PRESCRIBING INFORMATION

[N]TYLENOL®* No. 1
acetaminophen, caffeine and codeine phosphate caplets

[N]TYLENOL®* with Codeine No. 2
[N]TYLENOL®* with Codeine No. 3
acetaminophen, caffeine and codeine phosphate tablets

[N]TYLENOL®* with Codeine No. 4
acetaminophen and codeine phosphate tablets, USP

[N]TYLENOL®* with Codeine Elixir
acetaminophen and codeine phosphate oral solution, House Std.

Analgesic-Antipyretic

NOT A PRODUCT MONOGRAPH

Janssen Inc.
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Markham, Ontario
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McNeil Consumer Healthcare
Division of Johnson & Johnson Inc.
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DATE OF REVISION:
July 29, 2011

Submission Control No.: 148252

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Analgesic-Antipyretic

CLINICAL PHARMACOLOGY

TYLENOL® acetaminophen and codeine phosphate, and TYLENOL® acetaminophen, caffeine and codeine phosphate are analgesic, antipyretic agents.

ACTION

TYLENOL® acetaminophen and codeine phosphate, and TYLENOL® acetaminophen, caffeine and codeine phosphate combine the analgesic effects of the centrally acting analgesic codeine, with a peripherally acting analgesic, acetaminophen. Caffeine stimulates the CNS at all levels including the cerebral cortex. In addition, it acts on the kidney to produce mild diuresis, stimulates cardiac muscle, and depresses smooth muscle.

Acetaminophen, codeine phosphate and caffeine are well absorbed orally.

Acetaminophen is distributed throughout most tissues of the body. Acetaminophen is metabolized primarily in the liver. Little unchanged drug is excreted in the urine, but most metabolic products appear in the urine within 24 hours.

Codeine retains at least one-half of its analgesic activity when administered orally. A reduced first-pass metabolism of codeine by the liver accounts for the greater oral potency of codeine when compared to most other morphine-like narcotics. Following absorption, codeine is metabolized by the liver and metabolic products are excreted in the urine. Approximately 10% of the administered codeine is demethylated to morphine, which may account for its analgesic activity.

Caffeine is absorbed efficiently from the gastrointestinal tract, and peak plasma concentrations

occur 15 to 120 minutes after ingestion. It is almost completely metabolized via oxidation, demethylation, and acetylation, with only about 1% of caffeine excreted via the urine. The principal metabolites in man are methyluric acid, 1-methylxanthine, paraxanthine, and theobromine.

Pharmacokinetics

Following oral administration of acetaminophen in combination with codeine, both drugs are rapidly absorbed with peak plasma levels occurring within 60 minutes. Given two tablets of TYLENOL® with codeine No. 3, acetaminophen 600 mg produces a peak plasma level of 6.25 μg/mL within 40 minutes, codeine phosphate 60 mg produces a peak plasma level of 150 ng/mL within 60 minutes.

Following oral administration, caffeine is rapidly absorbed with a peak plasma level occurring within 15 to 120 minutes. Given an oral dose of 100 mg peak plasma caffeine concentrations of 1.5 to 1.8 μg/mL are reached within 60 minutes.

The plasma elimination half-life ($t_{1/2}$) ranges from 1.5 to 3.5 hours for acetaminophen, 1.5 to 4 hours for codeine, and from 2.5 to 4.5 hours for caffeine. Metabolism is rapid; the principal metabolites are conjugates of glucuronic acid which are excreted in the urine. Less than 1% of an administered dose of codeine or caffeine, and less than 4% of an administered dose of acetaminophen, is excreted unchanged in the urine.

INDICATIONS AND CLINICAL USE

TYLENOL® with Codeine No. 1, 2 and 3

TYLENOL® acetaminophen, caffeine and codeine phosphate tablets and caplets are indicated for the relief of mild to moderate pain associated with conditions such as headache, dental pain, myalgia, dysmenorrhea, pain following trauma, and pain following operative procedures. TYLENOL® acetaminophen, caffeine and codeine phosphate may also be effective in relieving the pain associated with various forms of arthritis, but is not indicated as primary therapy for rheumatoid arthritis and similar inflammatory conditions.

