

or serious burns. Do not use in case of rectal bleeding, as this may indicate serious disease.

HEXADENOL. (See § 310.201(a)(11) of this chapter.)

*Caution*—Do not use for treatment of serious burns or skin conditions or for conditions which persist for prolonged periods. In such cases, consult your physician. Do not spray in vicinity of eyes, mouth, nose, or ears. Do not store above 120 °F.

IPECAC SYRUP IN ONE-FLUID OUNCE CONTAINERS FOR EMERGENCY TREATMENT OF POISONING, TO INDUCE VOMITING. (See § 201.308 of this chapter.)

Ipecac syrup packaged for over-the-counter sale must bear statements to the following effect, in a prominent and conspicuous manner:

The following statement (boxed and in red letters):

“For emergency use to cause vomiting in poisoning. Before using, call physician, the Poison Control Center, or hospital emergency room immediately for advice.”

The following warning: *Warning*—Keep out of reach of children. Do not use in unconscious persons. Ordinarily, this drug should not be used if strychnine, corrosives such as alkalis (lye) and strong acids, or petroleum distillates such as kerosene, gasoline, coal oil, fuel oil, paint thinner, or cleaning fluid have been ingested.

ISOAMYLHYDROCUPREINE AND ZOLAMINE HYDROCHLORIDE RECTAL PREPARATIONS FOR EXTERNAL USE (See § 310.201(a)(3) of this chapter.)

*Warning*—Do not use this preparation in case of rectal bleeding, as this may indicate serious disease.

NEOMYCIN SULFATE WITH A VASOCONSTRICTOR, IN NASAL PREPARATIONS (SPRAY OR DROPS).

*Caution*—Do not exceed recommended dosage. Do not administer to children under 3 years of age unless directed by physician.

PRAMOXINE HYDROCHLORIDE FOR EXTERNAL USE. (See § 310.201(a)(19) of this chapter.)

*Caution*—Do not use in the eyes or nose. Not for prolonged use. Do not

apply to large areas of the body. If redness, irritation, swelling, or pain persists or increases, discontinue use unless directed by a physician.

SODIUM GENTISATE. (See §§ 201.314 and 310.301(a)(2) of this chapter.)

*Warning*—Do not use in children under 6 years of age or use for prolonged period unless directed by physician.

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

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.

TUAMINOHEPTANE SULFATE NASAL PREPARATIONS. (See § 310.201(a)(16) of this chapter.)

*Caution*—Do not exceed recommended dosage. Overdosage may cause nervousness, restlessness, or sleeplessness. Individuals with high blood pressure, heart disease, diabetes, or thyroid disease should use only as directed by physician. Do not use for more than 3 or 4 consecutive days unless directed by physician.

VIBESATE PREPARATIONS. (See § 310.201(a)(18) of this chapter.)

*Caution*—Do not use but consult physician for deep or puncture wounds or serious burns. If redness, irritation, swelling, or pain persists or increases, discontinue use and consult physician.

*Warning*—Contents under pressure. Do not puncture. Do not use or store near heat or open flame. Exposure to temperatures above 130 °Fahrenheit may cause bursting. Never throw container into fire or incinerator.

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EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 369.21, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at [www.fdsys.gov](http://www.fdsys.gov).

**PARTS 370–499 [RESERVED]**