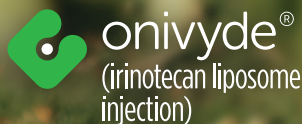


FOR ADULT PATIENTS WITH METASTATIC PANCREATIC CANCER



LEARN MORE ABOUT
ONIVYDE REGIMENS

Actor portrayals.

INDICATIONS AND IMPORTANT SAFETY INFORMATION

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.

Please see additional [Important Safety Information](#) on pages 26-30, and accompanying [full Prescribing Information](#), including **IMPORTANT WARNINGS**.

What is ONIVYDE used for?

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

ONIVYDE is given in combination with 3 other medicines, oxaliplatin, fluorouracil (also known as FU), and leucovorin (which is often abbreviated as LV) and is not given alone.

ONIVYDE can also be used in patients who have already received gemcitabine treatment for their pancreatic cancer. ONIVYDE is given in combination with 2 other medicines, fluorouracil and leucovorin, and is not given alone.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Who should not take ONIVYDE?

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

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.

Please see additional [Important Safety Information](#) on pages 26-30, and accompanying [full Prescribing Information](#), including **IMPORTANT WARNINGS**.

STARTING TREATMENT WITH ONIVYDE

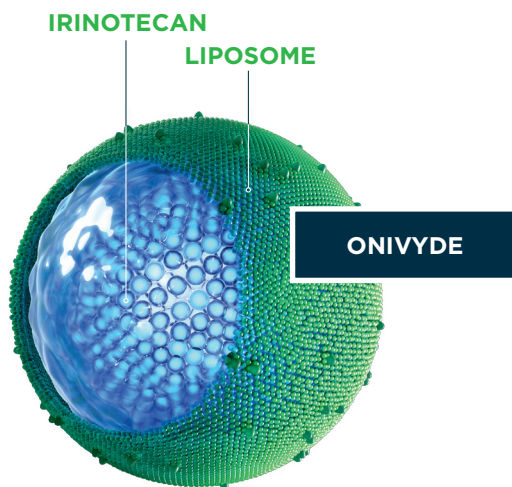


Actor portrayals. Safety and effectiveness of ONIVYDE have not been established in pediatric patients.

People with metastatic pancreatic cancer each have their own treatment journey. ONIVYDE has been proven in medical studies to help patients live longer when given in combination with the regimen recommended by their healthcare provider.

HOW ONIVYDE WORKS

ONIVYDE® (irinotecan liposome injection) has a design that helps it treat metastatic pancreatic cancer. A protective shell, called a liposome, surrounds an anti-tumor drug, called irinotecan. The liposome helps ONIVYDE stay in circulation in your body and reach the tumor.



One of the reasons pancreatic cancer is challenging to treat is because of a dense wall of tissue, known as the stroma, that makes it difficult for some anti-tumor medicines to reach the tumor.

ONIVYDE was designed to help irinotecan get through the dense stroma of the pancreatic tumor.



IMPORTANT SAFETY INFORMATION (CONTINUED)

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.

Please see additional [Important Safety Information](#) on pages 26-30, and accompanying [full Prescribing Information](#), including IMPORTANT WARNINGS.



Actor portrayal.

Please see additional [Important Safety Information](#) on pages 26-30, and accompanying [full Prescribing Information](#), including **IMPORTANT WARNINGS**.

CONSIDERATIONS WITH YOUR TREATMENT

Before receiving ONIVYDE® (irinotecan liposome injection), your healthcare provider may give you medicine to prevent or reduce nausea or vomiting. During your treatment, they may also administer or prescribe a medication which may treat diarrhea.

During therapy, your healthcare provider will test your blood from time to time. This is to check your white blood cell count, specifically your absolute neutrophil count (also known as ANC), to make sure you have enough of certain white blood cells (such as neutrophils and lymphocytes) that fight infection.



During treatment, you may experience certain side effects that can be serious and life-threatening. To learn more about side effects, see pages 10-15 and talk to your healthcare provider.

IMPORTANT SAFETY INFORMATION (CONTINUED)

What are possible side effects of ONIVYDE? (continued)

- **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).

