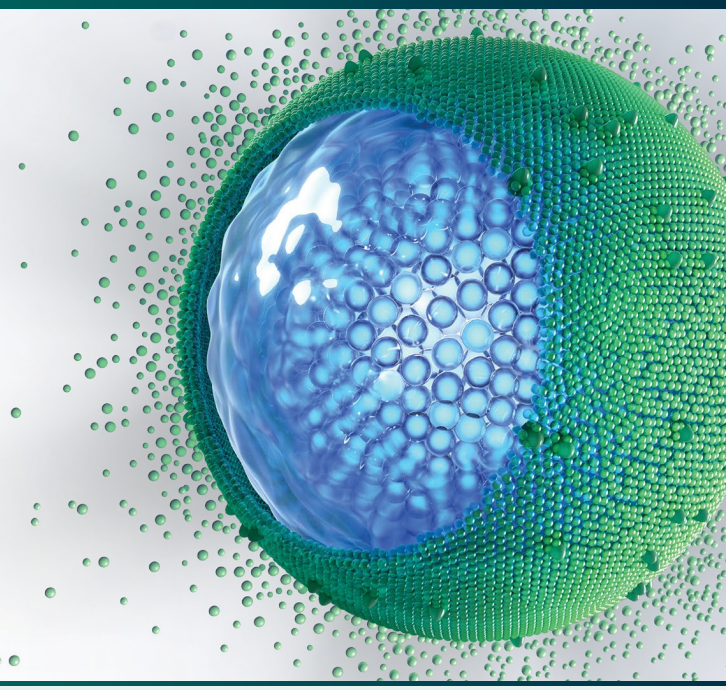
onivyde®
(irinotecan liposome injection)

ELECTRONIC HEALTH RECORD (EHR) INSTRUCTIONS

INSTRUCTIONS FOR THE EPIC® ELECTRONIC HEALTH RECORD (EHR) SYSTEM TO CREATE OR UPDATE ORDER SETS WITH ONIVYDE, AS PART OF THE NALIRIFOX REGIMEN (IRINOTECAN LIPOSOME INJECTION)



NCCN Category 1 – Recommended Options[1]

Liposomal irinotecan (ONIVYDE) + oxaliplatin + FU/LV (NALIRIFOX) is an NCCN Category 1 – Preferred treatment option in 1L mPDAC (Good PS 0-1)*†‡

* NCCN Category 1: Based upon high-level evidence (≥1 randomized phase 3 trials or high-quality, robust meta-analyses), there is uniform NCCN consensus (≥85% support of the Panel) that the intervention is appropriate.[1]
† Preferred interventions: Interventions that are based on superior efficacy, safety, and evidence; and, when appropriate, affordability.[1]
‡ NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.[1]

INDICATION[2]

- ONIVYDE is indicated, in combination with oxaliplatin, fluorouracil, and leucovorin, for the first-line treatment of adult patients with metastatic pancreatic adenocarcinoma.

Limitations of Use: ONIVYDE is not indicated as a single agent for the treatment of patients with metastatic pancreatic adenocarcinoma.

WARNING: SEVERE NEUTROPENIA AND SEVERE DIARRHEA

Neutropenia

- Severe and life-threatening neutropenia, including fatal neutropenic sepsis and fatal neutropenic fever, has occurred in patients receiving ONIVYDE in combination with oxaliplatin, fluorouracil, and leucovorin and in combination with fluorouracil and leucovorin. Withhold ONIVYDE for absolute neutrophil count below 1500/mm^3 or neutropenic fever. Monitor blood cell counts periodically during treatment.

Diarrhea

- Severe and life-threatening diarrhea has occurred in patients receiving ONIVYDE in combination with oxaliplatin, fluorouracil, and leucovorin and in combination with fluorouracil and leucovorin. 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.

Please see additional Important Safety Information on pages 7-9 and accompanying full Prescribing Information, including BOXED WARNING, for ONIVYDE.

Background and Considerations

BACKGROUND AND INTENDED USE

The information contained herein is intended for background and educational purposes only. This document is intended to provide medical groups with instruction to support creation of new 1L metastatic pancreatic ductal adenocarcinoma (1L mPDAC) order sets with ONIVYDE (as part of the NALIRIFOX regimen) within the approved indication and consistent with the Prescribing Information. The instructions are specific to 1L mPDAC and to the Epic® EHR system and are not appropriate for other conditions, treatments, or therapeutic areas or for other EHR systems.

