AXTLE™
(Pemetrexed for Injection)

Ordering Information

To order AXTLE™ (Pemetrexed for Injection), please contact one of these authorized specialty distributors and use the appropriate order number:

100 mg/vial
NDC: 83831-0131-01

500 mg/vial
NDC: 83831-0132-01

Institutions/Hospitals	100 mg/vial	500 mg/vial
Cardinal Health Specialty	5962121	5962139
CENCORA - ASD Healthcare	10295451	10295442
McKesson Plasma & Biologics	3005485	3005410
Physician Office	**100 mg/vial**	**500 mg/vial**
Cardinal Health Specialty	5962121	5962139
Oncology Supply	10295426	10295460
McKesson Specialty Health	5019191	5019190

Highlights[1]

- Available as pemetrexed dipotassium
- Free from preservative
- Reconstitute with 5% Dextrose Injection, USP (preservative-free)
- Not made with natural rubber latex
- Unique J-Code: J9292

UNIQUE
J-CODE
J9292

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AVYXASSIST™ can offer support to qualifying patients in need. The program provides the following services*

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- Copay assistance

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INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS

Non-Squamous Non-Small Cell Lung Cancer (NSCLC)

AXTLE™ is indicated for:

- in combination with cisplatin for the initial treatment of patients with locally advanced or metastatic, non-squamous NSCLC
- as a single agent for the maintenance treatment of patients with locally advanced or metastatic, non-squamous NSCLC whose disease has not progressed after four cycles of platinum-based first-line chemotherap
- as a single agent for the treatment of patients with recurrent, metastatic non-squamous, NSCLC after prior chemotherapy

Limitations of Use: AXTLE™ is not indicated for the treatment of patients with squamous cell, non-small cell lung cancer.

Mesothelioma

AXTLE™ is indicated, in combination with cisplatin, for the initial treatment of patients with malignant pleural mesothelioma whose disease is unresectable or who are otherwise not candidates for curative surgery.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

AXTLE™ is contraindicated in patients with a history of severe hypersensitivity reaction to pemetrexed.

WARNINGS AND PRECAUTIONS

Myelosuppression and Increased Risk of Myelosuppression without Vitamin Supplementation

AXTLE™ can cause severe myelosuppression resulting in a requirement for transfusions and which may lead to neutropenic infection. The risk of myelosuppression is increased in patients who do not receive vitamin supplementation. In Study JMCH incidences of Grade 3-4 neutropenia (38% versus 23%), thrombocytopenia (9% versus 5%), febrile neutropenia (9% versus 0.6%), and neutropenic infection (6% versus 0) were higher in patients who received pemetrexed plus cisplatin without vitamin supplementation as compared to patients who were fully supplemented with folic acid and vitamin B_{12} prior to and throughout pemetrexed plus cisplatin treatment.

Initiate supplementation with oral folic acid and intramuscular vitamin B_{12} prior to the first dose of AXTLE™; continue vitamin supplementation during treatment and for 21 days after the last dose of AXTLE™ to reduce the severity of hematologic and gastrointestinal toxicity of AXTLE™. Obtain a complete blood count at the beginning of each cycle. Do not administer AXTLE™ until the ANC is at least 1500 cells/mm^3 and platelet count is at least 100,000 cells/mm^3 . Permanently reduce AXTLE™ in patients with an ANC of less than 500 cells/mm^3 or platelet count of less than 50,000 cells/mm^3 in previous cycles.

In Studies JMDB and JMCH, among patients who received vitamin supplementation, incidence of Grade 3-4 neutropenia was 15% and 23%, the incidence of Grade 3-4 anemia was 6% and 4%, and incidence of Grade 3-4 thrombocytopenia was 4% and 5%, respectively. In Study JMCH, 18% of patients in the pemetrexed arm required red blood cell transfusions compared to 7% of patients in the cisplatin arm. In Studies JMEN, PARAMOUNT, and JMEI, where all patients received vitamin supplementation, incidence of Grade 3-4 neutropenia ranged from 3% to 5%, and incidence of Grade 3-4 anemia ranged from 3% to 5%.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Renal Failure

AXTLE™ can cause severe, and sometimes fatal, renal toxicity. The incidences of renal failure in clinical studies in which patients received pemetrexed with cisplatin were: 2.1% in Study JMDB and 2.2% in Study JMCH. The incidence of renal failure in clinical studies in which patients received pemetrexed as a single agent ranged from 0.4% to 0.6% (Studies JMEN, PARAMOUNT, and JMEI. Determine creatinine clearance before each dose and periodically monitor renal function during treatment with AXTLE™. Withhold AXTLE™ in patients with a creatinine clearance of less than 45 mL/minute.

