-See 12 for PATIENT COUNSELING INFORMATION.
-Revised: 1/2017
+See 17 for PATIENT COUNSELING INFORMATION.
+Revised: 10/2019
-13 NONCLINICAL TOXICOLOGY
+13
+NONCLINICAL TOXICOLOGY

-2. Obtain the following laboratory tests to monitor hepatic and renal function and electrolyte and fluid
-balance: aspartate aminotransferase (AST), alanine aminotransferase (ALT), bilirubin, international
-normalized ratio (INR), creatinine, blood urea nitrogen (BUN), blood glucose, and electrolytes.
+2. Obtain the following laboratory tests to monitor hepatic and renal function and electrolyte and fluid balance:
+aspartate aminotransferase (AST), alanine aminotransferase (ALT), bilirubin, international normalized ratio
+(INR), creatinine, blood urea nitrogen (BUN), blood glucose, and electrolytes.
-• Obtain an acetaminophen concentration to determine need for continued treatment [see Dosage
-and Administration (2.2)].
+• Obtain an acetaminophen concentration to determine need for continued treatment [see Dosage and
+Administration (2.2)].
-• Obtain an acetaminophen concentration to determine need for continued treatment [see Dosage
-and Administration (2.2)].
+• Obtain an acetaminophen concentration to determine need for continued treatment [see Dosage and
+Administration (2.2)].
-•
-Use the Rumack-Matthew nomogram (Figure 1) to determine whether or not to initiate treatment
+• Use the Rumack-Matthew nomogram (Figure 1) to determine whether or not to initiate treatment
-treatment initiation between 15 and 24 hours post-ingestion of acetaminophen yields limited efficacy. However, it
-does not appear to worsen the condition of patients and it should not be withheld, since the reported time of ingestion
-may not be correct.

+treatment initiation between 15 and 24 hours post-ingestion of acetaminophen yields limited efficacy. However, it does
+not appear to worsen the condition of patients and it should not be withheld, since the reported time of ingestion may
+not be correct.

-• Refer to the Rumack-Matthew nomogram (see Figure 1) to determine whether or not to initiate treatment
-with ACETADOTE.
-• Initiation of ACETADOTE depends on the plasma or serum acetaminophen concentration and also the
-clinical presentation of the patient.
+• Refer to the Rumack-Matthew nomogram (see Figure 1) to determine whether or not to initiate treatment with
+ACETADOTE.
+• Initiation of ACETADOTE depends on the plasma or serum acetaminophen concentration and also the clinical
+presentation of the patient.
-For patients with an acute overdose from an extended-release acetaminophen, if the acetaminophen concentration at
-4 hours post ingestion is below the possible toxicity line then obtain a second sample for acetaminophen
-concentration 8 to 10 hours after the acute ingestion. If the second value is at or above the “possible” toxicity line
-(dotted line in nomogram):
+For patients with an acute overdose from an extended-release acetaminophen, if the acetaminophen concentration at 4
+hours post ingestion is below the possible toxicity line then obtain a second sample for acetaminophen concentration
+8 to 10 hours after the acute ingestion. If the second value is at or above the “possible” toxicity line (dotted line in
+nomogram):
-Figure 1. Rumack-Matthew Nomogram for Estimating Potential for Hepatoxicity for Acetaminophen
-Posioning – Plasma or Serum Acetaminophen Concentration versus Time (hours) Post-acetaminophen
-Ingestion graph

+Figure 1. Rumack-Matthew Nomogram for Estimating Potential for Hepatoxicity for Acetaminophen Posic
+– Plasma or Serum Acetaminophen Concentration versus Time (hours) Post-acetaminophen Ingestion
-ACETADOTE® (acetylcysteine) Injection
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+Page 3
-The acetaminophen concentration was in the non-toxic range, but time of ingestion was unknown or less t
-hours:
+The acetaminophen concentration was in the non-toxic range, but time of ingestion was unknown or less
-consideration should be given to the need for continued treatment with ACETADOTE beyond a total of thr
-separate doses over a 21-hour infusion period.
+consideration should be given to the need for continued treatment with ACETADOTE beyond a total of th
+doses over a 21-hour infusion period.