TYLENOL® with Codeine Elixir

TYLENOL® acetaminophen and codeine phosphate oral solution is useful as an analgesic/antipyretic in the symptomatic treatment of mild to moderate pain and fever in children.

TYLENOL® with Codeine No. 4

TYLENOL® acetaminophen and codeine phosphate tablets are indicated for the relief of moderate to severe pain in adults only.

CONTRAINDICATIONS

TYLENOL® with Codeine No. 1, 2, and 3 (acetaminophen, caffeine and codeine phosphate) should not be administered to patients who have previously exhibited hypersensitivity to caffeine, acetaminophen, codeine, or other opioids.

TYLENOL® with Codeine No. 4 and Elixir (acetaminophen and codeine phosphate) should not be administered to patients who have previously exhibited hypersensitivity to acetaminophen, codeine or other opioids.

WARNINGS AND PRECAUTIONS

As with any other non-prescription analgesic drug, physicians should be cognizant of and supervise the use of acetaminophen in patients with alcoholism, serious kidney or serious liver disease. Chronic heavy alcohol abusers may be at increased risk of liver toxicity from excessive acetaminophen use, although reports of this event are rare. Reports usually involve cases of severe chronic alcoholics and the dosages of acetaminophen most often exceed recommended doses and often involve substantial overdose. Physicians should alert their patients who regularly consume large amounts of alcohol not to exceed the recommended doses of acetaminophen.

Patients should be counselled to consult a physician if redness or swelling is present in an area of pain, if symptoms do not improve or if they worsen, or if new symptoms such as high fever, rash, itching, wheezing or persistent headache occur, as these may be signs of a condition which requires medical attention.

Acetaminophen should not be taken for pain for more than 5 days or for fever for more than 3 days, unless directed by a physician. As with any drug, patients who are pregnant or nursing a baby should consult a physician before taking this product.

Patients should be counselled not to use with other products containing acetaminophen. Patients should be counselled to consult a physician before use if they are taking tranquilizers, sedatives, sedating antihistamines or other depressants, 3 or more alcoholic beverages per day, natural health products, prescription drugs, salicylates, any other pain and fever relief medication or nonsteroidal anti-inflammatory drugs (NSAIDS).

Patients should be counselled to consult a physician before use if they have difficulty breathing, have asthma or other chronic lung disease.

Keep out of the sight and reach of children.

In the presence of head injury or other intracranial lesions, the respiratory depressant effects of codeine and other narcotics may be markedly enhanced, as well as their capacity for elevating cerebrospinal fluid pressure. Narcotics also produce other CNS depressant effects, such as drowsiness, that may further obscure the clinical course of the patients with head injuries.

Codeine produces dose-related respiratory depression. Caution should be exercised when acetaminophen with codeine is used postoperatively, in patients with pulmonary disease or

shortness of breath or whenever ventilatory function is depressed.
Codeine or other narcotics may obscure signs on which to judge the diagnosis or clinical course of patients with acute abdominal conditions.

Use with caution in patients with seizures as the seizures may be exacerbated or induced by opioids.

Codeine is habit forming and potentially abusable. Consequently, the extended use of this product is not recommended.

General
TYLENOL® with Codeine (acetaminophen and codeine phosphate) tablets should be prescribed with caution in certain special-risk patients, such as the elderly or debilitated, and those with severe impairment of renal or hepatic function, head injuries, elevated intracranial pressure, acute abdominal conditions, hypothyroidism, urethral stricture, Addison's disease, or prostatic hypertrophy.

Ultra-Rapid Metabolizers of Codeine
Some individuals may be ultra-rapid metabolizers due to a specific CYP2D6*2x2 genotype. These individuals convert codeine into its active metabolite, morphine, more rapidly and completely than other people. This rapid conversion results in higher than expected serum morphine levels. Even at labeled dosage regimens, individuals who are ultra-rapid metabolizers may experience overdose symptoms such as extreme sleepiness, confusion, or shallow breathing.

The prevalence of this CYP2D6 phenotype varies widely and has been estimated at 0.5 to 1% in Chinese and Japanese, 0.5 to 1% in Hispanics, 1 to 10% in Caucasians, 3% in African Americans, and 16 to 28% in North Africans, Ethiopians, and Arabs. Data are not available for other ethnic groups.

When physicians prescribe codeine-containing drugs, they should choose the lowest effective dose for the shortest period of time and inform their patients about these risks and the signs of morphine overdose (see **WARNINGS AND PRECAUTIONS, Lactation**).

Lactation
Acetaminophen is excreted in breast milk in small amounts, but the significance of its effects on nursing infants is not known. Because of the potential for serious adverse reactions in nursing infants from acetaminophen, a decision should be made whether to discontinue the drug, taking into account the importance of the drug to the mother.

Codeine is secreted into human milk. In women with normal codeine metabolism (normal CYP2D6 activity), the amount of codeine secreted into human milk is low and dose-dependent. Despite the common use of codeine products to manage postpartum pain, reports of adverse events in infants are rare. However, **some women are ultra-rapid metabolizers of codeine. These women achieve higher-than-expected serum levels of codeine's active metabolite, morphine, leading to higher-than-expected levels of morphine in breast milk and potentially dangerously high serum morphine levels in their breastfed infants. Therefore, maternal use of codeine can potentially lead to serious adverse reactions, including death, in nursing**

infants.

The prevalence of this CYP2D6 phenotype varies widely and has been estimated at 0.5 to 1% in Chinese and Japanese, 0.5 to 1% in Hispanics, 1 to 10% in Caucasians, 3% in African Americans, and 16 to 28% in North Africans, Ethiopians, and Arabs. Data are not available for other ethnic groups.

The risk of infant exposure to codeine and morphine through breast milk should be weighed against the benefits of breastfeeding for both the mother and baby. Caution should be exercised when codeine is administered to a nursing woman. If a codeine containing product is selected, the lowest dose should be prescribed for the shortest period of time to achieve the desired clinical effect. Mothers using codeine should be informed about when to seek immediate medical care and how to identify the signs and symptoms of neonatal toxicity, such as drowsiness or sedation, difficulty breastfeeding, breathing difficulties, and decreased tone, in their baby. Nursing mothers who are ultra-rapid metabolizers may also experience overdose symptoms such as extreme sleepiness, confusion, or shallow breathing. Prescribers should closely monitor mother-infant pairs and notify treating pediatricians about the use of codeine during breastfeeding (see **WARNINGS AND PRECAUTIONS**, **Ultra-Rapid Metabolizers of Codeine**).

Caffeine is distributed into the milk of nursing women.

Occupational Hazards

Codeine may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks. Patients using this drug should be cautioned about driving a car or operating potentially hazardous machinery if they become drowsy or show impaired mental or physical abilities while taking this medication.

The patient should understand the single-dose and 24-hour dose limits, and the time interval between doses. Like other narcotic-containing medications, these drugs are subject to the Controlled Drugs and Substances Act.

Laboratory Tests

In patients with severe hepatic or renal disease, effects of therapy should be monitored with serial liver and/or renal function tests.

Drug Interactions

This drug may enhance the effects of other narcotic analgesics, alcohol, general anesthetics, tranquilizers such as chlordiazepoxide, sedative-hypnotics, or other CNS depressants, causing increased CNS depression.

Patients who concomitantly medicate with warfarin-type anticoagulants and regular doses of acetaminophen have occasionally been reported to have unforeseen elevations in their international normalized ratio [INR]. Physicians should be cognizant of this potential interaction and monitor the INR in such patients closely while therapy is established. Many factors, including diet, medications, and environmental and physical states, may affect how a patient responds to anticoagulant therapy. There have been several reports that suggest that acetaminophen may produce hypoprothrombinemia (elevated INR or prothrombin time) when administered with coumarin derivatives. In other studies, prothrombin time did not change.

Reported changes have been generally of limited clinical significance, however, periodic evaluation of prothrombin time should be performed when these agents are administered concurrently.

In the period immediately following discharge from the hospital or whenever other medications are initiated, discontinued, or taken regularly, it is important to monitor patient response to anticoagulation therapy with additional prothrombin time of INR determinations.

Drug/Laboratory Test Interactions

Codeine may increase serum amylase levels.

Acetaminophen may produce false-positive test results for urinary 5-hydroxyindoleacetic acid.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No adequate studies have been conducted in animals to whether acetaminophen or codeine have a potential for carcinogenesis or mutagenesis. No adequate studies have been conducted in animals to determine whether acetaminophen has a potential for impairment of fertility.

Acetaminophen and codeine have been found to have no mutagenic potential using the Ames Salmonella-Microsomal Activation test, the Basc test on Drosophila germ cells, and the Micronucleus test on mouse bone marrow.

Use in Pregnancy

Teratogenic Effects:

Codeine: A study in rats and rabbits reported no teratogenic effect of codeine administered during the period of organogenesis in doses ranging from 5 to 120 mg/kg. In the rat, doses at the 120 mg/kg level, in the toxic range for the adult animal, were associated with an increase in embryo resorption at the time of implantation. In another study, a single 100 mg/kg dose of codeine administered to pregnant mice reportedly resulted in delayed ossification in the offspring.

There are no adequate and well-controlled studies in pregnant women.

TYLENOL® acetaminophen and codeine phosphate, and TYLENOL® acetaminophen, caffeine and codeine phosphate should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Non-teratogenic Effects:

Dependence and withdrawal signs have been reported in newborns whose mothers took opiates regularly during pregnancy. These signs include irritability, excessive crying, tremors, hyperreflexia, fever, vomiting, and diarrhea. Signs usually appear during the first few days of life.

Labour and Delivery:
Narcotic analgesics cross the placental barrier. The closer to delivery and the larger the dose used, the greater the possibility of respiratory depression in the newborn. Narcotic analgesics should be avoided during labour if delivery of a premature infant is anticipated. If the mother has received narcotic analgesics during labour, newborn infants should be observed closely for signs of respiratory depression. Resuscitation may be required (see **OVERDOSAGE**). The effects of codeine, if any, on the later growth, development, and functional maturation of the child is unknown.

Children
These products contain codeine and should not be administered to children except as prescribed by a doctor or a dentist. Tablets and caplets should not be administered to children below the age of 12 years. Safe dosage of the TYLENOL® with Codeine Elixir has not been established in infants below the age of 2 years.

Drug Abuse and Dependence
Codeine 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 TYLENOL® acetaminophen and codeine phosphate, and TYLENOL® acetaminophen, caffeine and codeine phosphate. These drugs should be prescribed and administered with the same degree of caution appropriate to the use of other oral narcotic-containing medications.

ADVERSE REACTIONS

The most frequently observed adverse effects include drowsiness, lightheadedness, dizziness, sedation, shortness of breath, nausea, and vomiting. These effects seem to be more prominent in ambulatory patients than in non-ambulatory patients, and some of these adverse reactions may be alleviated if the patient lies down. Other adverse reactions include allergic reactions, euphoria, dysphoria, constipation, abdominal pain, pruritus, rash, thrombocytopenia, and agranulocytosis. The incidence and severity of gastrointestinal upset is less than that after salicylate administration.

The classic gastrointestinal irritation associated with non-steroidal anti-inflammatory drugs, including ASA, does not occur with acetaminophen. Sensitivity reactions are rare and may manifest as rash or urticaria. Cross-reactivity in ASA-sensitive persons has been rarely reported. If sensitivity is suspected, discontinue use of the drug.

Patients who concomitantly medicate with warfarin-type anticoagulants and regular doses of acetaminophen have occasionally been reported to have unforeseen elevations in their INR. Physicians should be cognizant of this potential interaction and monitor the INR in such patients closely while therapy is established (see **WARNINGS AND PRECAUTIONS**, **Drug Interactions**).

At higher doses, codeine has most of the disadvantages of morphine, including respiratory depression.

Higher doses of caffeine lead to overstimulation of the higher centres of the CNS. Adverse CNS

effects may include insomnia, restlessness, nervousness and mild delirium. Adverse gastrointestinal effects of caffeine may include nausea, vomiting, and gastric irritation. Although chronic administration of caffeine in animals has been associated with gastric ulceration, such a causal relationship in humans has not been adequately established to date.

SYMPTOMS AND TREATMENT OF OVERDOSAGE

In Case of Accidental Overdose: Call a Poison Control Centre or doctor immediately, even if you do not notice any signs or symptoms such as increased sweating, nausea, vomiting, stomach pain or loss of appetite.

Acetaminophen:

Typical Toxidrome: Significant overdoses of acetaminophen may result in potentially fatal hepatotoxicity. The physician should be mindful that there is no early presentation that is pathognomonic for the overdose. A high degree of clinical suspicion must always be maintained.

Due to the wide availability of acetaminophen, it is commonly involved in single and mixed drug overdose situations and the practitioner should have a low threshold for screening for its presence in a patient's serum. Acute toxicity after single dose overdoses of acetaminophen can be anticipated when the overdose exceeds 150 mg/kg. Chronic alcohol abusers, cachectic individuals, and persons taking pharmacologic inducers of the hepatic P450 microsomal enzyme system may be at risk with lower exposures. Chronic intoxication has rarely been reported in persons consuming in excess of 150 mg/kg of acetaminophen daily for several days.

Specific Antidote: NAC (N-acetylcysteine) administered by either the intravenous or the oral route is known to be a highly effective antidote for acetaminophen poisoning. It is most effective when administered within 8 hours of a significant overdose but reports have indicated benefits to treatment initiated well beyond this time period. It is imperative to administer the antidote as early as possible in the time course of acute intoxication to reap the full benefits of the antidote's protective effects.

General Management: When the possibility of acetaminophen overdose exists, treatment should begin immediately and include appropriate decontamination of the GI tract, proper supportive care, careful assessment of appropriately timed serum acetaminophen estimations evaluated against the Matthew-Rumack nomogram, timely administration of NAC as required and appropriate follow-up care. Physicians unfamiliar with the current management of acetaminophen overdose should consult with a poison control centre immediately. Delays in initiation of appropriate therapy may jeopardize the patient's chances for full recovery.

Codeine:

Typical Toxidrome: Narcotic/Opiate
Specific Antidote: Naloxone HCl.
General Management: Stabilize the patient (A, B, C's), undertake appropriate gastrointestinal tract decontamination procedures, initiate supportive care, administer antidote as needed (see manufacturer's product monograph), consult with a Regional Poison Control Centre regarding ongoing management, and arrange for appropriate follow-up care.

Caffeine:
Typical Toxidrome: Xanthine (theophylline-like picture), CNS excitation, skeletal muscle irritability
Specific Antidote: None.
General Management: Stabilize the patient (A, B, C's), undertake appropriate gastrointestinal tract decontamination procedures, initiate supportive care, consult with a Regional Poison Control Centre regarding ongoing management, and arrange for appropriate follow-up care.

DOSAGE AND ADMINISTRATION

Dosing Considerations

Do not co-administer with other drugs containing acetaminophen.

The maximum recommended dose of TYLENOL® should not be exceeded. Overdose may result in **severe or possibly fatal liver damage**.

Dosage should be adjusted according to severity of pain and response of the patient. However, it should be kept in mind that tolerance to codeine can develop with continued use and that the incidence of untoward effects is dose related. Adult doses of codeine, higher than 60 mg, fail to give commensurate relief of pain but merely prolong analgesia, and are associated with an appreciably increased incidence of undesirable side effects. Equivalently high doses in children would have similar effects.

TYLENOL® acetaminophen, caffeine and codeine phosphate tablets and caplets, as well as TYLENOL® acetaminophen and codeine phosphate tablets and oral solution are given orally.

Dosage

TYLENOL® No. 1 caplets:

Adults (≥ 12 years of age):
Take 1 caplet every 4-6 hours, not to exceed 12 caplets in 24 hours. If pain does not respond to 1 caplet, take 2 caplets at next dose.

TYLENOL® with Codeine No. 2 and No. 3 tablets:

Adults (≥ 12 years of age):
Take 1 tablet every 4-6 hours as required, not to exceed 12 tablets in 24 hours. If pain does not respond to 1 tablet, take 2 tablets at next dose.

TYLENOL® with Codeine No. 4 tablets:

Adults (≥ 12 years of age):
1 tablet every 4-6 hours as required, not to exceed 6 tablets in 24 hours.
Based on the dosage guidance, the number of tablets per dose and the maximum number of tablets per 24 hours should be conveyed in the prescription.

TYLENOL® with Codeine Elixir

Dosage should be adjusted according to severity of pain and response of the patient. As an analgesic-antipyretic, the dose is given every 4 hours as required. Not to exceed 5 doses in a 24-hour period.

Adults (≥ 12 years of age): 10 to 20 mL every 4 hours as required.
Children (< 12 years of age): Dosages for children under 12 years of age are provided in Table 1.

Table 1: Dosages for Children Under 12 years of Age

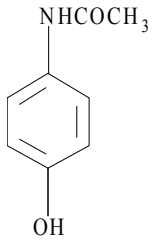
Age (years)	Single Dose (mL)
2 - 3	3.75 - 5
4 - 5	5.0 - 6.25
6 - 8	6.25 - 8.75
9 - 10	8.75 - 10.0
11to under 12	10.0 - 12.5

Safe dosage of this elixir has not been established in children below the age of 2 years.
Note: The recommended dose of codeine in children is 0.5 mg/kg body weight.

PHARMACEUTICAL INFORMATION

The components of TYLENOL® acetaminophen and codeine phosphate dosage forms have the following structural formulae:

Acetaminophen

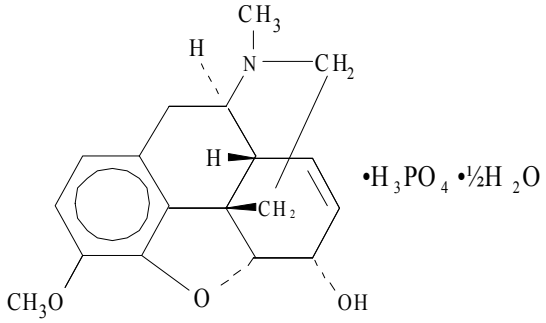


Chemical Name: N-(4-hydroxyphenyl) acetamide

Molecular Formula: $C_8H_9NO_2$

Molecular Weight: 151.2

Codeine Phosphate



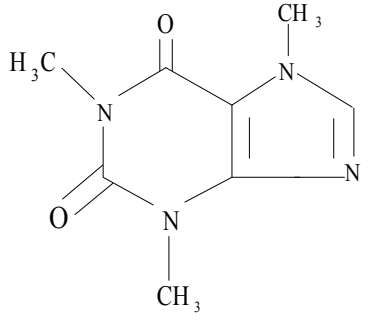
Chemical Name: 7, 8-didehydro-4,5α-epoxy-3-methoxy-17-methylmorphinan-6α-ol-phosphate(l:l) (salt) hemihydrate

Molecular Formula: $C_{18}H_{21}NO_3 \bullet H_3PO_4 \bullet ½H_2O$

Molecular Weight: 406.4

TYLENOL® acetaminophen, caffeine and codeine phosphate oral dosage forms have the additional component:

Caffeine



Chemical Name: 3,7-dihydro-1,3,7-trimethyl-1H-purine-2,6-dione

Molecular Formula: C8H10N4O2

Molecular Weight: 194.2

Physical State:

Acetaminophen	-	white crystalline powder
Codeine phosphate	-	white crystalline powder
Caffeine	-	odourless silky white crystals

Solubility:

Acetaminophen	-	in boiling water 1 g/20 mL; in alcohol 1 g/10 mL
Codeine phosphate	-	in water 4 g/mL; in alcohol 30 mg/10 mL
Caffeine	-	in water 1 g/46 mL; in boiling water 1 g/1.5 mL; in alcohol 1 g/66 mL; in acetone 1 g/50 mL

General Product Stability:

Temperature	-	stable
Moisture	-	avoid excess moisture
Light	-	sensitive, protect from light

Stability and Storage Recommendations:

Caplets No. 1: Store between 15- 30ºC.
Tablets No. 2, No. 3, No. 4 and Elixir: Keep bottle tightly closed. Store at 15-30ºC. Protect from light.

AVAILABILITY OF DOSAGE FORMS

TYLENOL® No. 1 caplets:

Each hard, white, capsule-shaped tablet imprinted with a stylized "M" and "McNEIL" on one face and imprinted with "NO. 1 " on the other face, contains: acetaminophen 300 mg, caffeine 15 mg, and codeine phosphate 8 mg. Nonmedicinal ingredients: cellulose, cornstarch, magnesium stearate and sodium starch glycolate. Energy: 0.761 kJ (0.182 kcal). Sodium: <1 mmol (0.4 mg). Gluten-, lactose-, sodium metabisulphite- and tartrazine-free. Bottles of 30, 50, and 100 (supplied by McNeil Consumer Healthcare, Division of Johnson & Johnson Inc.).

TYLENOL® with Codeine No. 2 and No. 3 tablets:

Each round, hard, white tablet, flat-faced, bevelled, engraved with "2" or "3" respectively on one side and has a flat-faced special design, bevelled, engraved with "McNEIL" on the other side, contains: acetaminophen 300 mg and caffeine 15 mg in combination with codeine phosphate 15 mg and 30 mg, respectively. Nonmedicinal ingredients: cellulose, microcrystalline cellulose, starch NF, sodium starch glycolate, pregelatinized starch, and magnesium stearate. Gluten-, lactose-, sodium metabisulphite- and tartrazine-free. Bottles of 500 (supplied by Janssen Inc.).

TYLENOL® with Codeine No. 4 tablets:

Each round, hard, white tablet, flat-faced, bevelled, engraved with "4" on one side and has a flat-faced special design, bevelled, engraved with "McNEIL" on the other side, contains: acetaminophen 300 mg and codeine phosphate 60 mg. Nonmedicinal ingredients: cellulose, cornstarch, magnesium stearate, sodium lauryl sulfate, sodium starch glycolate and talc. Energy: 1.704 kJ (0.405 kcal). Sodium: <1 mmol (0.6 mg). Gluten-, lactose-, sodium metabisulphite- and tartrazine-free. Bottles of 100 (supplied by Janssen Inc.).

TYLENOL® with Codeine Elixir:

Each 5 mL of elixir contains: acetaminophen 160 mg and codeine phosphate 8 mg in a slightly viscous clear red liquid that tastes and smells like cherry and contains alcohol 6% w/v (7% v/v) and sucrose 31% w/v. Nonmedicinal ingredients: alcohol, citric acid, D&C red No. 33, flavour, polyethylene glycol, sodium benzoate, sodium cyclamate, sorbitol and sucrose. Energy: 45.93 kJ (10.98 kcal)/5 mL. Gluten-, lactose-, and tartrazine-free. Dark amber plastic bottles of 500 mL (supplied by Janssen Inc.). Dispense in tight, light-resistant containers.