Bullous and Exfoliative Skin Toxicity

Serious and sometimes fatal, bullous, blistering and exfoliative skin toxicity, including cases suggestive of Stevens-Johnson Syndrome/Toxic epidermal necrolysis can occur with AXTLE™. Permanently discontinue AXTLE™ for severe and life-threatening bullous, blistering or exfoliating skin toxicity.

Interstitial Pneumonitis

Serious interstitial pneumonitis, including fatal cases, can occur with AXTLE™ treatment. Withhold AXTLE™ for acute onset of new or progressive unexplained pulmonary symptoms such as dyspnea, cough, or fever pending diagnostic evaluation. If pneumonitis is confirmed, permanently discontinue AXTLE™.

Radiation Recall

Radiation recall can occur with AXTLE™ in patients who have received radiation weeks to years previously. Monitor patients for inflammation or blistering in areas of previous radiation treatment. Permanently discontinue AXTLE™ for signs of radiation recall.

Increased Risk of Toxicity with Ibuprofen in Patients with Renal Impairment

Exposure to pemetrexed is increased in patients with mild to moderate renal impairment who take concomitant ibuprofen, increasing the risks of adverse reactions of AXTLE™. In patients with creatinine clearances between 45 mL/min and 79 mL/min, avoid administration of ibuprofen for 2 days before, the day of, and 2 days following administration of AXTLE™. If concomitant ibuprofen use cannot be avoided, monitor patients more frequently for pemetrexed adverse reactions, including myelosuppression, renal, and gastrointestinal toxicity.

Embryo-Fetal Toxicity

Based on findings from animal studies and its mechanism of action, AXTLE™ can cause fetal harm when administered to a pregnant woman. In animal reproduction studies, intravenous administration of pemetrexed to pregnant mice during the period of organogenesis was teratogenic, resulting in developmental delays and increased malformations at doses lower than the recommended human dose of 500 mg/m^2. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with AXTLE™ and for 6 months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with AXTLE™ and for 3 months after the last dose.

IMPORTANT SAFETY INFORMATION (CONTINUED)

ADVERSE REACTIONS

In clinical trials, the most common adverse reactions (incidence ≥20%) of pemetrexed, when administered as a single agent, are fatigue, nausea, and anorexia. The most common adverse reactions (incidence ≥20%) of pemetrexed, when administered in combination with cisplatin are vomiting, neutropenia, anemia, stomatitis/pharyngitis, thrombocytopenia, and constipation.

Non-Squamous NSCLC

Initial Treatment in Combination with Cisplatin (Study JMDB)

The safety of pemetrexed was evaluated in chemotherapy-naïve patients with locally advanced or metastatic NSCLC. Patients received either pemetrexed 500 mg/m^2 intravenously and cisplatin 75 mg/m^2 intravenously (N=839) or gemcitabine 1250 mg/m^2 intravenously and cisplatin 75 mg/m^2 intravenously (N=830).