-“special health professional assistance line for acetaminophen overdose” at 1-800-525-6115 for assistanc
-dosing recommendations, or 1-877-484-2700 for additional information.
+“special health professional assistance line for acetaminophen overdose” at 1-800-525-6115 for assistanc
+recommendations, or 1-877-484-2700 for additional information.
-Visually inspect for particular matter and discoloration prior to administration. The color of the diluted solut
-ranges from colorless to a slight pink or purple once the stopper is punctured (the color change does not a
-quality of the product). The diluted solution can be stored for 24 hours at room temperature. Discard unus
-portion. If a vial was previously opened, do not use for intravenous administration.
-ACETADOTE® (acetylcysteine) Injection
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+Visually inspect for particular matter and discoloration prior to administration. The color of the diluted solu
+from colorless to a slight pink or purple once the stopper is punctured (the color change does not affect th
+the product). The diluted solution can be stored for 24 hours at room temperature. Discard unused portion
+was previously opened, do not use for intravenous administration.
+Page 4
+Reference ID: 4513653
-105mL
+105 mL
-210mL
+210 mL
-140mL
+140 mL
-280mL
+280 mL
-diluent* infused over 1 hour
+diluent1 infused over 1 hour
-50 mg/kg in 500 mL of
-diluent* infused over 4 hours
+50 mg/kg in 500 mL of diluent1
+infused over 4 hours
-diluent* infused over 16 hours
+diluent1 infused over 16 hours
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-Reference ID: 4044640
-This label may not be the latest approved by FDA.
-For current labeling information, please visit https://www.fda.gov/drugsatfda
-
-Table 4. Recommended ACETADOTE Dosage and Dilution for Patients 41 kg or Greater
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+This label may not be the latest approved by FDA.
+For current labeling information, please visit https://www.fda.gov/drugsatfda
+

+Table 4. Recommended ACETADOTE Dosage and Dilution for Patients 41 kg or Greater
-≥ 100 kg**
+≥ 100 kg **
-* Dilute ACETADOTE in one of the following three solutions: sterile water for injection, 0.45% sodium chl
+* Dilute ACETADOTE in one of the following three solutions: sterile water for injection, 0.45% sodium chl
-of acute acetaminophen ingestion (i.e., the Rumack-Matthew nomogram) do not apply to patients with RS
-Therefore, obtain the following information to guide ACETADOTE treatment for RSI:
-• Acetaminophen serum or plasma concentrations. A reported history of the quantity of acetaminophen
-ingested is often inaccurate and is not a reliable guide to therapy.
-• Laboratory tests to monitor hepatic and renal function and electrolyte and fluid balance: AST, ALT,
-bilirubin, INR, creatinine, BUN, blood glucose, and electrolytes.
+of acute acetaminophen ingestion (i.e., the Rumack-Matthew nomogram) do not apply to patients with RS
+obtain the following information to guide ACETADOTE treatment for RSI:
+• Acetaminophen serum or plasma concentrations. A reported history of the quantity of acetaminophen in
+is often inaccurate and is not a reliable guide to therapy.
+• Laboratory tests to monitor hepatic and renal function and electrolyte and fluid balance: AST, ALT, biliru
+INR, creatinine, BUN, blood glucose, and electrolytes.
-ACETADOTE is contraindicated in patients with a previous hypersensitivity reaction to acetylcysteine [see
-Warnings and Precautions (5.1)].
+ACETADOTE is contraindicated in patients with a previous hypersensitivity reaction to acetylcysteine [se
+and Precautions (5.1)].
-Acute flushing and erythema of the skin may occur in patients receiving acetylcysteine intravenously. The
-reactions usually occur 30 to 60 minutes after initiating the infusion and often resolve spontaneously desp
-continued infusion of acetylcysteine. If a reaction to acetylcysteine involves more than simply flushing and
-of the skin, it should be treated as a hypersensitivity reaction.
-ACETADOTE® (acetylcysteine) Injection
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+Acute flushing and erythema of the skin may occur in patients receiving acetylcysteine intravenously. The
+usually occur 30 to 60 minutes after initiating the infusion and often resolve spontaneously despite contin
+of acetylcysteine. If a reaction to acetylcysteine involves more than simply flushing and erythema of the s
+be treated as a hypersensitivity reaction.
+Management of less severe hypersensitivity reactions should be based upon the severity of the reaction a
+temporary interruption of the infusion and/or administration of antihistaminic drugs. The ACETADOTE infu
+be carefully restarted after treatment of the hypersensitivity symptoms has been initiated; however, if the
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+Reference ID: 4513653
-Management of less severe hypersensitivity reactions should be based upon the severity of the reaction a
-temporary interruption of the infusion and/or administration of antihistaminic drugs. The ACETADOTE infu
-may be carefully restarted after treatment of the hypersensitivity symptoms has been initiated; however, if
-The total volume of ACETADOTE administered should be adjusted for patients less than 40 kg and for tho
-requiring fluid restriction. To avoid fluid overload, the volume of diluent should be reduced as needed [see
-and Administration (2)]. If volume is not adjusted fluid overload can occur, potentially resulting in hyponatr
-seizure and death.
+The total volume of ACETADOTE administered should be adjusted for patients less than 40 kg and for th
+fluid restriction. To avoid fluid overload, the volume of diluent should be reduced as needed [see Dosage
+Administration (2)]. If volume is not adjusted fluid overload can occur, potentially resulting in hyponatremi
+and death.
-were rash, urticaria and pruritus. The frequency of adverse reactions has been reported to be between 0.2
-21%, and they most commonly occur during the initial loading dose of acetylcysteine.
+were rash, urticaria and pruritus. The frequency of adverse reactions has been reported to be between 0.
+and they most commonly occur during the initial loading dose of acetylcysteine.
-poisoning, the rates of hypersensitivity reactions between a 15-minute and 60-minute intravenous infusion
-150 mg/kg loading dose of acetylcysteine were compared.
+poisoning, the rates of hypersensitivity reactions between a 15-minute and 60-minute intravenous infusio
+mg/kg loading dose of acetylcysteine were compared.
-administration is presented in Table 5. Overall, 17% of patients developed an acute hypersensitivity reacti
-in the 15-minute infusion group; 14% in the 60-minute infusion group) [see Warnings and Precautions (5.1
-Clinical Studies (14)].

+administration is presented in Table 5. Overall, 17% of patients developed an acute hypersensitivity react
+the 15-minute infusion group; 14% in the 60-minute infusion group) [see Warnings and Precautions (5.1),
+Studies (14)].
-15-mins
-60-mins
+15-minutes
+60-minutes
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-For current labeling information, please visit https://www.fda.gov/drugsatfda
-
-Treatment Group
-15-mins
-60-mins
-Pharyngitis
-Rhinorrhea
-Rhonchi
-Throat tightness
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+This label may not be the latest approved by FDA.
+For current labeling information, please visit https://www.fda.gov/drugsatfda
+
+8
+Treatment Group
+15-minutes
+60-minutes
+Pharyngitis
+Rhinorrhea
+Rhonchi
+Throat tightness
-Unkn=Unknown
+Unkn= Unknown; NOS= not otherwise specified
-Incidence (%)
-% of Patients (n=4709)
+Incidence (%) n=4709
-Table 7. Distribution of reported hypersensitivity reactions in pediatric patients receiving intravenous
-acetylcysteine
-Incidence (%)
+Table 7. Distribution of reported hypersensitivity reactions in pediatric patients receiving intravenous acet
-% of Patients (n=1905)
+Incidence (%) n=1905
-Limited published case reports and case series of pregnant women exposed to acetylcysteine during vario
-trimesters are not sufficient to inform any drug associated risk. Delaying treatment of acetaminophen over
-increase the risk of maternal or fetal morbidity and mortality [see Clinical Considerations]. Reproduction st
-ACETADOTE® (acetylcysteine) Injection
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-Reference ID: 4044640
-8
+Limited published case reports and case series of pregnant women exposed to acetylcysteine during vari
+are not sufficient to inform any drug associated risk. Delaying treatment of acetaminophen overdose may
+risk of maternal or fetal morbidity and mortality [see Clinical Considerations]. Reproduction studies in rats
+following oral administration of acetylcysteine during the period of organogenesis at doses similar to the t
+intravenous dose (based on the body surface area) did not cause any adverse effects to the fetus. The es
+background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S
+population, the estimated background risk of major birth defects and miscarriage in clinically recognized p
+is 2% to 4% and 15% to 20%, respectively.

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-rats and rabbits following oral administration of acetylcysteine during the period of organogenesis at dose
-the total intravenous dose (based on the body surface area) did not cause any adverse effects to the fetus
-estimated background risk of major birth defects and miscarriage for the indicated population is unknown.
-U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically
-recognized pregnancies is 2% to 4% and 15% to 20%, respectively.
-overdose and potentially toxic acetaminophen plasma levels may increase the risk of maternal and fetal m
-and mortality.
+overdose and potentially toxic acetaminophen plasma levels may increase the risk of maternal and fetal m
+mortality.
-of 300 mg/kg based on body surface area comparison) and in rabbits at oral doses up to 1000 mg/kg/day
-the recommended total human intravenous dose of 300 mg/kg based on body surface area comparison).
+of 300 mg/kg based on body surface area comparison) and in rabbits at oral doses up to 1000 mg/kg/day
+recommended total human intravenous dose of 300 mg/kg based on body surface area comparison). No
-There are no data on the presence of acetylcysteine in human milk, the effects on the breastfed infant, or
-on milk production. The developmental and health benefits of breastfeeding should be considered along w
-mother's clinical need for ACETADOTE and any potential adverse effects on the breastfed child from
-ACETADOTE or from the underlying maternal condition.
+There are no data on the presence of acetylcysteine in human milk, the effects on the breastfed infant, or
+milk production. The developmental and health benefits of breastfeeding should be considered along with
+clinical need for ACETADOTE and any potential adverse effects on the breastfed child from ACETADOTE
+the underlying maternal condition.
-controlled studies. Use of ACETADOTE in pediatric patients 5 kg and greater is based on clinical practice
-Dosage and Administration (2.4)].
+controlled studies. Use of ACETADOTE in pediatric patients 5 kg and greater is based on clinical practice
+and Administration (2.4)].
+An initial 150 mg/kg dose of acetylcysteine for a patient weighting 106 kg was mistakenly calculated as 1
+decimal point error resulting in a 10-fold higher than prescribed dose). An hour after the infusion started,
+complained of generalized heat sensation and body pain and developed widespread urticaria and hypote
+second acetylcysteine infusion was withheld and the patient was treated for anaphylaxis. Despite treatme
+subcomed to the acute inflammatory reaction and died.
-Acetylcysteine injection is an intravenous antidote for the treatment of acetaminophen overdose. Acetylcy
-the nonproprietary name for the N-acetyl derivative of the naturally occurring amino acid, L-cysteine (N-ac
-cysteine,). The compound is a white crystalline powder, which melts in the range of 104° to 110°C and ha
+Acetylcysteine injection is an intravenous antidote for the treatment of acetaminophen overdose. Acetylcy
+nonproprietary name for the N-acetyl derivative of the naturally occurring amino acid, L-cysteine (N-acety
+cysteine,). The compound is a white crystalline powder, which melts in the range of 104■ to 110■C and
-ACETADOTE® (acetylcysteine) Injection
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+The molecular formula of the compound is C5H9NO3S, and its molecular weight is 163.2. Acetylcysteine
+following structural formula:
+Page 9
+Reference ID: 4513653
-s
-tr
-uctu
-ra
-l f
-or
-mula
-The molecular formula of the compound is C5H9NO3S, and its molecular weight is 163.2. Acetylcysteine
-the following structural formula:
+CH3
+N
+SH
+O
+COOH

+H
-Acetylcysteine has been shown to reduce the extent of liver injury following acetaminophen overdose.
-Acetaminophen doses of 150 mg/kg or greater have been associated with hepatotoxicity. Acetylcysteine p
-protects the liver by maintaining or restoring the glutathione levels, or by acting as an alternate substrate f
-conjugation with, and thus detoxification of, the reactive metabolite of acetaminophen.
+Acetylcysteine has been shown to reduce the extent of liver injury following acetaminophen overdose. Ac
+doses of 150 mg/kg or greater have been associated with hepatotoxicity. Acetylcysteine probably protects
+maintaining or restoring the glutathione levels, or by acting as an alternate substrate for conjugation with,
+detoxification of, the reactive metabolite of acetaminophen.
-After a single intravenous dose of acetylcysteine, the plasma concentration of total acetylcysteine decline
+After a single intravenous dose of acetylcysteine, the plasma concentration of total acetylcysteine decline
-After a single oral dose of [35S]-acetylcysteine 100 mg, between 13 to 38% of the total radioactivity admin
-was recovered in urine within 24 hours. In a separate study, renal clearance was estimated to be approxim
-of total body clearance.
+After a single oral dose of [35S]-acetylcysteine 100 mg, between 13 to 38% of the total radioactivity admi
+recovered in urine within 24 hours. In a separate study, renal clearance was estimated to be approximate
+body clearance.
-AUC) increased 1.6-fold in subjects with hepatic impairment compared to subjects with normal hepatic fun
-These changes are not considered to be clinically meaningful.
+AUC) increased 1.6-fold in subjects with hepatic impairment compared to subjects with normal hepatic fu
+changes are not considered to be clinically meaningful.
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+13 NONCLINICAL TOXICOLOGY
+13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
+Long-term studies in animals have not been performed to evaluate the carcinogenic potential of acetylcys
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-13 NONCLINICAL TOXICOLOGY
-13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
-Long-term studies in animals have not been performed to evaluate the carcinogenic potential of acetylcys
-A randomized, open-label, multi-center clinical study was conducted in Australia in patients with
-acetaminophen poisoning to compare the rates of hypersensitivity reactions between two rates of infusion
-the intravenous acetylcysteine loading dose. One hundred nine subjects were randomized to a 15-minute
-infusion rate and seventy-one subjects were randomized to a 60 minute infusion rate. The loading dose w
-mg/kg followed by a maintenance dose of 50 mg/kg over 4 hours and then 100 mg/kg over 16 hours. Of th
-180 patients, 27% were male and 73% were female. Ages ranged from 15 to 83 years, with the mean age
-30 years (+13.0).
+A randomized, open-label, multi-center clinical study was conducted in Australia in patients with acetamin
+poisoning to compare the rates of hypersensitivity reactions between two rates of infusion for the intraven
+acetylcysteine loading dose. One hundred nine subjects were randomized to a 15-minute infusion rate an
+seventy-one subjects were randomized to a 60 minute infusion rate. The loading dose was 150 mg/kg fol
+by a maintenance dose of 50 mg/kg over 4 hours and then 100 mg/kg over 16 hours. Of the 180 patients
+were male and 73% were female. Ages ranged from 15 to 83 years, with the mean age being 30 years (+
-within 8 hours of acetaminophen ingestion. No hepatotoxicity occurred within this subgroup; however, with
-95% confidence, the true hepatotoxicity rates could range from 0% to 9% for the 15-minute infusion group
-from 0% to 12% for the 60-minute infusion group.
+within 8 hours of acetaminophen ingestion. No hepatotoxicity occurred within this subgroup; however, wit
+confidence, the true hepatotoxicity rates could range from 0% to 9% for the 15-minute infusion group and
+0% to 12% for the 60-minute infusion group.
-acetaminophen overdose over a 16-year period. Of the 1749 patients, 65% were female, 34% were male
-less than 1% was transgender. Ages ranged from 2 months to 96 years, with 72% of the patients falling in
-16- to 40-year-old age bracket. A total of 399 patients received acetylcysteine treatment. A post-hoc analy
-identified 56 patients who (1) were at high or probable risk for hepatotoxicity (APAP greater than 150 mg/l
-the four hours line according to the Australian nomogram) and (2) had a liver function test. Of the 53 patie
-who were treated with intravenous acetylcysteine (300 mg/kg intravenous acetylcysteine administered ove
-21 hours) within 8 hours, two (4%) developed hepatotoxicity (AST or ALT greater than 1000 U/L). Twenty-
-one of 48 (44%) patients treated with acetylcysteine after 15 hours developed hepatotoxicity. The actual

-number of hepatotoxicity outcomes may be higher than what is reported here. For patients with multiple
-admissions for acetaminophen overdose, only the first overdose treated with intravenous acetylcysteine w
-examined. Hepatotoxicity may have occurred in subsequent admissions.
-Evaluable data were available from a total of 148 pediatric patients (less than 16 years of age) who were
-admitted for poisoning following ingestion of acetaminophen, of whom 23 were treated with intravenous
-acetylcysteine. There were no deaths of pediatric patients. None of the pediatric patients receiving intrave
-acetylcysteine developed hepatotoxicity while two patients not receiving intravenous acetylcysteine develo
-hepatotoxicity. The number of pediatric patients is too small to provide a statistically significant finding of
-efficacy; however the results appear to be consistent to those observed for adults.
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+acetaminophen overdose over a 16-year period. Of the 1749 patients, 65% were female, 34% were male
+than 1% was transgender. Ages ranged from 2 months to 96 years, with 72% of the patients falling in the
+40-year-old age bracket. A total of 399 patients received acetylcysteine treatment. A post-hoc analysis id
+56 patients who (1) were at high or probable risk for hepatotoxicity (APAP greater than 150 mg/L at the fo
+hours line according to the Australian nomogram) and (2) had a liver function test. Of the 53 patients who
+treated with intravenous acetylcysteine (300 mg/kg intravenous acetylcysteine administered over 20-21 h
+within 8 hours, two (4%) developed hepatotoxicity (AST or ALT greater than 1000 U/L). Twenty-one of 48
+(44%) patients treated with acetylcysteine after 15 hours developed hepatotoxicity. The actual number of
+hepatotoxicity outcomes may be higher than what is reported here. For patients with multiple admissions
+acetaminophen overdose, only the first overdose treated with intravenous acetylcysteine was examined.
+Hepatotoxicity may have occurred in subsequent admissions.
+Evaluable data were available from a total of 148 pediatric patients (less than 16 years of age) who were
+for poisoning following ingestion of acetaminophen, of whom 23 were treated with intravenous acetylcyst
+There were no deaths of pediatric patients. None of the pediatric patients receiving intravenous acetylcys
+developed hepatotoxicity while two patients not receiving intravenous acetylcysteine developed hepatoto
+The number of pediatric patients is too small to provide a statistically significant finding of efficacy; howev
+results appear to be consistent to those observed for adults.
+16 HOW SUPPLIED/STORAGE AND HANDLING
+ACETADOTE (acetylcysteine) injection is available as a 20% solution (200 mg/mL) in 30 mL single-dose
+Each single dose vial contains 6 g/30mL (200 mg/mL) of ACETADOTE injection. ACETADOTE is sterile a
+be used for intravenous administration. It is available as follows:
+•
+30 mL vials, carton of 4 (NDC 66220-207-30)
+Page 11
+Reference ID: 4513653
-16 HOW SUPPLIED/STORAGE AND HANDLING
-ACETADOTE (acetylcysteine) injection is available as a 20% solution (200 mg/mL) in 30 mL single-dose
-vials. Each single dose vial contains 6 g/30mL (200 mg/mL) of ACETADOTE injection. ACETADOTE is st
-and can be used for intravenous administration. It is available as follows:
-•
-30 mL vials, carton of 4 (NDC 66220-207-30)
-The stopper in the ACETADOTE vial is formulated with a synthetic base-polymer and does not contain Na
-Rubber Latex, Dry Natural Rubber, or blends of Natural Rubber.
-Store unopened vials at controlled room temperature, 20° to 25°C (68° to 77°F) [See USP Controlled Roo
+The stopper in the ACETADOTE vial is formulated with a synthetic base-polymer and does not contain N
+Latex, Dry Natural Rubber, or blends of Natural Rubber.
+Store unopened vials at controlled room temperature, 20■ to 25■C (68■ to 77■F) [See USP Controlled
-Advise patients and caregivers that hypersensitivity reactions related to administration and infusion may o
-during and after ACETADOTE treatment, including hypotension, wheezing, shortness of breath and bronc
-[see Warnings and Precautions (5.1)].
-For specific treatment information regarding the clinical management of acetaminophen overdose, please
-your regional poison center at 1-800-222-1222, or alternatively, a special health professional assistance li
+Advise patients and caregivers that hypersensitivity reactions related to administration and infusion may o
+and after ACETADOTE treatment, including hypotension, wheezing, shortness of breath and bronchospa
+Warnings and Precautions (5.1)].
+For specific treatment information regarding the clinical management of acetaminophen overdose, please
+regional poison center at 1-800-222-1222, or alternatively, a special health professional assistance line fo