Document Warnings Before Firing Bad Employees

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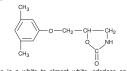
MIAMI — A "progressive discipline" system of warnings and suggestions for improvement before firing an underperforming employee maximizes chances of winning a wrongful termination lawsuit, according to a labor and employee attorney.

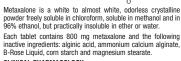
In addition, perform regular and honest performance evaluations and keep all employee documents under lock and key.

SKELAXIN® (Metaxalone) Tablets

DESCRIPTION

SKELAXIN® (metaxalone) is available as an 800 mg oval, scored pink tablet. emically, meta xalone is 5-[(3,5- dimethylphenoxy) methyl]-The empirical formula is C12H16NO2, which zolidinone. The empirical formula is $C_{12}H_{15}NU_3$, which sponds to a molecular weight of 221.25. The structural formula is:





B-Hose Liquic, corn starch and magnesium stearate. **CLINICAL PHARMACOLOGY Mechanism of Action:** The mechanism of action of metax-alone in humans has not been established, but may be due to general central nervous system depression. Metaxalone has no direct action on the contractile mechanism of striated muscle, the motor end plate or the nerve fiber.

Pharmacokinetics:

The pharmacokinetics: The pharmacokinetics of metaxalone have been evaluated in healthy adult volunteers after single dose administration of SKELAXIN under fasted and fed conditions at doses ranging from 400 mg to 800 mg.

Absorption

Peak plasma concentrations of metaxalone occur approximate Peak plasma concentrations of metaatome occur approximate-ly 3 hours after a 400 mg oral dose under fasted conditions. Thereafter, metaxalone concentrations decline log-linearly with a terminal half-life of 9.0 \pm 4.8 hours. Doubling the dose of SKELAXIN from 400 mg to 800 mg results in a roughly propor-tional increase in metaxalone exposure as indicated by peak plasma concentrations (C_{max}) and area under the curve (AUC). Dose proportionality at doses above 800 mg has not been stud-ied. The absolute bioavailability of metaxalone is not known.

The single-dose pharmacokinetic parameters of metaxalone in two groups of healthy volunteers are shown in Table 1. Table 1: Mean (%CV) Metavalone Pharmacokinetic Parameters

| Dose (mg) | | T _{max} (h) | AUC∞ | t _{1/2} (h) | CL/F |
|-----------------------------------|------------|----------------------|-------------|----------------------|----------|
| | (ng/mL) | | (ng·h/mL) | | (L/h) |
| 400 ¹ | 983 (53) | 3.3 (35) | 7479 (51) | 9.0 (53) | 68 (50) |
| 800 ² | 1816 (43) | 3.0 (39) | 15044 (46) | 8.0 (58) | 66 (51) |
| ¹ Subjects r (N=42) | eceived 1x | 400 mg 1 | ablet under | fasted co | nditions |

 $^2\mbox{Subjects}$ received 2x400 mg tablets under fasted conditions (N=59)

Food Effects

Food Effects A randomized, two-way, crossover study was conducted in 42 healthy volunteers (31 males, 11 females) administered one 400 mg SKELAXIN tablet under fasted conditions and following a standard high-fat breakfast. Subjects ranged in age from 18 to 48 years (mean age $= 23.5 \pm 5.7$ years). Compared to fast-ed conditions, the presence of a high fat meal at the time of drug administration increased C_{max} by 177.5% and increased AUC (AUC₀₋₃, AUC₂₋₃) by 123.5% and 115.4%, respectively, Time-to-peak concentration (T_{max}) was also delayed (4.3 h ver-sus 3.3 h) and terminal half-life was decreased (2.4 h versus 9.0 h) under fed conditions compared to fasted.

Sus 3.3.1 minute terminian nain-tine was becreased (2.4.1) Versus 9.0.5 minute fed conditions compared to fasted. In a second food effect study of similar design, two 400 mg SKELAXIN tablets (800 mg) were administered to healthy volunteers (N=59, 37 males, 22 females), ranging in age from 18-50 years (mean age = 25.6 ± 8.7 years). Compared to fasted conditions, the presence of a high fat meal at the time of drug administration increased C_{max} by 139.6% and increased AUC (AUC_{Q-1}, AUC₂₋₁) y 146.4% and 142.2%, respectively. Time-to-peak concentration (T_{max}) was also delayed (4.9 h versus 3.0 h) and terminah half-life was decreased (4.2 h versus 8.0 h) under fed conditions compared to fasted conditions. Similar food effect results were observed in the above study when one SKE-LAXIN 800 mg tablet. The increase in metaxalone exposure coinciding with a reduction in half-life may be attributed to more complete absorption of metaxalone in the presence of a high fat meal (Figure 1).

"I suggest to my clients that they do not fire someone until there is enough of a paper trail," said Chad K. Lang, a labor and employee attorney practicing in Miami.