DISCLAIMER AND LIMITATIONS

The process outlined below is variable, and not all steps will apply to every medical group. Any steps or settings below that are not part of a medical group's standard process should be excluded or modified accordingly. Any questions should be directed to the appropriate EHR service provider. The medical group is solely responsible for implementing, testing, monitoring, and ongoing operation of any EHR tools.

This document is not intended to provide any clinical advice or clinical recommendations, suggest that ONIVYDE is the sole or preferred treatment option, or to establish ONIVYDE as an appropriate, sole or preferred treatment option for any patient. All treatment decisions, including assessment, and referral decisions should always be made by a healthcare provider in consultation with the individual patient after a review of the patient's medical records to determine eligibility as each individual patient's situation will vary. The information provided below is not intended to be an exhaustive list of all potential considerations or inputs for the use of ONIVYDE as part of the NALIRIFOX regimen. Medical groups are solely responsible for ensuring all relevant information, including but not limited to any site-specific protocol and any information regarding the other NALIRIFOX regimen components (including oxaliplatin, flurouracil, and leucovorin), is included in each order set.

Please consult the most recent version of the ONIVYDE prescribing information for full medication details. The most recent version of the prescribing information can be found at **https://www.onivyde.com/prescribinginformation.**

A new order set will be available once the order set optimization process is complete. If the original order set used to update or create the new order set includes ONIVYDE, confirm the original order set is retired or removed from the EHR production system according to the medical group's EHR governing principles.

The medical groups shall be solely responsible for implementation, testing, and monitoring of the instructions to ensure proper orientation in each medical group's EHR system. This guide should not replace instructions from your internal or external EHR support teams.

Capabilities, functionality, terminology, and setup for each individual EHR system vary, and may change as new software versions are released. Ipsen is not responsible for revising the implementation instructions it provides to any medical group. The medical group is responsible for ensuring data accuracy within the EHR system used.

While Ipsen tests its implementation instructions on multiple EHR systems, the instructions are not guaranteed to work for all available EHR systems and Ipsen shall have no liability, therefore.

STEP-BY-STEP INSTRUCTIONS

Existing order sets may be used as a foundation for 1L metastatic pancreatic cancer. Consider modifying a Beacon order set as a starting template, while saving the original order set.

There are 3 steps to update a Beacon order set in the Epic EHR system:

1	**Create 4 order groups to hold ONIVYDE (as part of the NALIRIFOX Regimen), the ONIVYDE Treatment Conditions, ONIVYDE Warnings and Precautions and ONIVYDE Premedications**
2	**Add the ONIVYDE prescribing information and resource links to the medication record**
3	**Add the Order Groups to the Beacon order set**

Epic Beacon Order Set Instructions: Step 1

STEP 1: General Instructions for Creating the Order Groups

- ☐ 1. Review the Regimen Category Order Group to confirm Medications are values in the category list
- ☐ 2. Select the Order Group Builder (Admin > Beacon Admin > Order Group Builder)
- ☐ 3. Create a new Order Group named “Medications”
- ☐ 4. Set the default category to Medications
- ☐ 5. Create the following 4 Order Groups:

Order Group 1: ONIVYDE, as part of the NALIRIFOX regimen (ONIVYDE + OXALIPLATIN + 5-FU + LEUCOVORIN)

- ☐ 1. Right click in the empty field located on the bottom of the window
- ☐ 2. Select Add > Orders
- ☐ 3. Select ONIVYDE and complete the ONIVYDE medication details:

  50 mg/m² intravenous infusion over 90 minutes every two weeks.
  For all of the latest administration instructions, dosage modifications, dose reductions, and other information, refer to the ONIVYDE Prescribing Information at https://www.onivyde.com/prescribinginformation
- ☐ 4. Select oxaliplatin and complete the oxaliplatin medication details:

  Per NAPOLI 3 Protocol and as mentioned in Section 14 of the ONIVYDE Prescribing Information: 60 mg/m² intravenous infusion over 120 minutes every two weeks
- ☐ 5. Select leucovorin and complete the leucovorin medication details:

  Per NAPOLI 3 Protocol and as mentioned in Section 14 of the ONIVYDE Prescribing Information: 400 mg/m² intravenous infusion over 30 minutes every two weeks
- ☐ 6. Select fluorouracil (5-FU) and complete the fluorouracil (5-FU) medication details:

  Per NAPOLI 3 Protocol and as mentioned in Section 14 of the ONIVYDE Prescribing Information: 2400 mg/m² intravenous infusion over 46 hours every two weeks)

Order Group 2: ONIVYDE TREATMENT CONDITIONS

(Alternatively, consider Monitoring and Holding Parameters)

- ☐ 1. Review the Regimen Category Order Group to confirm Treatment Conditions (or Monitoring and Hold Parameters) is a value in the category list
- ☐ 2. Select the Order Group Builder (Admin > Beacon Admin > Order Group Builder)
- ☐ 3. Create a new Order Group named “ONIVYDE Treatment Conditions (or Monitoring and Hold Parameters)”
- ☐ 4. Set the default category to Treatment Conditions (or Monitoring and Hold Parameters)
- ☐ 5. Complete the following ONIVYDE Treatment Conditions (or Monitoring and Hold Parameters) Order Group:
- ☐ a. Right click in the empty field located at the bottom of the window
- ☐ b. Select Add > ONIVYDE Treatment Conditions (or Monitoring and Hold Parameters)

(Continued on next page)

STEP 1 (CONTINUED)

☐ 1. Enter:

- *For all of the latest administration instructions (see Section 2), dosage modifications (see Table 1), dose reductions, and other information, refer to the ONIVYDE Prescribing Information at* **https://www.onivyde.com/prescribinginformation.**
- *Recommended Dosage Modifications for ONIVYDE in combination with oxaliplatin, fluorouracil, and leucovorin*

Toxicity[a]	Occurrence	ONIVYDE adjustment in patients receiving 50 mg/m²
Grade 3 or 4 Adverse reactions[b]	Withhold ONIVYDE Upon recovery to ≤ Grade 1[c,d,e], resume ONIVYDE at:	
	First	40 mg/m²
	Second	32.5 mg/m²
	Third	25 mg/m²
	Fourth	Discontinue ONIVYDE
Grade 3 or 4 Hand foot syndrome	First	Discontinue ONIVYDE
Any grade neurocerebellar toxicity	First	Discontinue ONIVYDE
Grade ≥ 2 cardiac toxicity	First	Discontinue ONIVYDE
Interstitial lung disease	First	Discontinue ONIVYDE
Anaphylactic reaction	First	Discontinue ONIVYDE

[a]Toxicity grading per NCI CTCAE v5.0.

[b]No dosage modification is necessary for asthenia, alopecia and Grade 3 anorexia.

[c]Do not resume until the absolute neutrophil count is ≥2000/mm^3 (2x10^9/L) and the platelet count is ≥100,000/mm^3 (100x10^9/L).

[d]For Grade ≥3 nausea and vomiting, reduce dose only if occurs despite optimal anti-emetic therapy.

[e]Refer to the Full Prescribing Information of fluorouracil and oxaliplatin. When ONIVYDE dose is reduced for adverse reactions, reduce fluorouracil (FU) and oxaliplatin doses: for first occurrence, reduce dose to 80% of original dose; for second occurrence, reduce dose to 65% of original dose; for third occurrence, reduce dose to 50% of original dose; discontinue therapy for fourth occurrence. Oxaliplatin may be discontinued if not well tolerated and treatment with ONIVYDE + FU/LV can continue. Maintain original dose level of leucovorin for first, second and third occurrence of toxicity.

Order Group 3: ONIVYDE WARNINGS AND PRECAUTIONS

☐ 1. Review the Regimen Category Order Group to confirm Warnings and Precautions is a value in the category list

☐ 2. Select the Order Group Builder (Admin > Beacon Admin > Order Group Builder)

☐ 3. Create a new Order Group named “ONIVYDE Warnings and Precautions”

☐ 4. Set the default category to Warnings and Precautions

☐ 5. Complete the following ONIVYDE Warnings and Precautions Order Group:

- ☐ a. Right click in the empty field located at the bottom of the window
- ☐ b. Select Add > ONIVYDE Warnings and Precautions
- ☐ c. Enter a link to the ONIVYDE Prescribing Information https://www.onivyde.com/prescribinginformation for the most recent information regarding Warnings and Precautions (See Section 5)
  Note: this link directs users to Warnings and Precautions for ONIVYDE as part of the NALIRIFOX regimen as included in ONIVYDE’S Prescribing Information. Consider adding links to Warnings and Precautions information for the other NALIRIFOX regimen components (oxaliplatin, flurouracil, and leucovorin) for additional information.

