.)

Warning—In case of deep or puncture
wounds or serious burns consult physi-
cian. If redness, irritation, swelling or
pain persists or increases or if infection
occurs consult physician. Keep away
from eyes or other mucous membranes.
Avoid inhaling.
See also Dispensers Pressurized by
Gaseous Propellants * * * for addi-
tional warnings to be included for prod-
ucts under pressure.

IODINE AND IODIDES (ORAL).

Caution—If a skin rash appears, dis-
continue use and consult physician.

MERCURY PREPARATIONS FOR EX-
TERNAL USE.

Warning—Discontinue use if rash or
irritation develops or if condition for
which used persists. Frequent or pro-
longed use, or application to large
areas may cause serious mercury poi-
sioning.

MINERAL OIL LAXATIVES. (See also
§ 201.302 of this chapter.)

Caution—Take only at bedtime.
Avoid prolonged use. Do not administer
to infants or young children, in preg-
nancy, or to bedridden or aged patients
unless directed by physician.

NASAL PREPARATIONS: VASO-
CONSTRICTORS (PHENYL-
PROPANOLAMINE).

Caution—Do not exceed recommended
dosage.

NUX VOMICA AND STRYCHNINE
PREPARATIONS.

“Do not use more than the rec-
ommended dosage. Keep out of reach of
children. In case of overdose, get med-
cal help or contact a Poison Control
Center right away.”

OPHTHALMIC PREPARATIONS. (See
also § 200.50 of this chapter.)

Boric acid offered for use in the prep-
aration of ophthalmic solutions should
bear the statement: Prepare solution
by boiling in water. Store in a sterile
container. Prepare sufficient for one
day’s use and discard unused portion.

PHENACETIN-CONTAINING PREPA-
RATION. (See acetophenetidin.)

PHENYLPROPANOLAMINE HY-
DROCHLORIDE PREPARATIONS,
ORAL.

Caution—Individuals with high blood
pressure, heart disease, diabetes, or
thyroid disease should use only as di-
rected by physician.

POTASSIUM PERMANGANATE
AQUEOUS SOLUTIONS (CONTAINING
NOT MORE THAN 0.04 PERCENT PO-
TASSIUM PERMANGANATE). (See
§ 250.108 of this chapter.)

Warning—for external use on the
skin only. Severe injury may result
from use internally or as a douche.
Avoid contact with mucous mem-
branes.

QUININE AND OTHER CINCHONA DE-
RIVATIVES (EXCEPT FOR USE IN
MALARIA).

Caution—Discontinue use if ringing
in the ears, deafness, skin rash, or vis-
ual disturbances occur.

RESINS, OLEORESINS, AND VOLA-
TILE OILS.

Caution—If nausea, vomiting, abdom-
nal discomfort, diarrhea, or skin rash
occurs, discontinue use and consult
physician.

RESORCINOL (NOT THE
MONOACETATE) HAIR PREPARA-
TIONS.

Caution—Excessive use of this prepa-
ration may temporarily discolor blond,
white, or red hair.

SALICYLATES, INCLUDING ASPIRIN
AND SALICYLAMIDE (EXCEPT
METHYL SALICYLATE, EFFER-
VESCENT SALICYLATE PREPARA-
TIONS, AND PREPARATIONS OF
AMINOSALICYLIC ACID AND ITS
Food and Drug Administration, HHS § 369.21

SALTS). (See also §201.314 of this chapter.)

"Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away," or "Keep out of children."

If the article is an aspirin preparation, it should bear the first of the above two warning statements. In either case, the above information should appear on the label.

Caution—For children under 3 years of age, consult your physician; or

Caution—For younger children, consult your physician.

One of the two immediately preceding caution statements is required on the label of all aspirin tablets, but such a statement is not required on the labels of other salicylates clearly offered for administration to adults only.

If offered for use in arthritis or rheumatism, in juxtaposition therewith, the statement:

Caution—If pain persists for more than 10 days, or redness is present, or in conditions affecting children under 12 years of age, consult a physician immediately.

SALICYLATES: METHYL SALICYLATE (WINTERGREEN OIL). (See also §§ 201.303 and 201.314 of this chapter.)

"Do not use otherwise than as directed. Keep out of reach of children to avoid accidental poisoning. If swallowed, get medical help or contact a Poison Control Center right away."

If the preparation is a counter-irritant or rubefacient the statement:

Caution—Discontinue use if excessive irritation of the skin develops. Avoid getting into the eyes or on mucous membranes.

If offered for use in arthritis or rheumatism, in juxtaposition therewith, the statement:

Caution—If pain persists for more than 10 days, or redness is present, or in conditions affecting children under 12 years of age consult a physician immediately.

SODIUM PERBORATE MOUTHWASH AND GARGLE AND TOOTHPASTE.

Caution—Discontinue use if irritation or inflammation develops, or increases. Avoid swallowing.

SULFONAMIDE NOSE DROPS.

Caution—Do not use if a known allergy to sulfonamide drugs exists.

SULFUR PREPARATION FOR EXTERNAL USE.

Caution—If undue skin irritation develops or increases, discontinue use and consult physician.

THROAT PREPARATIONS FOR TEMPORARY RELIEF OF MINOR SORE THROAT: LOZENGES, TROCHES, WASHES, GARGLES, ETC. (See also §201.315 of this chapter.)

Warning—Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult physician promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by physician.

TOOTHCARE PREPARATIONS.

For temporary use only until a dentist can be consulted.

ZINC STEARATE DUSTING POWDERS.

"Keep out of reach of children: avoid inhaling. If swallowed, get medical help or contact a Poison Control Center right away."

§ 369.21 Drugs; warning and caution statements required by regulations.

ACETAMINOPHEN (N-ACETYL-p-AMINOPHENOL) (See §310.201(a)(1) of this chapter.)

Warning—Do not give to children under 3 years of age or use for more than 10 days unless directed by a physician.