"Progressive discipline ... is about fairness. The No. 1 reason employees file lawsuits is they believe they were not treated fairly, regardless of how many warnings you gave them. They truly believe they are right," Mr. Lang said. There is no legal requirement for progressive discipline, but it will look "very fair to a

jury." It will be perceived as, "We gave them benefit of the doubt, they chose not to listen, and we had to let them go." Avoid oral warnings about perfor-

mance, Mr. Lang said. But if an initial warning is spoken, document it in writing afterward. E-mail is acceptable. For example, send an e-mail stating, "Thank you for meeting with me today. This is what we discussed.'

Subsequent warnings are more formal and always should be in writing, Mr. Lang

PRECAUTIONS

Metaxalone should be administered with great care to patients with pre-existing liver damage. Serial liver function studies should be performed in these patients. False-positive Benedict's tests, due to an unknown reducing substance, have been noted. A glucose-specific test will differ-

Taking SKELAXIN with food may enhance general CNS depres sion; elderly patients may be especially susceptible to this CNS effect. (see CLINICAL PHARMACOLOGY: Pharmacokinetics and PRECAUTIONS: Information for Patients section).

PRECAUTIONS: Information for Patients section). Information for Patients SKELAXIN may impair mental and/or physical abilities required for performance of hazardous tasks, such as oper-ating machinery or driving a motor vehicle, especially when used with alcohol or other CNS depressants. Drug Interactions

SKELAXIN may enhance the effects of alcohol, barbiturates and other CNS depressants. other CNS depressants. *Carcinogenesis, Mutagenesis, Impairment of Fertility* The carcinogenic potential of metaxalone has not been determined

Pregnancy

Pregnancy Reproduction studies in rats have not revealed evidence of impaired fertility or harm to the fetus due to metaxalone. Post marketing experience has not revealed evidence of fetal injury, but such experience cannot exclude the possibility of infrequent or subtle damage to the human fetus. Safe use of metaxalone has not been established with regard to possible adverse effects upon fetal development. Therefore, metaxalone tablets should not be used in women who are or may become pregnant and particular-ted during early pregnancy unders in the undersent of the ly during early pregnancy unless in the judgement of physician the potential benefits outweigh the possible haza nt of the Nursing Mothers

It is not known whether this drug is secreted in human milk. As a general rule, nursing should not be undertaken while a patient is on a drug since many drugs are excreted in human milk. on a drug since many drugs are excreted in norman man. **Pediatric Use** Safety and effectiveness in children 12 years of age and below have not been established.

ADVERSE REACTIONS

The most frequent reactions to metaxalone include: CNS: drowsiness, dizziness, headache, and nervousness or "irritability";

Digestive: nausea, vomiting, gastrointestinal upset. Other adverse reactions are: Immune System: hypersensitivity reaction, rash with or without

pruritus Hematologic: leukopenia; hemolytic anemia;

Hepatobiliary: jaundice. Though rare, anaphylactoid reactions have been reported with metaxalone.

OVERDOSAGE Deaths by deliberate or accidental overdose have occurred with metaxalone, particularly in combination with antidepressants. netaxalone, particularly in combination with antidepressants, and have been reported with this class of drug in combination

with alcohol. When determining the LD_{sp} in rats and mice, progressive sedation, hypnosis and finally respiratory failure were noted as the dosage increased. In dogs, no LD_{sp} could be determined as the higher doses produced an emetic action in 15 to 30 minutes. Treatment - Gastric lavage and supportive therapy. Consultation with a regional poison control center is recommended.

DOSAGE AND ADMINISTRATION The recommended dose for adults and children over 12 years of age is one 800 mg tablet three to four times a day.

HOW SUPPLIED SKELAXIN (metaxalone) is available as an 800 mg oval, scored pink tablet inscribed with 8667 on the scored side and "S" on the other.Available in bottles of 100 (NDC 60793-136-01) and in bottles of 500 (NDC 60793-136-05).

Store at Controlled Room Temperature, between 15°C and 30°C (59°F and 86°F). **Rx Only**

Prescribing Information as of April 2007.

SKE5180



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said at a pediatric update sponsored by Miami Children's Hospital.

Have a witness in the room when presenting an employee with a written performance warning, Mr. Lang suggested. "A lot of people do these in a closed-door situation." The presence of a manager or supervisor is recommended, preferably one of the same gender as the employee in question to avoid allegations of sexual harassment before termination.

Link the written warning to prior oral discussions and require the employee to sign and date it. "A lot of times, people remember the signature but forget to date it," Mr. Lang said. "They might countersue and say they signed it at a different time." If an employee refuses to sign the written warning, note this, sign and date it, and have the witness do the same. "The witness does not need to say a word. They are observers, so if it comes down to it, it does not become a 'he said, she said' situation."

Employees also should sign an employee handbook acknowledgment form, Mr. Lang said. "An employee will most likely lie and say [he or she] never received it."

A written company policy should state that these progressive steps are a guideline, and in some instances there will be immediate termination, Mr. Lang said. The employee handbook should include an "at-will" employee policy. This implies there is no contract for you to keep them.

Honest, written performance evaluations for all employees are another protection against a future lawsuit, Mr. Lang said. "A lukewarm evaluation will not help if you fire them for doing a poor job. If you are going to take the time to do these, tell the truth and be accurate."