Please see additional Important Safety Information on pages 7-9 and accompanying full Prescribing Information, including BOXED WARNING, for ONIVYDE.

Epic Beacon Order Set Instructions: Step 1 (continued) & Step 2

STEP 1 (CONTINUED)

Order Group 4: ONIVYDE PREMEDICATIONS

- ☐ 1. Select the Order Group Builder (Admin > Beacon Admin > Order Group Builder)
- ☐ 2. Create a new Order Group named “ONIVYDE Premedications”
- ☐ 3. Set the default category to Premedications
- ☐ 4. Complete the following ONIVYDE Premedications Order Group:
  - ☐ a. Right click in the empty field located on the bottom of the window
  - ☐ b. Select Add > Orders
  - ☐ c. Select the desired corticosteroid and anti-emetic medicines
  - ☐ d. Complete the medication details: “Administer a corticosteroid and an anti-emetic 30 minutes prior to each ONIVYDE infusion.”

Note: Consider an alternative Order Group, if desired, based on the medical group governing Beacon Regimen conventions.

STEP 2

Add the ONVIYDE website links to the medication record

- ☐ 1. Log in to the Medication Master File (ERX) with authorized user credentials.
- ☐ 2. Use the search feature in the Medication Master File to search and select the desired medication (ONIVYDE)
- ☐ 3. Select the Patient Medication References Screen and 2 new rows

  Row 1: For Display Name, enter “ONIVYDE Prescribing Information”

  In the Text field, enter “See URL for additional ONIVYDE dosing and administration information”

  In the URL field, enter this hyperlink: “https://www.onivyde.com/en-us/hcp”

  Row 2: For Display Name, enter “ONIVYDE Resources for Providers (HCPs) and Patients”

  In the Text Field, enter “See URL for additional ONIVYDE Resources for Providers (HCPs) and Patients such as a Treatment Guide, Patient Brochure, and Patient Savings Offers”

  In the URL field, enter this hyperlink: “https://www.onivyde.com/en-us/hcp”
- ☐ 4. Save the record
- ☐ 5. Release the record to production after satisfactory testing has been completed

Epic Beacon Order Set Instructions: Step 3
Notes and References

STEP 3

Add the Order Groups to the ONIVYDE 1L mPDAC Beacon order set

The steps detail how to add the Order Groups (4 order groups) created in **Step 1** to an existing Beacon order set to create a new ONIVYDE order group or order set for **1L mPDAC**:

- ▢ **1.** Click the Epic logo > Admin > Beacon Admin > Order Set Builder.
- ▢ Search for order sets using the search query “metastatic pancreatic cancer.” An existing ONIVYDE order set may be available to optimize. Note: the existing order set will serve as a template for the new order set only. Follow the customer’s EHR governing principles to minimize duplicates.
- ▢ **2.** Select the treatment regimen and add the newly created order group(s) from the previous Step 1 to the treatment regimen
- ▢ **3.** Add in the second Order Group created in Step 1 with the ONIVYDE Treatment Conditions (or Monitoring and Hold Parameters)
- ▢ **4.** Add in the third Order Group created in Step 1 with the ONIVYDE Warnings and Precautions
- ▢ **5.** Add in the fourth Order Group created in Step 1 with the ONIVYDE Premedications
- ▢ **6.** Update the Beacon order set description to “ONIVYDE for 1L MPDAC”
- ▢ **7.** Click Save
- ▢ **8.** Release to production environment after satisfactory testing has been completed

NOTES

These instructions have not been designed to and are not tools and/or solutions for meeting Advancing Care Information and/or any other quality/accreditation requirement.

This guide should not replace instructions from your internal or external EHR support teams.