HOW ONIVYDE IS GIVEN TO YOU

There are two ONIVYDE® (irinotecan liposome injection) regimens. One regimen is given as a first treatment for adult patients with metastatic pancreatic cancer. This regimen is ONIVYDE in combination with 3 medicines called oxaliplatin, fluorouracil (FU), and leucovorin (LV). This is also known as the NALIRIFOX regimen.

The other regimen is to treat adult patients with metastatic pancreatic cancer only after patients have already received gemcitabine treatment. This regimen is ONIVYDE in combination with 2 medicines called fluorouracil (FU) and leucovorin (LV). This is also known as the ONIVYDE FU/LV regimen.

ONIVYDE NALIRIFOX as a first treatment regimen



ONIVYDE

Given for
90 min

at the infusion center 



Oxaliplatin

Given for
120 min

at the infusion center 



Leucovorin (LV)



Given for
30 min

at the infusion center 



Fluorouracil (FU)

Given for
46 hrs

at the infusion center  and at home 

Steps 1-4 are completed every two weeks.

ONIVYDE FU/LV regimen for patients following gemcitabine treatment



ONIVYDE

Given for
90 min

at the infusion center 



Leucovorin (LV)



Given for
30 min

at the infusion center 



Fluorouracil (FU)

Given for
46 hrs

at the infusion center  and at home 

Steps 1-3 are completed every two weeks.

IMPORTANT SAFETY INFORMATION (CONTINUED)

What are possible side effects of ONIVYDE? (continued)

- **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.

Please see additional [Important Safety Information](#) on pages 26-30, and accompanying [full Prescribing Information](#), including **IMPORTANT WARNINGS**.

 onivyde®
(irinotecan liposome injection)



Actor portrayals.

Please see [Important Safety Information](#) on pages 26-30, and accompanying [full Prescribing Information](#), including **IMPORTANT WARNINGS**.

WHAT TO KNOW ABOUT SIDE EFFECTS



ONIVYDE® (irinotecan liposome injection) can cause problems that can sometimes become serious and life-threatening and can lead to death. See pages 14-15 for more information.

Serious side effects can be severe and include infections (particularly if your white blood cells are low), diarrhea, lung problems (interstitial lung disease), and immune reaction (hypersensitivity).

With the NALIRIFOX regimen, the most common side effects included: diarrhea, fatigue (feeling tired), nausea, vomiting, loss of appetite, abdominal pain (pain around the stomach), mucosal inflammation (the mucous membranes that line your mouth and gastrointestinal tract become inflamed), constipation, and weight loss.

With the ONIVYDE FU/LV regimen, the most common side effects included: diarrhea, fatigue/asthenia (feeling tired), vomiting, nausea, loss of appetite, stomatitis (inflammation in the mouth), and pyrexia (fever).

With the help of your healthcare provider and treatment team, there may be ways to help manage some of these side effects.

If you experience certain serious side effects during treatment, your healthcare provider may choose to delay or withhold your dose, or stop your treatment. More than half of the patients in the clinical studies that led to the approval of both ONIVYDE regimens had a dose delayed or withheld.

Tell your healthcare provider about any side effects you experience.

MANAGING DIARRHEA DURING TREATMENT

Diarrhea is a common—and sometimes serious—side effect of chemotherapy. If you experience diarrhea during your treatment, your healthcare provider may give you anti-diarrhea medicine, such as loperamide or atropine. If you experience diarrhea that is serious, your healthcare provider will withhold your treatment, and may continue it at a lower dose if your diarrhea gets better.

IMPORTANT! If you have any symptoms of diarrhea, you should contact your healthcare provider and treatment team right away.

If you have diarrhea, it's a good idea to **track the time, duration, and consistency of your stools**, so you can give these details to your healthcare provider and treatment team. To do so, you can **use the side effects/symptoms log that's included with this brochure on pages 22-23**. It's also a good idea to track how much fluid you're taking in, since diarrhea can cause dehydration.

Tell your healthcare provider about all the medicines you take, including prescriptions, over-the-counter medicines, vitamins, and herbal supplements.

Please see [Important Safety Information](#) on pages 26-30, and accompanying [full Prescribing Information](#), including **IMPORTANT WARNINGS**.

In addition to your healthcare provider's advice, here are some things you can do that may help manage diarrhea:

Eat



- Smaller amounts of food, and more often (about 6-8 small servings per day)
- Foods containing soluble fiber such as high-pectin fruits (bananas, strawberries, peeled apples) and certain cooked vegetables (carrots)
- Foods rich in potassium (bananas, oranges, peeled potatoes)
- Foods low in fat

Drink



- Plenty of cool (but not hot), clear liquids (such as water or soup) that can help you rehydrate. It's important to stay hydrated, to avoid losing excess fluid from your body
- 1 cup of liquid for each stool that appears. If you're feeling nauseated and can't keep water down, try sucking on ice chips. If you're not drinking enough water or notice any symptoms of dehydration, be sure to alert your healthcare provider and treatment team right away

Avoid



- Foods with insoluble fiber such as whole grain bread/cereal, raw fruits with thick peels, nuts, and uncooked vegetables
- Foods that are greasy, fatty, fried, or spicy (such as fast foods, some meats and cheeses, sour cream, and whole milk)
- Coffee, tea, or alcohol
- Dairy products

ABOUT SERIOUS SIDE EFFECTS

In medical studies, patients experienced serious side effects that were severe and sometimes fatal, such as, but not limited to, low white blood cell count (neutropenia), diarrhea, and lung problems. Severe immune reactions (hypersensitivity) also occurred.

IMPORTANT! If you feel you have any side effect from treatment, get in touch with a healthcare professional right away.

Please see [Important Safety Information](#) on pages 26-30, and accompanying [full Prescribing Information](#), including **IMPORTANT WARNINGS**.

Serious side effects of treatment included but were not limited to:

SERIOUS SIDE EFFECTS	COMMON SYMPTOMS	WHAT YOU SHOULD DO
Low white blood cell counts (neutropenia) can occur during your treatment with ONIVYDE® (liposome irinotecan injection), especially if your white blood cell count is low.	Fever, chills, feeling dizzy, feeling short of breath.	Contact your healthcare provider or care team. Your healthcare provider will monitor your white blood cell count throughout your treatment.
Diarrhea can start early (within 24 hours after being given ONIVYDE) or late (over 24 hours after being given ONIVYDE).	Diarrhea that won't stop, discolored stools (black or bloody), symptoms of dehydration (feeling dizzy, lightheaded, or faint).	Contact your healthcare provider or care team. Your healthcare provider may give you anti-diarrhea medicine, such as loperamide or atropine, or reduce your dose or stop your treatment.
Serious lung problems (interstitial lung disease) can occur during your treatment with ONIVYDE.	New coughing, difficulty breathing, fever.	Contact your healthcare provider or care team.
A severe immune reaction (hypersensitivity) can occur during your treatment with ONIVYDE.	Tightness in your chest, feeling short of breath, feeling dizzy or faint, wheezing, swelling of your face, eyelids, or lips—either while being given or within 24 hours after being given ONIVYDE.	SEEK MEDICAL ATTENTION IMMEDIATELY.
Embryo-fetal toxicity		<ul style="list-style-type: none"> 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. Males should use condoms during treatment with ONIVYDE and for at least 4 months after last dose. ONIVYDE may harm the unborn baby of your partner. In addition, females should not breastfeed during treatment with ONIVYDE and for 1 month after the last dose.

These are not all the possible side effects. There are other potential side effects with treatment. Please talk to your healthcare provider.





Actor portrayal.

Please see [Important Safety Information](#) on pages 26-30, and accompanying [full Prescribing Information](#), including **IMPORTANT WARNINGS**.

SIGN UP FOR IPSEN CARES[®]

Once your healthcare provider has prescribed ONIVYDE[®] (irinotecan liposome injection), the IPSEN CARES[®] Patient Access Managers are dedicated to:

- Facilitating your access to prescribed medications
- Providing information and support for the interactions among you, healthcare provider's offices, and insurance companies



Help with copays?

Check for copay coverage. Our copay assistance program may help eligible* commercially insured patients with the cost of their treatment.



