

§ 369.22

21 CFR Ch. I (4-1-99 Edition)

SODIUM GENTISATE. (See §§201.314, 310.201(a)(2) of this chapter.)

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

Warning—Keep this and all medications out of the reach of children; or

Warning—Keep out of the reach of children. 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.

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§369.22 Drugs; warning and caution statements specifically required by law.

PREPARATIONS CONTAINING HABIT-FORMING DERIVATIVES OF

SUBSTANCES NAMED IN SECTION 502(d) OF THE ACT. (See §§329.1, 329.10, and 329.20 of this chapter.)

The statement “*Warning*—May be habit forming” is required to appear on the labels of all drugs containing derivatives designated in §329.1 of this chapter as habit forming, including exempt narcotic preparations described in §329.20(a) of this chapter and preparations containing one or more derivatives of barbituric acid, unless such drug is not suitable for internal use and is distributed and sold exclusively for such external use as involves no possibility of habit formation.

PARTS 370-499 [Reserved]