Many employers tie evaluation scores to salary and bonus pay. It will look inconsistent to a judge or jury, however, if an underperformer gets the same raise as another employee doing well. "If it goes to disposition, they will ask why you gave an underperformer a raise in the first place, and then why was it equal to someone you did not fire," Mr. Lang said.

Praise and criticism are not mutually exclusive. Recognize tasks they are doing well in their performance evaluations, Mr. Lang said. Use objective criteria and standards when possible, and include an improvement plan for underperformers. It can state, for example, that within 30 days or 60 days they have 'X' and 'Y' to do. "Improvement plans are good and they are objective."

In addition, "I highly recommend you keep the documents under lock and key," Mr. Lang said. Often, employees know when their firing is coming, and a day or two beforehand their personnel files miraculously disappear.

A final piece of advice is to have a specific document retention strategy in your office policies, Mr. Lang said. "This is where lawsuits are won and lost nowadays." It is advantageous, for example, to state that all e-mail messages are automatically deleted after 6 months or 1 year. Otherwise, a judge can deem failure to preserve electronic records "willful spoliation," and the jury will be instructed to presume that the records were harmful to the defendant's case.



sm, and Excretion

Distribution, metabolism, and excretion Although plasma protein binding and absolute bioavailability of metaxalone are not known, the apparent volume of distribution ($VIF \sim 800 \text{ L}$) and lipophilicity (log P = 2.42) of metaxalone sug-gest that the drug is extensively distributed in the tissues. Metaxalone is metabolized by the liver and excreted in the urine as unidentified metabolites.

Pharmacokinetics in Special Populations

Pharmacokinetics in Special Populations Age: The effects of age on the pharmacokinetics of metaxalone were determined following single administration of two 400 mg tablets (800 mg) under fasted and fed conditions. The results were analyzed separately, as well as in combination with the results indicate that the pharmacokinetics of metaxalone are significantly more affected by age under fasted conditions than under fed conditions, with bioavailability under fasted condi-tions increasing with age.

The bioavailability of metaxalone under fasted and fed condi-tions in three groups of healthy volunteers of varying age is

Table 2: Mean (%CV) Pharmacokinetics Parameters lowing Single Administration of Two 400 mg SKELAXIN Tablets (800 mg) under Fasted and Fed Conditions

| Younger Volunteers | | | Older Volunteers | | | |
|-----------------------------|--------------|--------------|------------------|--------------|--------------|--------------|
| Age (years) | 25.6 ± 8.7 | | 39.3 ± 10.8 | | 71.5 ± 5.0 | |
| N | 59 | 9 | 21 | | 23 | |
| Food | Fasted | Fed | Fasted | Fed | Fasted | Fed |
| C _{max} (ng/mL) | 1816 (43) | 3510 (41) | 2719 (46) | 2915 (55) | 3168 (43) | 3680 (59) |

| T _{max} (h) | 3.0 | 4.9 | 3.0 | 8.7 | 2.6 | 6.5 |
|----------------------|-------|-------|-------|-------|-------|-------|
| | (39) | (48) | (40) | (91) | (30) | (67) |
| AUC _{0-t} | 14531 | 20683 | 19836 | 20482 | 23797 | 24340 |
| (ng·h/mL) | (47) | (41) | (40) | (37) | (45) | (48) |
| AUC | 15045 | 20833 | 20490 | 20815 | 24194 | 24704 |
| (ng·h/mL) | (46) | (41) | (39) | (37) | (44) | (47) |

Gender: The effect of gender on the pharmacokinetics of metaxalone was assessed in an open label study, in which 48 healthy adult volunteers (24 males, 24 females) were admin-istered two SKELAXIN 400 mg tablets (800 mg) under fasted conditions. The bioavailability of metaxalone was significantconditions. The bioavailability of metaxalone was significantly higher in fremales compared to males as evidenced by C_{max} (2115 ng/mL versus 1335 ng/mL) and AUC_∞ (17884 ng-h/mL versus 10328 ng-h/mL). The mean half-life was 11.1 hours in females and 7.6 hours in males. The apparent volume of distribution of metaxalone was approximately 22% higher in males than in females, but not significantly different when adjusted for body weight. Similar findings were also seen when the previously described combined dataset was used in the analysis the analysis.

Hepatic/Renal Insufficiency: The impact of hepatic and renal disease on the pharmacokinetics of metaxalone has not been determined. In the absence of such information, SKELAXIN should be used with caution in patients with hepatic and/or renal impairment

NDICATIONS AND USAGE

SKELAXIN (metaxalone) is indicated as an adjunct to rest, physical therapy, and other measures for the relief of discom-forts associated with acute, painful musculoskeletal conditions. The mode of action of this drug has not been clearly identified, but may be related to its sedative proper-ties. Metaxalone does not directly relax tense skeletal muscles in man. CONTRAINDICATIONS

Known hypersensitivity to any components of this product.

Known tendency to drug induced, hemolytic, or other anemias Significantly impaired renal or hepatic function. WARNINGS

SKELAXIN may enhance the effects of alcohol and other CNS

Distributed by: King Pharmaceuticals, Inc., Bristol, TN 37620 Manufactured by: Mallinckrodt Inc., Hobart, NY 13788