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CONSULTANTS TO THE PHARMACEUTICAL AND ALLIED INDUSTRIES

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0134 6 11-5 11:00

January 4, 2006

OVERNIGHT COURIER 1/4/06

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services, HFA-305
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

The undersigned, on behalf of a client, submits this petition in quadruplicate under Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act ("the FDC Act"), 21 U.S.C. § 355(j)(2)(C), and 21 C.F.R. §§ 10.20, 10.30, and 314.93 to request that the Commissioner of Food and Drugs make a determination that an Abbreviated New Drug Application (ANDA) may be submitted for Oxycodone Hydrochloride and Acetaminophen Oral Solution, 10 mg / 300 mg / 5 mL.

A. Action Requested

The petitioner requests that the Commissioner of Food and Drugs make a determination that an Oxycodone Hydrochloride and Acetaminophen Oral Solution, 10 mg / 300 mg / 5 mL, is suitable for submission as an ANDA. The reference-listed drug product upon which this petition is based is Roxicet[®] (Oxycodone Hydrochloride and Acetaminophen) Oral Solution, 5 mg / 325 mg / 5 mL, ANDA 89-351 held by Roxane.

B. Statement of Grounds

Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act provides for the submission of an ANDA for a new drug that differs in strength from a listed drug, provided that the FDA has approved a petition seeking permission to file such an application. This petition requests a change in the strength of the non-narcotic active ingredient, acetaminophen, from 325 mg / 5 mL to 300 mg / 5 mL and a change in the narcotic component, oxycodone hydrochloride, from 5 mg / 5 mL to 10 mg / 5 mL found in the RLD, Roxicet[®] Oral Solution (Roxane).

A copy of the listing of Roxicet[®] (oxycodone hydrochloride and acetaminophen) Oral Solution, 5 mg / 325 mg / 5 mL from the electronic Approved Drug Products with Therapeutic Equivalents Evaluation (commonly referred to as "The Orange Book") as accessed on January 4, 2006 is provided as Attachment A.

2006 P-0007

CPI

According to the approved labeling of the reference-listed drug product, Roxicet® (oxycodone hydrochloride and acetaminophen) Oral Solution, 5 mg / 325 mg / 5 mL, the usual adult dosage is:

“5 mL (one teaspoonful) every six hours as needed for pain.”

The labeling further states that:

“Dosage should be adjusted to severity of pain and response of the patient. It may occasionally be necessary to exceed the usual dosage recommendation in cases of more severe pain or in those patients who have become tolerant to the analgesic effects of narcotics.”

The proposed product will provide the prescribing physician the flexibility of providing a higher narcotic dose, while maintaining approximately the same acetaminophen dose for patients that are deemed to require a higher narcotic dose, but for whom the physician does not want to increase or limit the intake of acetaminophen.

It should be noted that there is an FDA-approved tablet product that contains 10 mg of oxycodone hydrochloride and 300 mg of acetaminophen in a single-dosage unit (see Attachment B). This further supports the fact that the change in strength proposed from that of the RLD does not raise any safety or efficacy questions, as the proposed strength represents the exact same doses that the FDA has already approved as safe and effective.

In summary, the proposed change in strength of the non-narcotic component from that of the reference-listed drug (i.e., a change of acetaminophen from 325 mg to 300 mg per 5 mL) and the narcotic component (i.e., oxycodone hydrochloride from 5 mg to 10 mg per 5 mL) will not raise questions of the safety or efficacy of the proposed product. The indications remain unchanged and the proposed dosing is consistent with that recommended in the labeling of the approved reference-listed drug product. The efficacy of a 300 mg dose of acetaminophen in combination with the same doses of the narcotic component, as well as other similar equipotent narcotic components is supported by other FDA-approved products containing that same proposed dose. Therefore, the Agency should conclude that clinical investigations are not necessary to demonstrate the proposed product's safety or effectiveness.

The proposed labeling for Oxycodone Hydrochloride and Acetaminophen Oral Solution, 10 mg / 300 mg / 5 mL is included as Attachment C. Labeling for the proposed product will be consistent with the approved labeling for the reference-listed drug, Roxicet® (oxycodone hydrochloride and acetaminophen) Oral Solution, 5 mg / 325 mg / 5 mL, upon which this petition is based and other approved oxycodone hydrochloride and acetaminophen combination drug products. A copy of the approved labeling of the RLD is included in Attachment D.