Reference to these EHRs is not intended to imply affiliation with or sponsorship of the EHR manufacturer and/or its affiliates. Ipsen does not endorse any specific EHR system; however, it is using EPIC as an example. Ipsen did not sponsor, design, create, or otherwise modify the EHR system, tools, and functionalities in any manner. These instructions have not been reviewed or endorsed by the creators of the EHR software, and Ipsen has no affiliation or relationship with the creators of the EHR software regarding these materials.

REFERENCES

1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Pancreatic Adenocarcinoma [V.2.2025]. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed February 12, 2025. To view the most recent and complete version of the NCCN Guidelines, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.
2. ONIVYDE® [package insert]. Cambridge, MA. Ipsen Biopharmaceuticals, Inc.; 2024.

ONIVYDE® (irinotecan liposome injection) Indications, Limitations of Use, and Important Safety Information

INDICATION

- ONIVYDE is indicated, in combination with oxaliplatin, fluorouracil, and leucovorin, for the first-line treatment of adult patients with metastatic pancreatic adenocarcinoma.

Limitations of Use: ONIVYDE is not indicated as a single agent for the treatment of patients with metastatic pancreatic adenocarcinoma.

IMPORTANT SAFETY INFORMATION

WARNING: SEVERE NEUTROPENIA AND SEVERE DIARRHEA

Neutropenia

- Severe and life-threatening neutropenia, including fatal neutropenic sepsis and fatal neutropenic fever, has occurred in patients receiving ONIVYDE in combination with oxaliplatin, fluorouracil, and leucovorin and in combination with fluorouracil and leucovorin. Withhold ONIVYDE for absolute neutrophil count below 1500/mm^3 or neutropenic fever. Monitor blood cell counts periodically during treatment.

Diarrhea

- Severe and life-threatening diarrhea has occurred in patients receiving ONIVYDE in combination with oxaliplatin, fluorouracil, and leucovorin and in combination with fluorouracil and leucovorin. 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 or anaphylaxis to ONIVYDE or irinotecan HCl.

WARNINGS AND PRECAUTIONS

Severe Neutropenia: ONIVYDE can cause severe or life-threatening neutropenia and fatal neutropenic sepsis. In NAPOLI 3, Grade 3 and 4 neutropenia occurred in 26% of patients receiving ONIVYDE in combination with oxaliplatin, fluorouracil, and leucovorin (NALIRIFOX) and fatal neutropenic fever in 0.3% of patients. In NAPOLI 3, the incidence of Grade 3 or 4 neutropenia was similar among Asian patients [6 of 20 (30%)] compared to White patients [76 of 289 (26%)]. Neutropenic fever/neutropenic sepsis was reported in 5% of Asian patients (1 of 20) compared to 2.3% of White patients (7 of 306). In NAPOLI-1, Grade 3 and 4 neutropenia occurred in 20% of patients receiving ONIVYDE in combination with fluorouracil and leucovorin (ONIVYDE/FU/LV). Neutropenic sepsis occurred in 3% and fatal neutropenic sepsis in 0.8%. In NAPOLI-1, the incidence of Grade 3 or 4 neutropenia was higher among Asian patients [18 of 33 (55%)] compared to White patients [13 of 73 (18%)]. Neutropenic fever/neutropenic sepsis was reported in 6% of Asian patients compared to 1% of White patients.

Monitor complete blood cell counts on Days 1 and 8 of every cycle and more frequently if clinically indicated. Withhold ONIVYDE if the absolute neutrophil count (ANC) is below 1500/mm^3 or if neutropenic fever occurs. Resume ONIVYDE when the ANC is 1500/mm^3 or above. Reduce ONIVYDE dose for Grade 3-4 neutropenia or neutropenic fever following recovery in subsequent cycles.

WARNINGS AND PRECAUTIONS

Severe Diarrhea: In NAPOLI 3, Grade 3 and 4 diarrhea (early-onset [within 24 hours of chemotherapy] and late-onset [more than 24 hours following chemotherapy]) occurred in 20% receiving NALIRIFOX. In NAPOLI-1, Grade 3 or 4 diarrhea occurred in 13% receiving ONIVYDE/FU/LV. The incidence of Grade 3 or 4 late-onset diarrhea was 9% in patients receiving ONIVYDE/FU/LV. The incidence of Grade 3 or 4 early-onset diarrhea was 3% in patients receiving ONIVYDE/FU/LV.