The following adverse reactions occurred in ≥5% of fully vitamin-supplemented patients (with folic acid and vitamin B_{12}) who received pemetrexed in combination with cisplatin chemotherapy compared to those who received gemcitabine in combination with cisplatin, respectively: anemia (33% [6% Grade 3-4] versus 46% [10% Grade 3-4], respectively), neutropenia (29% [15% Grade 3-4] versus 38% [27% Grade 3-4], respectively), thrombocytopenia (10% [4% Grade 3-4] versus 27% [13% Grade 3-4], respectively), elevated creatinine (10% [1% Grade 3-4] versus 7% [1% Grade 3-4], respectively), fatigue (43% [7% Grade 3-4] versus 45% [5% Grade 3-4], respectively), nausea (56% [7% Grade 3-4] versus 53% [4% Grade 3-4], respectively), vomiting (40% [6% Grade 3-4] versus 36% [6% Grade 3-4], respectively), anorexia (27% [2% Grade 3-4] versus 24% [1% Grade 3-4], respectively), constipation (21% [1% Grade 3-4] versus 20% [0% Grade 3-4], respectively), stomatitis/pharyngitis (14% [1% Grade 3-4] versus 12% [0% Grade 3-4], respectively), diarrhea (12% [1% Grade 3-4] versus 13% [2% Grade 3-4], respectively), dyspepsia/heartburn (5% [0% Grade 3-4] versus 6% [0% Grade 3-4], respectively), sensory neuropathy (9% [0% Grade 3-4] versus 12% [1% Grade 3-4], respectively), taste disturbance (8% [0% Grade 3-4] versus 9% [0% Grade 3-4], respectively), alopecia (12% [0% Grade 3-4] versus 21% [1% Grade 3-4], respectively), and rash/desquamation (7% [0% Grade 3-4] versus 8% [1% Grade 3-4], respectively).

The following additional adverse reactions of pemetrexed were observed with an incidence of 1% to <5%: febrile neutropenia, infection, pyrexia, dehydration, increased AST, increased ALT, renal failure, and conjunctivitis.

The following additional adverse reactions of pemetrexed were observed with an incidence of <1%: arrhythmia, chest pain, increased GGT, and motor neuropathy.

Maintenance Treatment Following First-line Non-Pemetrexed Containing Platinum-Based Chemotherapy

The safety of pemetrexed was evaluated in patients with non-progressive locally advanced or metastatic NSCLC following four cycles of a first-line, platinum-based chemotherapy regimen. Patients received either pemetrexed 500 mg/^{2} (N=438) or matching placebo (N=218) intravenously.

The following adverse reactions occurred in ≥5% of fully vitamin-supplemented patients (with folic acid and vitamin B_{12}) who received pemetrexed compared to placebo, respectively: anemia (15% [3% Grade 3-4] versus 6% [1% Grade 3-4], respectively), neutropenia (6% [3% Grade 3-4] versus 0%, respectively), increased ALT (10% [0% Grade 3-4] versus 4% [0% Grade 3-4], respectively), increased AST (8% [0% Grade 3-4] versus 4% [0% Grade 3-4], respectively), fatigue (25% [5% Grade 3-4] versus 11% [1% Grade 3-4], respectively), nausea (19% [1% Grade 3-4] versus 6% [1% Grade 3-4], respectively), anorexia (19% [2% Grade 3-4] versus 5% [0% Grade 3-4], respectively), vomiting (9% [0% Grade 3-4] versus 1% [0% Grade 3-4], respectively), mucositis/stomatitis (7% [1% Grade 3-4] versus 2% [0% Grade 3-4], respectively), diarrhea (5% [1% Grade 3-4] versus 3% [0% Grade 3-4], respectively), sensory neuropathy (9% [1% Grade 3-4] versus 4% [0% Grade 3-4], respectively), and rash/desquamation (10% [0% Grade 3-4] versus 3% [0% Grade 3-4], respectively).

IMPORTANT SAFETY INFORMATION (CONTINUED)

The requirement for transfusions (9.5% versus 3.2%), primarily red blood cell transfusions, and for erythropoiesis stimulating agents (5.9% versus 1.8%) were higher in the pemetrexed arm compared to the placebo arm.

The following additional adverse reactions were observed in 1% to <5% of patients who received pemetrexed: alopecia, pruritis/itching, constipation, edema, fever, thrombocytopenia, ocular surface disease (including conjunctivitis), and increased lacrimation.

The following additional adverse reactions were observed in <1% of patients who received pemetrexed: supraventricular arrhythmia, erythema multiforme, febrile neutropenia, allergic reaction/hypersensitivity, motor neuropathy, and renal failure.