For the aforementioned reasons, the undersigned requests that the Commissioner approve this petition and find that an application for Oxycodone Hydrochloride and Acetaminophen Oral Solution, 10 mg / 300 mg / 5 mL is suitable for submission as an ANDA.

C. Environmental Impact

The petitioner claims a categorical exclusion under 21 CFR 25.31.

D. Economic Impact Statement

According to 21 C.F.R. § 10.30(b), petitioner will, upon request by the Commissioner, submit economic impact information.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.

Respectfully submitted,


pk

Robert W. Pollock
Senior Vice President
Lachman Consultant Services, Inc.
1600 Stewart Avenue
Westbury, NY 11590

RWP/pk

cc: Arianne Camphire (Office of generic Drugs)

Attachments:

- A. Copy of Electronic Orange Book page listing Roxicet® as the RLD, Accessed January 4, 2006
- B. Copy of Electronic Orange Book page listing approval of Oxycodone Hydrochloride and Acetaminophen Tablets, 10 mg/ 300 mg, accessed January 4, 2006
- C. Copy of the proposed draft insert labeling for Oxycodone Hydrochloride and Acetaminophen Oral Solution, 10 mg / 300 mg / 5 mL
- D. Copy of the Roxicet® RLD labeling

A43P6004

ATTACHMENT A

Search results from the "OB_Rx" table for query on "089351."

Active Ingredient: ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE
Dosage Form;Route: SOLUTION; ORAL
Proprietary Name: ROXICET
Applicant: ROXANE
Strength: 325MG/5ML;5MG/5ML
Application Number: 089351
Product Number: 001
Approval Date: Dec 3, 1986
Reference Listed Drug: Yes
RX/OTC/DISCN: RX
TE Code:
Patent and Exclusivity Info for this product: [View](#)

[Return to Electronic Orange Book Home Page](#)

FDA/Center for Drug Evaluation and Research

Office of Generic Drugs

Division of Labeling and Program Support

Update Frequency:

Orange Book Data - **Monthly**

Generic Drug Product Information & Patent Information - **Daily**

Orange Book Data Updated Through November, 2005

Patent and Generic Drug Product Data Last Updated: January 03, 2006

ATTACHMENT B

Search results from the "OB_Rx" table for query on "040608."

Active Ingredient: ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE
Dosage Form;Route: TABLET; ORAL
Proprietary Name: OXYCODONE AND ACETAMINOPHEN
Applicant: MIKART
Strength: 300MG;2.5MG
Application Number: 040608
Product Number: 001
Approval Date: Dec 30, 2005
Reference Listed Drug: Yes
RX/OTC/DISCN: RX
TE Code:
Patent and Exclusivity Info for this product: [View](#)

Active Ingredient: ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE
Dosage Form;Route: TABLET; ORAL
Proprietary Name: OXYCODONE AND ACETAMINOPHEN
Applicant: MIKART
Strength: 300MG;5MG
Application Number: 040608
Product Number: 002
Approval Date: Dec 30, 2005
Reference Listed Drug: Yes
RX/OTC/DISCN: RX
TE Code:
Patent and Exclusivity Info for this product: [View](#)

Active Ingredient: ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE
Dosage Form;Route: TABLET; ORAL
Proprietary Name: OXYCODONE AND ACETAMINOPHEN
Applicant: MIKART
Strength: 300MG;7.5MG
Application Number: 040608
Product Number: 003
Approval Date: Dec 30, 2005
Reference Listed Drug: Yes
RX/OTC/DISCN: RX
TE Code:
Patent and Exclusivity Info for this product: [View](#)

Active Ingredient: ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE
Dosage Form;Route: TABLET; ORAL
Proprietary Name: OXYCODONE AND ACETAMINOPHEN
Applicant: MIKART
Strength: 300MG;10MG
Application Number: 040608
Product Number: 004
Approval Date: Dec 30, 2005

Reference Listed Drug Yes

RX/OTC/DISCN: RX

TE Code:

Patent and Exclusivity Info for this product: [View](#)

[Return to Electronic Orange Book Home Page](#)

FDA/Center for Drug Evaluation and Research

Office of Generic Drugs

Division of Labeling and Program Support

Update Frequency:

Orange Book Data - **Monthly**

Generic Drug Product Information & Patent Information - **Daily**

Orange Book Data Updated Through November, 2005

Patent and Generic Drug Product Data Last Updated: January 03, 2006

ATTACHMENT C



Oxycodone and Acetaminophen

ORAL SOLUTION

R_x only.