To reduce the risk of severe diarrhea, patients should stop lactose-containing products, eat a low-fat diet, and maintain hydration during treatment with ONIVYDE. Withhold ONIVYDE for Grade 2-4 diarrhea. Local institutional guidelines should be followed for the treatment of diarrhea that does not improve within 48 hours and may include the addition of diphenoxylate hydrochloride plus atropine sulfate or octreotide. Following recovery to Grade 1 diarrhea, resume ONIVYDE at a reduced dose.

Interstitial Lung Disease (ILD): ONIVYDE can cause severe and fatal ILD. Postmarketing cases of severe and fatal ILD have been reported with ONIVYDE. Risk factors include pre-existing lung disease, use of pneumotoxic medicinal products, colony stimulating factors or having previously received radiation therapy. Patients with risk factors should be closely monitored for respiratory symptoms before and during ONIVYDE therapy. 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 Reaction: Irinotecan, including ONIVYDE, 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 7 months after the last dose of ONIVYDE treatment.

ADVERSE REACTIONS FOR NALIRIFOX

- The most common adverse reactions (≥20%) of NALIRIFOX were diarrhea (72%), fatigue (62%), nausea (59%), vomiting (40%), decreased appetite (37%), abdominal pain (35%), mucosal inflammation (28%), constipation (25%), and weight decreased (22%).
- Permanent discontinuation of ONIVYDE due to an adverse reaction occurred in 17% of patients. Adverse reactions that resulted in permanent discontinuation of ONIVYDE in ≥1% of patients included neutropenia, thrombocytopenia, diarrhea, fatigue, infections, and cerebrovascular accident.
- Dosage reduction of ONIVYDE due to an adverse reaction occurred in 52% of patients. Adverse reactions that required dosage reduction in ≥1% of patients included anemia, decreased appetite, diarrhea, fatigue, febrile neutropenia, hypokalemia, liver function test abnormalities, nausea, mucosal inflammation, neutropenia, peripheral neuropathy, vomiting, thrombocytopenia, and weight decreased.
- Dosage interruptions of ONIVYDE due to an adverse reaction occurred in 1.9% of patients. Adverse reactions which required dosage interruption in ≥0.5% of patients included hypersensitivity and infusion-related reaction.
- The most common laboratory abnormalities (≥10% Grade 3 or 4) were decreased neutrophils (26%), decreased potassium (22%), decreased lymphocytes (11%), and decreased hemoglobin (10%).

Please see additional Important Safety Information on pages 7-9 and accompanying full Prescribing Information, including BOXED WARNING, for ONIVYDE.

ONIVYDE® (irinotecan liposome injection) Indications, Limitations of Use, and Important Safety Information

ADVERSE REACTIONS FOR ONIVYDE/FU/LV

- The most common adverse reactions (≥20%) were diarrhea (59%), fatigue/asthenia (56%), vomiting (52%), nausea (51%), decreased appetite (44%), stomatitis (32%), and pyrexia (23%).
- Adverse reactions led to permanent discontinuation of ONIVYDE in 11% of patients receiving ONIVYDE/FU/LV; the most frequent adverse reactions resulting in discontinuation of ONIVYDE were diarrhea, vomiting, and sepsis.
- Dose reductions of ONIVYDE for adverse reactions occurred in 33% of patients receiving ONIVYDE/FU/LV; the most frequent adverse reactions requiring dose reductions were neutropenia, diarrhea, nausea, and anemia.
- ONIVYDE was withheld or delayed for adverse reactions in 62% of patients receiving ONIVYDE/FU/LV; the most frequent adverse reactions requiring interruption or delays were neutropenia, diarrhea, fatigue, vomiting, and thrombocytopenia.
- The most common severe laboratory abnormalities (≥10% Grade 3 or 4) were lymphopenia and neutropenia.

Postmarketing Experience

The following adverse reactions have been identified during post approval use of ONIVYDE:

• Hypersensitivity (including anaphylactic reaction and angioedema).

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: 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. There are no available data in pregnant women. Advise pregnant women of the potential risk to a fetus.
- Lactation: Advise nursing women not to breastfeed during and for 1 month after the last dose of ONIVYDE.

To report SUSPECTED ADVERSE REACTIONS, contact Ipsen Biopharmaceuticals, Inc. at 1-855-463-5127 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch