onivyde® (irinotecan liposome injection)

Please print the form, sign it, and fax it to IPSEN CARES® at **1-888-525-2416**, or send the form to:

IPSEN CARES® Program
Ipsen Biopharmaceuticals, Inc.
11800 Weston Parkway
Cary, NC 27513

PATIENT AUTHORIZATION

Patient Authorization and Signature - IPSEN CARES® Program

I authorize my healthcare providers (including those pharmacies that may receive my prescription for ONIVYDE®), to disclose personal health information (PHI) about me, including health information relating to my medical condition, treatment, and insurance coverage, to Ipsen Biopharmaceuticals, Inc., its affiliates, and its agents that have been hired to administer the Ipsen Coverage, Access, Reimbursement & Education Support (IPSEN CARES®) program on its behalf (collectively, "Ipsen") in order for Ipsen to (1) enroll me in IPSEN CARES®; (2) establish my benefit eligibility and potential out-of-pocket costs for ONIVYDE®; (3) communicate with my healthcare providers and health plans about my treatment plan; (4) provide support services including patient education and financial assistance for ONIVYDE®; (5) help get ONIVYDE® shipped to me or my healthcare providers; (6) evaluate my eligibility for home health administration if requested by my physician; and (7) facilitate my participation in ONIVYDE® patient programs that I have elected to receive information about, as indicated below. I agree that, using the contact information I provide, Ipsen may get in touch with me for reasons related to the IPSEN CARES® program and support services and may leave messages for me that may disclose that I am on ONIVYDE® therapy. I consent to being contacted by an IPSEN CARES® program representative in order for the program to obtain further information or clarification regarding any adverse event I may experience. Similarly, I consent to a program representative contacting my doctor or other healthcare professional for the same purpose.

I understand that once my PHI has been disclosed to Ipsen, it is no longer protected by federal privacy laws and Ipsen may re-disclose it; however, Ipsen has agreed to protect my PHI by using and disclosing it only for the purposes described above or as required by law. I understand that my healthcare providers may receive remuneration from Ipsen in exchange for my PHI and/or for any therapy support services provided to me.

I can withdraw this authorization by calling IPSEN CARES® at 1-866-435-5677 or mailing a letter requesting such revocation to IPSEN CARES®, 11800 Weston Parkway, Cary, NC 27513, but it will not change any actions taken before I withdraw authorization. Withdrawal of authorization will end further uses and disclosures of PHI by the parties identified in this form except to the extent those uses and disclosures have been made in reliance upon my authorization. I understand that I may refuse to sign this form and, if I do so, I will not be able to participate in IPSEN CARES® programs, but it will not affect my eligibility to obtain medical treatment, my ability to seek payment for this treatment or affect my insurance enrollment or eligibility for insurance coverage. This authorization expires one year after the date I sign it below. I understand that I will receive a copy of the signed authorization.

Patient Name _____ Caregiver _____
Name _____ Relationship to Patient _____
Signature _____ Date _____
Patient Date of Birth _____ Patient Phone Number _____

ADDITIONAL PRODUCT AND SUPPORT INFORMATION

In addition to participating in the IPSEN CARES® program, I would also like to receive information from Ipsen, which may include marketing and educational material about ONIVYDE® and programs that support patients. I understand that I do not have to sign this section of the form in order to participate in the IPSEN CARES® program and that I may revoke my authorization to receive additional product information at any time. By signing below, I agree that Ipsen and its agents may use and disclose my personal information (including name, address, phone number, and/or email of the parent/caregiver) to provide these services and Ipsen may also contact me to solicit my opinions regarding ONIVYDE® and Ipsen's products and services. I understand that my cell phone carrier's standard rates may apply for calls to my cell phone. This authorization is valid for one year from the date I sign the form. I may revoke this authorization, by calling 866.435.5677 or sending a request in writing to: IPSEN CARES®, 11800 Weston Parkway, Cary, NC 27513.

Patient Name _____ Caregiver _____
Name _____ Relationship to Patient _____
Signature _____ Date _____

INDICATION

ONIVYDE® (irinotecan liposome injection) is indicated, in combination with fluorouracil (5-FU) and leucovorin (LV), for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy.

Limitation of Use: ONIVYDE® is not indicated as a single agent for the treatment of patients with metastatic adenocarcinoma of the pancreas.

