NEW INDICATIONS

IOFLUPANE I 123
(DaTscan—GE Healthcare)

Indication: DaTscan is indicated as an adjunct to other diagnostic evaluations for striatal dopamine transporter visualization using single photon emission computed tomography (SPECT) brain imaging in adult patients with suspected Parkinsonian syndromes or suspected dementia with Lewy bodies.

Recommended dosage and administration: The recommended dose of DaTscan in adults is 111 MBq to 185 MBq (3 mCi to 5 mCi) administered intravenously over at least 20 seconds. The patient dose should be measured using a dose calibrator immediately prior to administration. SPECT imaging should begin between 3 and 6 hours postinjection. A thyroid-blocking agent should be administered at least 1 hour before the dose of DaTscan is administered.

Common adverse effects: The most common adverse reactions in patients who are administered DaTscan include headache, nausea, vertigo, dry mouth, and dizziness.

Warnings and precautions: DaTscan is contraindicated in patients with known serious hypersensitivity to ioflupane I 123. Hypersensitivity reactions such as dyspnea, edema, rash, erythema, and pruritus have been reported. Treatment measures should be available prior to DaTscan administration. Thyroid uptake of iodine-123 may result in an increased long-term risk for thyroid neoplasia. Ensure safe handling of DaTscan to minimize radiation exposure to the patient and health care providers. Advise patients to hydrate before and after administration and to void frequently after administration.

Use should be avoided in pregnancy as DaTscan may cause fetal harm. Lactating patients should be advised to interrupt breastfeeding and pump and discard breastmilk for at least 6 days after DaTscan administration. Amoxapine, amphetamine, armodafinil, benztropine, bupropion, buspirone, cocaine, mazindol, phentermine, phenylpropanolamine, selegiline, sertraline, citalopram, and paroxetine may interfere with DaTscan imaging. The effects of dopamine agonists and antagonists on DaTscan imaging have not been established.

LEVONORGESTREL
(Liletta—Medicines360)

Indication: Liletta is a progestin-containing intrauterine system (IUS) indicated for prevention of pregnancy for up to 8 years.

Recommended dosage and administration: The initial release rate of levonorgestrel is approximately 20 mcg/day and declines progressively to approximately 6.5 mcg/day after 8 years. Liletta can be removed at any time but must be removed by end of the eighth year. Insertion instructions should be followed exactly as described. Liletta should be inserted into the uterine cavity with the provided inserter by a trained health care professional using strict aseptic technique. Re-examination and evaluation should be considered 4 to 6 weeks after insertion and during routine care, or more often if clinically indicated.

Common adverse effects: The most common adverse reactions reported in patients using Liletta are vulvovaginal mycotic infections, vaginal bacterial infections, acne, nausea, or vomiting.

Warnings and precautions: Liletta is contraindicated in pregnancy, use for postcoital contraception, congenital or acquired uterine anomaly that distorts the uterine cavity and would be incompatible with correct IUS placement, acute pelvic inflammatory disease, postpartum endometritis or infected abortion in the past 3 months, known or suspected uterine or cervical neoplasia, known or suspected breast cancer or other hormone-sensitive cancer, uterine bleeding of unknown etiology, untreated acute cervicitis or vaginitis or other lower genital tract infections, acute liver disease or liver tumor, increased susceptibility to pelvic infections, a previously inserted IUS that has not been removed, and hypersensitivity to any component of Liletta.

Remove Liletta if pregnancy occurs with Liletta in place and Liletta is in the uterus. If pregnancy occurs, there is increased risk of ectopic pregnancy, pregnancy loss, septic abortion, and premature labor and delivery. Severe infection or sepsis, including Group A streptococcal sepsis, have been reported following insertion of levonorgestrel-releasing IUSs. Before using Liletta, consider the risks of pelvic infection. Perforation may occur and reduce contraceptive effectiveness or require surgery. This risk is increased if inserted in patients who have fixed retroverted uteri, are postpartum, or are lactating. Partial or complete expulsion may occur. Evaluate persistent enlarged ovarian follicles or ovarian cysts. Bleeding patterns can become altered, may remain irregular, and amenorrhea may ensue.

PEMETREXED
(Pemetrexed—Actavis)

Indication: Pemetrexed is a folate analog metabolic inhibitor indicated

in combination with pembrolizumab and platinum chemotherapy for the initial treatment of patients with metastatic non-squamous non-small cell lung cancer (NSCLC) with no epidermal growth factor receptor or anaplastic lymphoma kinase genomic tumor aberrations, in combination with cisplatin for the initial treatment of patients with locally advanced or metastatic NSCLC, as a single agent for the maintenance treatment of patients with locally advanced or metastatic NSCLC whose disease has not progressed after 4 cycles of platinum-based first-line chemotherapy, as a single agent for the treatment of patients with recurrent, metastatic NSCLC after prior chemotherapy and initial treatment, in combination with cisplatin, of patients with malignant pleural mesothelioma whose disease is unresectable or who otherwise are not candidates for curative surgery. Pemetrexed injection is not indicated for the treatment of patients with squamous cell, non-small cell lung cancer.

Recommended dosage and administration: The recommended dose of Pemetrexed administered with pembrolizumab and platinum chemotherapy in patients with a creatinine clearance of ≥45 mL/min is 500 mg/m^2 as an intravenous infusion over 10 minutes, administered after pembrolizumab and prior to platinum chemotherapy, on day 1 of each 21-day cycle. The recommended dose of pemetrexed administered as a single agent or with cisplatin in patients with a creatine clearance of ≥45 mL/min is 500 mg/m^2 as an intravenous infusion over 10 minutes on day 1 of each 21-day cycle. Initiate folic acid 400 mcg to 1,000 mcg orally, once daily, beginning 7 days prior to the first dose of Pemetrexed and continue until 21 days after the last dose of pemetrexed. Administer vitamin B12, 1 mg intramuscularly, 1 week prior to the first dose of pemetrexed and every 3 cycles. Administer dexamethasone 4 mg orally, twice daily the day before, the day of, and the day after Pemetrexed administration.

Label change for Amoxil

In early November 2022, FDA approved several safety-related label changes for Amoxil (GSK). One of the most significant changes includes a new addition to the warnings and precautions section for "severe cutaneous adverse reactions" (SCARs). This new subsection states that Amoxil may cause SCARs like Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms, and acute generalized exanthematous pustulosis. Skin rash accompanied by arthritis, arthralgia, myalgia, and fever was also listed as a possible immune reaction to the medication. Aseptic meningitis was listed as a potential central nervous system adverse reaction.

The label change also advises prescribers to educate patients about the signs and symptoms of serious skin manifestations and to instruct patients to discontinue treatment if rashes or skin lesions progress. Another notable change is related to the storage and special handling of Amoxil. The updated label states that while it is preferable to keep Amoxil suspensions in the refrigerator, it is not a requirement. Amoxil suspensions can be kept at room temperature as long as the lid is securely fastened between uses.

Common adverse effects: The most common adverse reactions of Pemetrexed when administered as a single agent are fatigue, nausea, and anorexia. The most common adverse reactions of Pemetrex ed when administered with cisplatin are vomiting, neutropenia, anemia, stomatitis/pharyngitis, thrombocytopenia, and constipation. The most common adverse reactions of Pemetrexed when administered in combination with pembrolizumab and platinum chemotherapy are fatigue/asthenia, nausea, constipation, diarrhea, decreased appetite, rash, vomiting, cough, dyspnea, and pyrexia.

Warnings and precautions: Pemetrexed is contraindicated in patients with a history of severe hypersensitivity reaction to Pemetrexed. Pemetrexed can cause severe bone marrow suppression resulting in cytopenia and in increased risk of infection. Do not administer when the absolute neutrophil count is <1,500 cells/mm^3 and platelets are <100,000 cells/mm^3. Initiate supplementation with oral folic acid and intramuscular vitamin B12 to reduce the severity of hematologic and GI toxicity of Pemetrexed. Use can cause severe, and sometimes fatal, renal failure. Do not administer when creatinine clearance is <45 mL/min.

Permanently discontinue for severe and life-threatening bullous, blistering, or exfoliating skin toxicity. Withhold for acute onset of new or progressive unexplained pulmonary symptoms. Permanently discontinue if pneumonitis is confirmed. Radiation recall can occur in patients who received radiation weeks to years previously. Permanently discontinue if signs of radiation recall occur. Pemetrexed can cause fetal harm and patients should be advised of the potential risk to a fetus and to use effective contraception. Patients should be advised not to breastfeed. Ibuprofen use increases risk of Pemetrexed toxicity in patients with mild to moderate renal impairment. Modify the ibuprofen dosage as recommended for patients with a creatine clearance between 45 mL/min and 79 mL/min. ■

Also in this issue
FDA approves ScPharmaceuticals' heart failure therapy (page 18)