

Medication Support Nurse Program

A resource for patients
prescribed Onivyde and
enrolled in IPSEN CARES

Actor portrayal



Individualized Support Services Provided by an IPSEN CARES Nurse Include:

- Disease state and therapy education, consistent with the US Prescribing Information
- Identification of potential gaps in care

The Medication Support
Nurses are available
Monday – Friday,
8:00 AM – 8:00 PM ET.

Please call 1-866-435-5677

Medication Support Nurses are provided by Ipsen and do not work under the direction of the patient's healthcare provider or give medical advice. They are trained to direct patients to their provider for treatment-related advice.

Indication and Important Safety Information about ONIVYDE[®] (irinotecan liposome injection)

WHAT IS ONIVYDE?

ONIVYDE[®] (irinotecan liposome injection) is a prescription medicine used to treat adults with pancreatic cancer that has spread to other parts of the body:

- As a first treatment option, ONIVYDE is given in combination with 3 other medicines, oxaliplatin, fluorouracil (also known as FU), and leucovorin (which is often abbreviated as LV).
- ONIVYDE in combination with FU and LV can be used in patients who have already received gemcitabine treatment for their pancreatic cancer.
- ONIVYDE is not given alone.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about ONIVYDE?

ONIVYDE can cause serious side effects that can be severe and life threatening and can lead to death, including fever and infection associated with a low white blood cell count (severe neutropenic fever or neutropenic sepsis) and severe diarrhea.

Call your doctor or get medical help right away if you experience these problems after treatment with ONIVYDE.

Who should not take ONIVYDE?

Do not take ONIVYDE if you have had a severe allergic reaction to ONIVYDE or irinotecan HCl.

Please see additional Important Safety Information on next page and accompanying full Prescribing Information, including IMPORTANT WARNINGS.

IMPORTANT SAFETY INFORMATION (continued)

What should I tell my healthcare provider before taking ONIVYDE?

Before taking ONIVYDE, tell your healthcare provider if you:

- have had an allergic reaction to ONIVYDE or irinotecan HCl.
- have a problem in your bowel that prevents food, fluids, or gas from moving through your intestines.
- are pregnant or planning to become pregnant. Females who can potentially become pregnant should use effective birth control (contraception) during treatment with ONIVYDE and for 7 months following the last dose of ONIVYDE due to potential risk to the fetus.
- are a male with a female partner of reproductive potential. Males should use condoms during treatment with ONIVYDE and for at least 4 months after the last dose. ONIVYDE may harm the unborn baby of your partner.
- are breastfeeding or plan to breastfeed. Patients should not breastfeed during treatment with ONIVYDE and for 1 month after the last dose.
- have pre-existing lung disease, have used medications that are known to cause toxicity to your lungs, medicines called colony-stimulating factors, or have previously received radiation therapy.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines may interact with ONIVYDE. Keep a list of all your medicines and show it to your healthcare provider and pharmacist and ask if it is safe to take ONIVYDE with all of your other medicines.

What are possible side effects of ONIVYDE?

ONIVYDE can cause serious side effects, including:

- **Infections (particularly if your white blood cells are low).** Symptoms of infection may include fever, chills, dizziness, or shortness of breath. Blood cell counts will be monitored periodically by your healthcare provider during treatment. Contact your healthcare provider immediately if you are experiencing signs of infection, such as fever, chills, dizziness, or shortness of breath.
- **Severe Diarrhea.** Symptoms may include persistent vomiting or diarrhea; discolored stools (black, green or bloody); or symptoms of dehydration such as lightheadedness, dizziness, or faintness. Contact your healthcare provider if you experience any of these symptoms. Tell your healthcare provider if you experience persistent vomiting or diarrhea. Your healthcare provider may treat diarrhea with anti-diarrhea medicines (loperamide or atropine).
- **Lung problems (interstitial lung disease).** Symptoms of interstitial lung disease include new onset of cough or difficulty breathing and fever. Tell your healthcare provider right away if you get these symptoms.
- **Allergic reactions (hypersensitivity).** Seek immediate medical attention for signs of severe reaction such as chest tightness; shortness of breath; wheezing; dizziness or faintness; or swelling of the face, eyelids, or lips when receiving or during the 24 hours after receiving ONIVYDE.

Your healthcare provider will check you for these problems during treatment with ONIVYDE. Your healthcare provider may also need to delay or completely stop treatment with ONIVYDE, if you have severe side effects.

What are the most common side effects of ONIVYDE in combination with oxaliplatin, fluorouracil, and leucovorin?

- The most common side effects that were seen in people with pancreatic cancer treated with ONIVYDE include: diarrhea, feeling tired (fatigue), nausea, vomiting, decreased appetite, pain around the stomach, the mucous membranes that line your mouth and gastrointestinal tract becoming inflamed (mucosal inflammation), constipation, and weight loss.
- The most frequent side effects resulting in **permanent discontinuation** of ONIVYDE were low white blood cells (neutropenia), low platelet counts (thrombocytopenia) (platelets are important for clotting to stop bleeding), diarrhea, feeling tired, infections, and stroke (cerebrovascular accident (CVA), an interruption in the flow of blood to the cells in the brain).
- The most frequent side effects requiring **dose reductions** of ONIVYDE were low red blood cell count (anemia), decreased appetite, diarrhea, feeling tired, low white blood cell count with a fever (febrile neutropenia), low potassium (hypokalemia), abnormal liver tests, nausea, the mucous membranes that line your mouth and gastrointestinal tract becoming inflamed, low white blood cell count, peripheral neuropathy (condition that results when nerves that carry messages to and from the brain and spinal cord and to the rest of the body are damaged or diseased), vomiting, low platelet counts, and weight loss.
- The most frequent side effects requiring **dose interruptions** of ONIVYDE were hypersensitivity (the body reacts with an exaggerated immune response to a foreign substance) and infusion-related reaction (any signs or symptoms experienced by the patient during the infusion).

What are the most common side effects of ONIVYDE in combination with fluorouracil and leucovorin?

- The most common side effects that were seen in people with pancreatic cancer treated with ONIVYDE include: diarrhea, feeling tired, vomiting, nausea, decreased appetite, inflammation in the mouth, fever, and dehydration.
- The most frequent side effects resulting in **permanent discontinuation** of ONIVYDE were diarrhea, vomiting, and sepsis.
- The most frequent side effects requiring **dose reductions** of ONIVYDE were low white blood cells (neutropenia), diarrhea, nausea, and low red blood cell count (anemia).
- The most frequent side effects requiring **dose interruptions or delays** of ONIVYDE were neutropenia, diarrhea, fatigue, vomiting, and low platelet counts (thrombocytopenia) (platelets are important for clotting to stop bleeding).

These are not all the possible side effects of ONIVYDE. Tell your healthcare provider if you have any side effects that bother you or that do not go away. To learn more, talk to your healthcare provider. You can ask your healthcare provider or pharmacist for information about ONIVYDE that is written for healthcare professionals, and it can be found at [ONIVYDE.com](https://www.onivyde.com).

If you think you or someone you know has experienced an adverse event related to an Ipsen product or has a product complaint, please contact Ipsen Biopharmaceuticals, Inc. at 1-855-463-5127. You are encouraged to report side effects of prescription drugs to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including IMPORTANT WARNINGS.



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