IMPORTANT SAFETY INFORMATION

WARNING: SEVERE NEUTROPENIA and SEVERE DIARRHEA

Fatal neutropenic sepsis occurred in 0.8% of patients receiving ONIVYDE®. severe or life- threatening neutropenic fever or sepsis occurred in 3% and severe or life-threatening neutropenia occurred in 20% of patients receiving ONIVYDE® in combination with 5-FU and LV. withhold ONIVYDE® for absolute neutrophil count below 1500/mm3 or neutropenic fever. Monitor blood cell counts periodically during treatment.

severe diarrhea occurred in 13% of patients receiving ONIVYDE® in combination with 5-FU/LV. Do not administer ONIVYDE® to patients with bowel obstruction. withhold ONIVYDE® for diarrhea of Grade 2–4 severity. Administer loperamide for late diarrhea of any severity. Administer atropine, if not contraindicated, for early diarrhea of any severity.

CONTRAINDICATIONS

ONIVYDE® is contraindicated in patients who have experienced a severe hypersensitivity reaction to ONIVYDE® or irinotecan HCl.

WARNINGS AND PRECAUTIONS

Severe Neutropenia

ONIVYDE® can cause severe or life-threatening neutropenia and fatal neutropenic sepsis. In a clinical study, the incidence of fatal neutropenic sepsis was 0.8% among patients receiving ONIVYDE®, occurring in 1/117 patients in the ONIVYDE® + 5-FU/LV arm and 1/147 patients receiving ONIVYDE® as a single agent. Severe or life-threatening neutropenia occurred in 20% of patients receiving ONIVYDE® + 5-FU/LV vs 2% of patients receiving 5-FU/LV. Grade 3/4 neutropenic fever/neutropenic sepsis occurred in 3% of patients receiving ONIVYDE® + 5-FU/LV, and did not occur in patients receiving

5-FU/LV. In patients receiving ONIVYDE® + 5-FU/LV, the incidence of Grade 3/4 neutropenia was higher among Asian (18/33 [55%]) vs White patients (13/73 [18%]). Neutropenic fever/ neutropenic sepsis was reported in 6% of Asian vs 1% of White patients.

Severe Diarrhea

ONIVYDE® can cause severe and life-threatening diarrhea. Do not administer ONIVYDE® to patients with bowel obstruction. Severe and life-threatening lateonset (onset >24 hours after chemotherapy) and earlyonset diarrhea (onset =24 hours after chemotherapy, sometimes with other symptoms of cholinergic reaction) were observed. An individual patient may experience both early- and late-onset diarrhea. In a clinical study, Grade 3/4 diarrhea occurred in 13% of patients receiving ONIVYDE® + 5-FU/LV vs 4% receiving 5-FU/LV. Grade 3/4 late-onset diarrhea occurred in 9% of patients receiving ONIVYDE® + 5-FU/LV vs 4% in patients receiving 5-FU/LV; the incidences of earlyonset diarrhea were 3% and no Grade 3/4 incidences, espectively. Of patients receiving ONIVYDE® + 5-FU/LV, 34% received loperamide for late-onset diarrhea and 26% received atropine for early-onset diarrhea.

Interstitial Lung Disease (ILD)

Irinotecan HCl can cause severe and fatal ILD. Withhold ONIVYDE® in patients with new or progressive dyspnea, cough, and fever, pending diagnostic evaluation. Discontinue ONIVYDE® in patients with a confirmed diagnosis of ILD.

Severe Hypersensitivity Reactions

Irinotecan HCl can cause severe hypersensitivity reactions, including anaphylactic reactions. Permanently discontinue ONIVYDE® in patients who experience a severe hypersensitivity reaction.

Embryo-Fetal Toxicity

Based on animal data with irinotecan HCl and the mechanism of action of ONIVYDE®, ONIVYDE® can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during and for 1 month after ONIVYDE® treatment.

ADVERSE REACTIONS

The most common (=20%) adverse reactions in which patients receiving ONIVYDE® (irinotecan liposome injection) + 5-FU/LV experienced a =5%higher incidence of any Grade vs the 5-FU/LV arm, were diarrhea (any 59%, 26%; severe 13%, 4%) (early diarrhea [any 30%, 15%; severe 3%, 0%], late diarrhea [any 43%, 17%; severe 9%, 4%]), fatigue/asthenia (any 56%, 43%; severe 21%, 10%), vomiting (any 52%, 26%; severe 11%, 3%), nausea (any 51%, 34%; severe 8%, 4%), decreased appetite (any 44%, 32%; severe 4%, 2%), stomatitis (any 32%, 12%; severe 4%, 1%), pyrexia (any 23%, 11%; severe 2%, 1%).

Of less common (<20%) adverse reactions, patients receiving ONIVYDE® + 5-FU/LV who experienced Grade 3/4 adverse reactions at a =2% higher incidence of Grade 3/4 toxicity vs the 5-FU/LV arm, respectively, were sepsis (3%, 1%), neutropenic fever/ neutropenic sepsis (3%, 0%), gastroenteritis (3%, 0%), intravenous catheter-related infection (3%, 0%), weight loss (2%, 0%), and dehydration (4%, 2%).

The laboratory abnormalities in which patients receiving ONIVYDE® + 5-FU/LV experienced a =5% higher incidence vs the 5-FU/LV arm, were anemia (any 97%, 86%; severe 6%, 5%), lymphopenia (any 81%, 75%; severe 27%, 17%), neutropenia (any 52%, 6%; severe 20%, 2%), thrombocytopenia (any 41%, 33%; severe 2%, 0%), increased alanine aminotransferase (any 51%, 37%; severe 6%, 1%), hypoalbuminemia (any 43%, 30%; severe 2%, 0%), hypomagnesemia (any 35%, 21%; severe 0%, 0%), hypokalemia (any 32%, 19%; severe 2%, 2%), hypocalcemia (any 32%, 20%; severe 1%, 0%), hypophosphatemia (any 29%, 18%; severe 4%, 1%), hyponatremia (any 27%, 12%; severe 5%, 3%), increased creatinine (any 18%, 13%; severe 0%, 0%). ONIVYDE® can cause cholinergic reactions manifesting as rhinitis, increased salivation, flushing, bradycardia, miosis, lacrimation, diaphoresis, and intestinal hyperperistalsis with abdominal cramping and early-onset diarrhea. Grade 1/2 cholinergic symptoms other than early diarrhea occurred in 12 (4.5%) ONIVYDE® -treated patients.

Infusion reactions, consisting of rash, urticaria, periorbital edema, or pruritus, occurring on the day of ONIVYDE® administration were reported in 3% of patients receiving ONIVYDE® or ONIVYDE® + 5- FU/LV. The most common serious adverse reactions (=2%) of ONIVYDE® were diarrhea, vomiting, neutropenic fever or neutropenic sepsis, nausea, pyrexia, sepsis, dehydration, septic shock, pneumonia, acute renal failure, and thrombocytopenia.

DRUG INTERACTIONS

Avoid the use of strong CYP3A4 inducers, if possible, and substitute non-enzyme–inducing therapies =2 weeks prior to initiation of ONIVYDE. Avoid the use of strong CYP3A4 or UGT1A1 inhibitors, if possible, and discontinue strong CYP3A4 inhibitors =1 week prior to starting therapy.

USE IN SPECIFIC POPULATIONS

Pregnancy and Reproductive Potential

Advise pregnant women of the potential risk to a fetus. Advise males with female partners of reproductive potential to use effective contraception during and for 4 months after ONIVYDE® treatment.

Lactation

Advise nursing women not to breastfeed during and for 1 month after ONIVYDE® treatment.

Pediatric

Safety and effectiveness of ONIVYDE® have not been stablished in pediatric patients.

DOSAGE AND ADMINISTRATION

The recommended dose of ONIVYDE® is 70 mg/m2 intravenous (IV) infusion over 90 minutes every 2 weeks, administered prior to LV and 5-FU. The recommended starting dose of ONIVYDE® in patients known to be homozygous for the UGT1A1*28 allele is 50 mg/m2 administered by IV infusion over 90 minutes. There is no recommended dose of ONIVYDE® for patients with serum bilirubin above the upper limit of normal. Premedicate with a corticosteroid and an anti-emetic 30 minutes prior to ONIVYDE®. Withhold ONIVYDE® for Grade 3/4 adverse reactions. Resume ONIVYDE® with reduced dose once adverse reaction recovered to =Grade 1. Discontinue ONIVYDE® in patients who experience a severe hypersensitivity reaction and in patients with a confirmed diagnosis of ILD.

Do not substitute ONIVYDE® for other drugs containing irinotecan HCl.

Please click here for Full Prescribing Information.

IPSEN CARES®
Coverage, Access, Reimbursement & Education Support

Please see Indication and Important Safety Information, including Boxed WARNING, for ONIVYDE® (irinotecan liposome injection). Please see Full Prescribing Information.

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