DESCRIPTION

Each 5 mL contains:

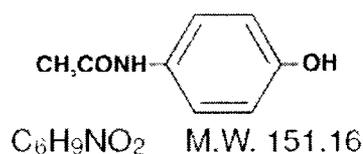
Oxycodone Hydrochloride 10 mg

(10 mg Oxycodone Hydrochloride is equivalent to 8.963 mg Oxycodone)

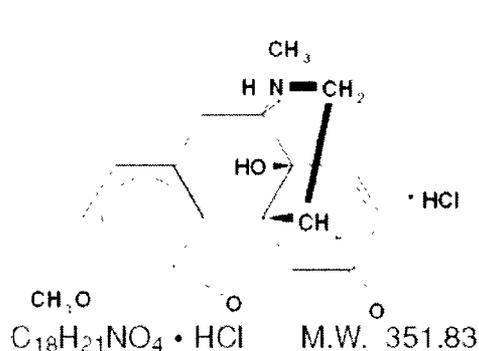
Acetaminophen 300 mg

Alcohol [TBD]%

Acetaminophen, 4'-hydroxyacetanilide, is a non-opiate, non-salicylate analgesic and antipyretic which occurs as a white, odorless, crystalline powder, possessing a slightly bitter taste. Its structure is as follows:



The oxycodone component is 14-hydroxydihydrocodeinone, a white, odorless crystalline powder which is derived from the opium alkaloid, thebaine, and may be represented by the following structural formula:



The solution, for oral administration, contains 10 mg oxycodone hydrochloride and 300 mg acetaminophen per 5 mL. In addition, the solution contains the following inactive ingredients: [to be determined].

CLINICAL PHARMACOLOGY

The principal ingredient, oxycodone, is a semi-synthetic narcotic with multiple actions qualitatively similar to those of morphine; the most prominent of these involve the central nervous system and organs composed of smooth muscle. The principal actions of therapeutic value of oxycodone are analgesia and sedation.

Oxycodone is similar to codeine and methadone in that it retains at least one-half of its analgesic activity when administered orally.

Acetaminophen is a non-opiate, non-salicylate analgesic and antipyretic.

INDICATIONS AND USAGE

For the relief of moderate to moderately severe pain.

CONTRAINDICATIONS

Hypersensitivity to oxycodone or acetaminophen.

WARNINGS

Drug Dependence: Oxycodone can produce drug dependence of the morphine type and, therefore, has the potential for being abused. Psychic dependence, physical dependence and tolerance may develop upon repeated administration of this drug, and it should be prescribed and administered with the same degree of caution appropriate to the use of other oral narcotic-containing medications. Like other narcotic-containing medications, this drug is subject to the Federal Controlled Substances Act (Schedule II).

PRECAUTIONS

1. General:

Head Injury and Increased Intracranial Pressure: The respiratory depressant effects of narcotics and their capacity to elevate cerebrospinal fluid pressure may be markedly exaggerated in the presence of head injury, other intracranial lesions or a pre-existing increase in intracranial pressure. Furthermore, narcotics produce adverse reactions which may obscure the clinical course of patients with head injuries.

Acute Abdominal Conditions: The administration of products containing oxycodone or other narcotics may obscure the diagnosis or clinical course in patients with acute abdominal conditions.

Special Risk Patients: Oxycodone and Acetaminophen should be given with caution to certain patients such as the elderly or debilitated, and those with severe impairment of hepatic or renal function, hypothyroidism, Addison's disease, and prostatic hypertrophy or urethral stricture.

2. Information for Patients: Oxycodone may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery. The patient taking this drug should be cautioned accordingly.

3. Drug Interactions: Patients receiving other narcotic analgesics, general anesthetics, phenothiazines, other tranquilizers, sedative-hypnotics, or other CNS depressants (including alcohol) concomitantly with oxycodone and acetaminophen may exhibit additive CNS depression. When such therapy is contemplated, the dose of one or both agents should be reduced.

The concurrent use of anticholinergics with narcotics may produce paralytic ileus.

4. Pregnancy:

Teratogenic Effects: Pregnancy Category C. Animal reproductive studies have not been conducted with oxycodone and acetaminophen. It is also not known whether oxycodone and acetaminophen can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Oxycodone and acetaminophen should not be given to a pregnant woman, unless in the judgment of the physician, the potential benefits outweigh the possible hazards.

Nonteratogenic Effects: Use of narcotics during pregnancy may produce physical dependence in the neonate.

Labor and Delivery: As with all narcotics, administration of oxycodone and acetaminophen to the mother shortly before delivery may result in some degree of respiratory depression in the newborn and the mother, especially if higher doses are used.