Maintenance Treatment Following First-line Pemetrexed Plus Platinum Chemotherapy

The safety of pemetrexed was evaluated in patients with non-squamous NSCLC with non-progressive (stable or responding disease) locally advanced or metastatic NSCLC following four cycles of pemetrexed in combination with cisplatin as first-line therapy for NSCLC.

The following adverse reactions occurred in ≥5% of fully vitamin-supplemented patients (with folic acid and vitamin B_{12}) who received pemetrexed (500 mg/m^2; N=333) intravenously compared to placebo (N=167), respectively: anemia (15% [4.8% Grade 3-4] versus 4.8% [0.6% Grade 3-4], respectively), neutropenia (9% [3.9% Grade 3-4] versus 0.6% [0% Grade 3-4], respectively), fatigue (18% [4.5% Grade 3-4] versus 11% [0.6% Grade 3-4], respectively), nausea (12% [0.3% Grade 3-4] versus 2.4% [0% Grade 3-4], respectively), vomiting (6% [0% Grade 3-4] versus 1.8% [0% Grade 3-4], respectively), mucositis/stomatitis (5% [0.3% Grade 3-4] versus 2.4% [0% Grade 3-4], respectively), and edema (5% [0% Grade 3-4] versus 3.6% [0% Grade 3-4], respectively).

The requirement for red blood cell (13% versus 4.8%) and platelet (1.5% versus 0.6%) transfusions, erythropoiesis stimulating agents (12% versus 7%), and granulocyte colony stimulating factors (6% versus 0%) were higher in the pemetrexed arm compared to the placebo arm.

The following additional Grade 3 or 4 adverse reactions were observed more frequently in patients who received pemetrexed.

At an incidence of 1% to <5%: thrombocytopenia and febrile neutropenia.

At an incidence of <1%: ventricular tachycardia, syncope, pain, gastrointestinal obstruction, depression, renal failure, and pulmonary embolism.

Treatment of Recurrent Disease After Prior Chemotherapy

The safety of pemetrexed was evaluated in patients who had progressed following platinum-based chemotherapy. The following adverse reactions occurred in ≥5% of fully vitamin-supplemented patients (with folic acid and vitamin B_{12}) who received pemetrexed (500 mg/m^2; N=265) intravenously compared to those who received docetaxel (75 mg/m^2; N=276), respectively: anemia (19% [4% Grade 3-4] versus 22% [4% [Grade 3-4], respectively), neutropenia (11% [5% Grade 3-4] versus 45% [40% Grade 3-4], respectively), thrombocytopenia (8% [2% Grade 3-4] versus 1% [0% Grade 3-4], respectively), increased ALT (8% [2% Grade 3-4] versus 1% [0% Grade 3-4], respectively), increased AST (7% [1% Grade 3-4] versus 1% [0% Grade 3-4], respectively), nausea (31% [3% Grade 3-4] versus 17% [2% Grade 3-4], respectively), anorexia (22% [2% Grade 3-4] versus 24% [3% Grade 3-4], respectively), vomiting (16% [2% Grade 3-4] versus 12%

IMPORTANT SAFETY INFORMATION (CONTINUED)

[1% Grade 3-4], respectively), stomatitis/pharyngitis (15% [1% Grade 3-4] versus 17% [1% Grade 3-4], respectively), diarrhea (13% [0% Grade 3-4] versus 24% [3% Grade 3-4], respectively), constipation (6% [0% Grade 3-4] versus 4% [0% Grade 3-4], respectively), fatigue (34% [5% Grade 3-4] versus 36% [5% Grade 3-4], respectively), fever (8% [0% Grade 3-4] versus 8% [0% Grade 3-4], respectively), rash/desquamation (14% [0% Grade 3-4] versus 6% [0% Grade 3-4], respectively) pruritus (7% [0% Grade 3-4] versus 2% [0% Grade 3-4], respectively), and alopecia (6% [1% Grade 3-4] versus 38% [2% Grade 3-4], respectively).

The following additional adverse reactions were observed in 1% to <5% of patients who received pemetrexed: abdominal pain, allergic reaction/hypersensitivity, febrile neutropenia, infection, erythema multiforme, motor neuropathy, and sensory neuropathy.

The following additional adverse reactions were observed in <1% of patients who received pemetrexed: supraventricular arrhythmias, and renal failure.

Mesothelioma

The safety of pemetrexed was evaluated in patients with MPM who had received no prior chemotherapy for MPM. Among 226 patients who received pemetrexed in combination with cisplatin, 74% (n=168) received full supplementation with folic acid and vitamin B_{12}, 14% (n=32) were never supplemented, and 12% (n=26) were partially supplemented. The following adverse reactions occurred in ≥5% of patients who received pemetrexed (500 mg/m^2) intravenously in combination with cisplatin (75 mg/m^2) intravenously (N=168) compared to those who received cisplatin (75 mg/m^2; N=163), respectively: neutropenia (56% [23% Grade 3-4] versus 13% [3% Grade 3-4], respectively), anemia (26% [4% Grade 3-4] versus 10% [0% Grade 3-4], respectively), thrombocytopenia (23% [5% Grade 3-4] versus 9% [0% Grade 3-4], respectively), elevated creatinine (11% [1% Grade 3-4] versus 10% [1% Grade 3-4], respectively), decreased creatinine clearance (16% [1% Grade 3-4] versus 18% [2% Grade 3-4], respectively), conjunctivitis (5% [0% Grade 3-4] versus 1% [0% Grade 3-4], respectively), nausea (82% [12% Grade 3-4] versus 77% [6% Grade 3-4], respectively), vomiting (57% [11% Grade 3-4] versus 50% [4% Grade 3-4], respectively), stomatitis/pharyngitis (23% [3% Grade 3-4] versus 6% [0% Grade 3-4], respectively), anorexia (20% [1% Grade 3-4] versus 14% [1% Grade 3-4], respectively), diarrhea (17% [4% Grade 3-4] versus 8% [0% Grade 3-4], respectively), constipation (12% [1% Grade 3-4] versus 7% [1% Grade 3-4], respectively), dyspepsia (5% [1% Grade 3-4] versus 1% [0% Grade 3-4], respectively), fatigue (48% [10% Grade 3-4] versus 42% [9% Grade 3-4], respectively), dehydration (7% [4% Grade 3-4] versus 1% [1% Grade 3-4], respectively), sensory neuropathy (10% [0% Grade 3-4] versus 10% [1% Grade 3-4], respectively), taste disturbance (8% [0% Grade 3-4] versus 6% [0% Grade 3-4], respectively), rash (16% [1% Grade 3-4] versus 5% [0% Grade 3-4], respectively), and alopecia (11% [0% Grade 3-4] versus 6% [0% Grade 3-4], respectively).

The following additional adverse reactions were observed in 1% to <5% of patients who received pemetrexed in combination with cisplatin: febrile neutropenia, infection, pyrexia, urticaria, chest pain, increased AST, increased ALT, increased GGT, and renal failure.

The following additional adverse reactions were observed in <1% of patients who received pemetrexed in combination with cisplatin: arrhythmia and motor neuropathy.

Exploratory subgroup analyses demonstrated that NCI CTCAE Grade 3 or 4 adverse reactions were reported in more pemetrexed-treated patient who did not receive vitamin supplementation (never supplemented; N=32) compared to those who received daily folic acid and vitamin B_{12} (fully supplemented; N=168). Selected Grade 3-4 adverse reactions that occurred in patients receiving pemetrexed in combination with cisplatin with or without full vitamin supplementation, respectively, included: neutropenia (23% versus 38%, respectively), thrombocytopenia (5% versus 9%, respectively), vomiting (11% versus 31%, respectively), febrile neutropenia (1% versus 9%, respectively), infection with Grade 3 or 4 neutropenia (0% versus 6%, respectively), and diarrhea (4% versus 9%, respectively).

IMPORTANT SAFETY INFORMATION (CONTINUED)

The following adverse reactions occurred more frequently in patients who were fully vitamin supplemented than in patients who were never supplemented: hypertension (11% versus 3%, respectively), chest pain (8% versus 6%, respectively), and thrombosis/embolism (6% versus 3%, respectively).

Additional Experience Across Clinical Trials

Sepsis, with or without neutropenia, including fatal cases occurred in 1% of patients. Severe esophagitis, resulting in hospitalization occurred in <1%.

Postmarketing Experience

The following adverse reactions have been identified during post-approval use of pemetrexed. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Immune-mediated hemolytic anemia, colitis, pancreatitis, edema, radiation recall, interstitial pneumonitis, serious and fatal bullous skin conditions, Stevens-Johnson syndrome, and toxic epidermal necrolysis were reported during post-approval use of pemetrexed.

DRUG INTERACTIONS

Effects of Ibuprofen on Pemetrexed

Ibuprofen increases exposure (AUC) of pemetrexed. In patients with creatinine clearance between 45 mL/min and 79 mL/min:

- Avoid administration of ibuprofen for 2 days before, the day of, and 2 days following administration of AXTLE™.
- Monitor patients more frequently for myelosuppression, renal, and gastrointestinal toxicity, if concomitant administration of ibuprofen cannot be avoided.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

Based on findings from animal studies and its mechanism of action, AXTLE™ can cause fetal harm when administered to a pregnant woman. There are no available data on pemetrexed use in pregnant women. In animal reproduction studies, intravenous administration of pemetrexed to pregnant mice during the period of organogenesis was teratogenic, resulting in developmental delays and malformations at doses lower than the recommended human dose of 500 mg/m^2. Advise pregnant women of the potential risk to a fetus.

In the 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.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Data

Animal Data

Pemetrexed was teratogenic in mice. Daily dosing of pemetrexed by intravenous injection to pregnant mice during the period of organogenesis increased the incidence of fetal malformations (cleft palate; protruding tongue; enlarged or misshaped kidney; and fused lumbar vertebra) at doses (based on BSA) 0.03 times the human dose of 500 mg/m^2. At doses, based on BSA, greater than or equal to 0.0012 times the 500 mg/m^2 human dose, pemetrexed administration resulted in dose-dependent increases in developmental delays (incomplete ossification of talus and skull bone; and decreased fetal weight).

Lactation

Risk Summary

There is no information regarding the presence of pemetrexed or its metabolites in human milk, the effects on the breastfed infant, or the effects on milk production. Because of the potential for serious adverse reactions in breastfed infants from pemetrexed, advise women not to breastfeed during treatment with AXTLE™ and for one week after last dose.

Females and Males of Reproductive Potential

Based on animal data, pemetrexed can cause malformations and developmental delays when administered to a pregnant woman.Verify pregnancy status of females of reproductive potential prior to initiating AXTLE™.

Because of the potential for genotoxicity, advise females of reproductive potential to use effective contraception during treatment with AXTLE™ and for 6 months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with AXTLE™ and for 3 months after the last dose.

AXTLE™ may impair fertility in males of reproductive potential. It is not known whether these effects on fertility are reversible.

Pediatric Use

The safety and effectiveness of AXTLE™ in pediatric patients have not been established.

Geriatric Use

Of the 3,946 patients enrolled in clinical studies of pemetrexed, 34% were 65 and over and 4% were 75 and over. No overall differences in effectiveness were observed between these patients and younger patients. The incidences of Grade 3-4 anemia, fatigue, thrombocytopenia, hypertension, and neutropenia were higher in patients 65 years of age and older as compared to younger patients: in at least one of five randomized clinical trials.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Patients with Renal Impairment

Pemetrexed is primarily excreted by the kidneys. Decreased renal function results in reduced clearance and greater exposure (AUC) to pemetrexed compared with patients with normal renal function. No dose is recommended for patients with creatinine clearance less than 45 mL/min.

OVERDOSAGE

No drugs are approved for the treatment of pemetrexed overdose. Based on animal studies, administration of leucovorin may mitigate the toxicities of pemetrexed overdosage. It is not known whether pemetrexed is dialyzable.

Please see the full Prescribing Information for safety information and dosing guidelines.

To report SUSPECTED ADVERSE REACTIONS, contact Avyxa Pharma, LLC at 1-888-520-0954 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.