5. Nursing Mothers: It is not known whether the components of this drug are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when oxycodone and acetaminophen is administered to a nursing mother.

6. Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

The most frequently observed adverse reactions include lightheadedness, dizziness, sedation, nausea and vomiting. These effects seem to be more prominent in ambulatory than in non-ambulatory patients, and some of these adverse reactions may be alleviated if the patient lies down.

Other adverse reactions include euphoria, dysphoria, constipation, skin rash, and pruritus. At higher doses, oxycodone has most of the disadvantages of morphine including respiratory depression.

DRUG ABUSE AND DEPENDENCE

Oxycodone and Acetaminophen oral solution is a Schedule II controlled substance.

Oxycodone can produce drug dependence and has the potential for being abused. (See **WARNINGS**.)

OVERDOSAGE

Acetaminophen:

Signs and Symptoms: In acute acetaminophen overdose, dose-dependent, potentially fatal hepatic necrosis is the most serious adverse effect. Renal tubular necrosis, hypoglycemic coma and thrombocytopenia may also occur.

In adults, hepatic toxicity has rarely been reported with acute overdoses of less than 10 grams and fatalities with less than 15 grams. Importantly, young children seem to be more resistant than adults to the hepatotoxic effect of an acetaminophen overdose. Despite this, the measures outlined below should be initiated in any adult or child suspected of having ingested an acetaminophen overdose.

Early symptoms following a potentially hepatotoxic overdose may include: nausea, vomiting, diaphoresis and general malaise. Clinical and laboratory evidence of hepatic toxicity may not be apparent until 48 to 72 hours post-ingestion.

Treatment: The stomach should be emptied promptly by lavage or by induction of emesis with syrup of ipecac. Patients' estimates of the quantity of a drug ingested are notoriously unreliable. Therefore, if an acetaminophen overdose is suspected, a serum acetaminophen assay should be obtained as early as possible, but no sooner than four hours following ingestion. Liver function studies should be obtained initially and repeated at 24-hour intervals.

The antidote, N-acetylcysteine, should be administered as early as possible, preferably within 16 hours of the overdose ingestion for optimal results, but in any case, within 24 hours. Following recovery, there are no residual, structural or functional hepatic abnormalities.

Oxycodone:

Signs and Symptoms: Serious overdose with oxycodone is characterized by respiratory depression (a decrease in respiratory rate and/or tidal volume, Cheyne-Stokes respiration, cyanosis), extreme somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, and sometimes bradycardia and hypotension. In severe overdose, apnea, circulatory collapse, cardiac arrest and death may occur.

Treatment: Primary attention should be given to the reestablishment of adequate respiratory exchange through provision of a patent airway and the institution of assisted or controlled ventilation. The narcotic antagonist naloxone is a specific antidote against respiratory depression which may result from overdose or unusual sensitivity to narcotics, including oxycodone. Therefore, an appropriate

dose of naloxone hydrochloride (usual initial adult dose 0.4 mg to 2 mg) should be administered, preferably by the intravenous route, and simultaneously with efforts at respiratory resuscitation (see package insert). Since the duration of action of oxycodone may exceed that of the antagonist, the patient should be kept under continued surveillance and repeated doses of the antagonist should be administered as needed to maintain adequate respiration.

An antagonist should not be administered in the absence of clinically significant respiratory or cardiovascular depression. Oxygen, intravenous fluids, vasopressors and other supportive measures should be employed as indicated.

Gastric emptying may be useful in removing unabsorbed drug.

DOSAGE AND ADMINISTRATION

Dosage should be adjusted according to severity of pain and response of the patient. It may occasionally be necessary to exceed the usual dosage recommended below in cases of more severe pain or in those patients who have become tolerant to the analgesic effect of narcotics.

Oral Solution:

The usual adult dose is 5 mL (one teaspoonful) every six hours as needed for pain.

HOW SUPPLIED

**Oxycodone and Acetaminophen Oral Solution
(Oxycodone Hydrochloride 10 mg and Acetaminophen 300 mg
Oral Solution per 5 mL)**

[TBD]

Store at Controlled Room Temperature
15°-30°C (59°-86°F).

DEA Order Form Required.

ATTACHMENT D

ROXANE LABORATORIES, INC.

ROXICET™
Oxycodone and
Acetaminophen 
ORAL SOLUTION

R_x only.

DESCRIPTION

Each 5 mL contains:

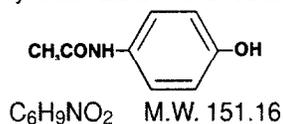
Oxycodone Hydrochloride 5 mg⁺

(*5 mg Oxycodone Hydrochloride is equivalent to 4.4815 mg Oxycodone)

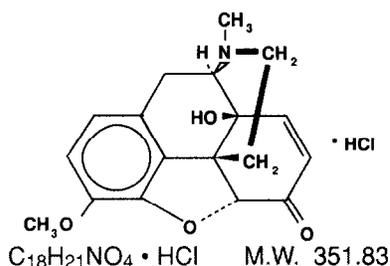
Acetaminophen 325 mg

Alcohol 0.4%

Acetaminophen, 4'-hydroxyacetanilide, is a non-opiate, non-salicylate analgesic and antipyretic which occurs as a white, odorless, crystalline powder, possessing a slightly bitter taste. Its structure is as follows:



The oxycodone component is 14-hydroxydihydrocodeinone, a white, odorless crystalline powder which is derived from the opium alkaloid, thebaine, and may be represented by the following structural formula:



The solution, for oral administration, contains 5 mg oxycodone hydrochloride and 325 mg acetaminophen per 5 mL. In addition, the solution contains the following inactive ingredients: alcohol (0.4%), polyethylene glycol, fructose, sodium saccharin, potassium sorbate, disodium edetate, citric acid, FD&C Red #40, flavors, and water.

CLINICAL PHARMACOLOGY

The principal ingredient, oxycodone, is a semi-synthetic narcotic with multiple actions qualitatively similar to those of morphine; the most prominent of these involve the central nervous system and organs composed of smooth muscle. The principal actions of therapeutic value of oxycodone are analgesia and sedation.

Oxycodone is similar to codeine and methadone in that it retains at least one-half of its analgesic activity when administered orally.

Acetaminophen is a non-opiate, non-salicylate analgesic and antipyretic.

INDICATIONS AND USAGE

For the relief of moderate to moderately severe pain.

CONTRAINDICATIONS

Hypersensitivity to oxycodone or acetaminophen.

WARNINGS

Drug Dependence: Oxycodone can produce drug dependence of the morphine type and, therefore, has the potential for being abused. Psychic dependence, physical dependence and tolerance may develop upon repeated administration of this drug, and it should be prescribed and administered with the same degree of caution appropriate to the use of other oral narcotic-containing medications. Like other narcotic-containing medications, this drug is subject to the Federal Controlled Substances Act (Schedule II).

PRECAUTIONS

1. General:

Head Injury and Increased Intracranial Pressure: The respiratory depressant effects of narcotics and their capacity to elevate cerebrospinal fluid pressure may be markedly exaggerated in the presence of head injury, other intracranial lesions or a pre-existing increase in intracranial pressure. Furthermore, narcotics produce adverse reactions which may obscure the clinical course of patients with head injuries.

Acute Abdominal Conditions: The administration of products containing oxycodone or other narcotics may obscure the diagnosis or clinical course in patients with acute abdominal conditions.

Special Risk Patients: Oxycodone and Acetaminophen should be given with caution to certain patients such as the elderly or debilitated, and those with severe impairment of hepatic or renal function, hypothyroidism, Addison's disease, and prostatic hypertrophy or urethral stricture.

2. **Information for Patients:** Oxycodone may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery. The patient taking this drug should be cautioned accordingly.

3. **Drug Interactions:** Patients receiving other narcotic analgesics, general anesthetics, phenothiazines, other tranquilizers, sedative-hypnotics, or other CNS depressants (including alcohol) concomitantly with oxycodone and acetaminophen may exhibit additive CNS depression. When such therapy is contemplated, the dose of one or both agents should be reduced.

The concurrent use of anticholinergics with narcotics may produce paralytic ileus.

4. **Pregnancy: Teratogenic Effects:** Pregnancy Category C. Animal reproductive studies have not been conducted with oxycodone and acetaminophen. It is also not known whether oxycodone and acetaminophen can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Oxycodone and acetaminophen should not be given to a pregnant woman, unless in the judgment of the physician, the potential benefits outweigh the possible hazards.

Nonteratogenic Effects: Use of narcotics during pregnancy may produce physical dependence in the neonate.

Labor and Delivery: As with all narcotics, administration of oxycodone and acetaminophen to the mother shortly before delivery may result in some degree of respiratory depression in the newborn and the mother, especially if higher doses are used.

5. **Nursing Mothers:** It is not known whether the components of this drug are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when oxycodone and acetaminophen is administered to a nursing mother.

6. **Pediatric Use:** Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

The most frequently observed adverse reactions include lightheadedness, dizziness, sedation, nausea and vomiting. These effects seem to be more prominent in ambulatory than in non-ambulatory patients, and some of these adverse reactions may be alleviated if the patient lies down.

Other adverse reactions include euphoria, dysphoria, constipation, skin rash, and pruritus. At higher doses, oxycodone has most of the disadvantages of morphine including respiratory depression.

DRUG ABUSE AND DEPENDENCE

Oxycodone and Acetaminophen oral solution is a Schedule II controlled substance.

Oxycodone can produce drug dependence and has the potential for being abused. (See **WARNINGS**.)

OVERDOSAGE

Acetaminophen:

Signs and Symptoms: In acute acetaminophen overdosage, dose-dependent, potentially fatal hepatic necrosis is the most serious adverse effect. Renal tubular necrosis, hypoglycemic coma and thrombocytopenia may also occur.

In adults, hepatic toxicity has rarely been reported with acute overdoses of less than 10 grams and fatalities with less than 15 grams. Importantly, young children seem to be more resistant than adults to the hepatotoxic effect of an acetaminophen overdose. Despite this, the measures outlined below should be initiated in any adult or child suspected of having ingested an acetaminophen overdose.

Early symptoms following a potentially hepatotoxic overdosage may include: nausea, vomiting, diaphoresis and general malaise. Clinical and laboratory evidence of hepatic toxicity may not be apparent until 48 to 72 hours post-ingestion.

Treatment: The stomach should be emptied promptly by lavage or by induction of emesis with syrup of ipecac. Patients' estimates of the quantity of a drug ingested are notoriously unreliable. Therefore, if an acetaminophen overdose is suspected, a serum acetaminophen assay should be obtained as early as possible, but no sooner than four hours following ingestion. Liver function studies should be obtained initially and repeated at 24-hour intervals.

The antidote, N-acetylcysteine, should be administered as early as possible, preferably within 16 hours of the overdose ingestion for optimal results, but in any case, within 24 hours. Following recovery, there are no residual, structural or functional hepatic abnormalities.

Oxycodone:

Signs and Symptoms: Serious overdose with oxycodone is characterized by respiratory depression (a decrease in respiratory rate and/or tidal volume, Cheyne-Stokes respiration, cyanosis), extreme somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, and sometimes bradycardia and hypotension. In severe overdose, apnea, circulatory collapse, cardiac arrest and death may occur.

Treatment: Primary attention should be given to the reestablishment of adequate respiratory exchange through provision of a patent airway and the institution of assisted or controlled ventilation. The narcotic antagonist naloxone is a specific antidote against respiratory depression which may result from overdosage or unusual sensitivity to narcotics, including oxycodone. Therefore, an appropriate dose of naloxone hydrochloride (usual initial adult dose 0.4 mg to 2 mg) should be administered, preferably by the intravenous route, and simultaneously with efforts at respiratory resuscitation (see package insert). Since the duration of action of oxycodone may exceed that of the antagonist, the patient should be kept under continued surveillance and repeated doses of the antagonist should be administered as needed to maintain adequate respiration.

An antagonist should not be administered in the absence of clinically significant respiratory or cardiovascular depression. Oxygen, intravenous fluids, vasopressors and other supportive measures should be employed as indicated.

Gastric emptying may be useful in removing unabsorbed drug.

DOSAGE AND ADMINISTRATION

Dosage should be adjusted according to severity of pain and response of the patient. It may occasionally be necessary to exceed the usual dosage recommended below in cases of more severe pain or in those patients who have become tolerant to the analgesic effect of narcotics.

Oral Solution:

The usual adult dose is 5 mL (one teaspoonful) every six hours as needed for pain.

HOW SUPPLIED

ROXICET™ Oral Solution,

Oxycodone and Acetaminophen Oral Solution

(Oxycodone Hydrochloride 5 mg and Acetaminophen 325 mg Oral Solution per 5 mL)

NDC 0054-8648-16: Unit dose Patient Cups™ filled to deliver 5 mL (Oxycodone Hydrochloride 5 mg, Acetaminophen 325 mg), ten 5 mL Patient Cups™ per shelf pack, four shelf packs per shipper.

NDC 0054-3686-63: Bottles of 500 mL.

Store at Controlled Room Temperature
15°-30°C (59°-86°F).

DEA Order Form Required.

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