Free medication

Uninsured patients may be eligible for free medication through our Patient Assistance Program.*



Sign up now

To learn more, call 1-866-435-5677 from 8 AM to 8 PM ET, Monday to Friday, to speak with an IPSEN CARES representative, or visit www.ipsencares.com.

*For eligible patients. See the full Terms and Conditions at www.ipsencares.com.

 onivyde[®]
(irinotecan liposome
injection)

SUPPORT RESOURCES FOR PANCREATIC CANCER

Coping with the physical and emotional impacts of cancer can be difficult. The following is a list of helpful organizations for people with pancreatic cancer and their caregivers.



Actor portrayals.

Please see [Important Safety Information](#) on pages 26-30, and accompanying [full Prescribing Information](#), including **IMPORTANT WARNINGS**.



Pancreatic Cancer Action Network®

(877) 272-6226

pancan.org

PanCAN® provides free, in-depth, and personalized resources and information on pancreatic cancer.

NCCN

National Comprehensive Cancer Network® (NCCN®)

(215) 690-0300

nccn.org

NCCN is dedicated to improving and facilitating quality, effective, equitable, and accessible cancer care so all patients can live better lives.*

NCCN=National Comprehensive Cancer Network® (NCCN®).



Let's Win! Pancreatic Cancer Initiative

letswinpc.org

Let's Win is the go-to resource for the pancreatic cancer community, providing vital information and much-needed hope and inspiration to patients and caregivers.

*Referenced with permission from the National Comprehensive Cancer Network, Inc. © National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed December 15, 2023. To view the most recent and complete version of the recommendations, 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.

The information above is provided for your information, and is not an endorsement of these organizations, nor an implication that these organizations endorse Ipsen or its products or services.



GUIDE FOR TALKING WITH YOUR HEALTHCARE PROVIDER



You, your healthcare provider, and your care team are all working together. Discussing your treatment, including any side effects you may have, can help your healthcare provider and your care team help you.

Check in regularly with your healthcare provider and care team so they know the status of your condition and treatment.

Here are some questions you may want to ask your healthcare provider:

- What can I do to prepare for my treatment?
- What can I expect from my treatment?
- How will I know if my treatment is working?
- Will I need any lab tests or procedures during my treatment?
- Will I need to adjust my daily activities or responsibilities?
- What are the side effects? How long might these last?
- What should I do if I experience side effects or symptoms?
- Will any medicines or substances I'm taking affect my treatment?
- If I have questions, what's the best way to get in touch?
- Who should I contact in case of emergency, and how?
- What does each member of my care team do?
- What support resources are available to me? What about my family?

Please see [Important Safety Information](#) on pages 26-30, and accompanying [full Prescribing Information](#), including **IMPORTANT WARNINGS**.

TRACK YOUR SYMPTOMS AND SIDE EFFECTS

All the symptoms and side effects you experience are important. Use this to start a log to record them and discuss with your healthcare provider and care team.

SYMPTOM OR SIDE EFFECT

DATE _____ TIME _____ DURATION _____

SYMPTOM OR SIDE EFFECT

DATE _____ TIME _____ DURATION _____

SYMPTOM OR SIDE EFFECT

DATE _____ TIME _____ DURATION _____

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

SYMPTOM OR SIDE EFFECT

DATE _____ TIME _____ DURATION _____

SYMPTOM OR SIDE EFFECT

DATE _____ TIME _____ DURATION _____

SYMPTOM OR SIDE EFFECT

DATE _____ TIME _____ DURATION _____

Please see [Important Safety Information](#) on pages 26-30, and accompanying [full Prescribing Information](#), including **IMPORTANT WARNINGS**.



GLOSSARY OF COMMON TERMS

The following is a list of common terms relating to pancreatic cancer and your treatment.

Chemotherapy (*kee-moh-THEH-ra-pee*)

Medicines or drugs used to treat cancer. Commonly referred to as “chemo.”

Fluorouracil (*floor-oh-YOOR-a-sil*)

A chemotherapy drug used to treat certain types of cancer. Also known as “FU.”

Gemcitabine (*gem-SITE-a-bean*)

A chemotherapy drug used to treat certain types of cancer.

Intravenous (*in-truh-VEE-nuss*) **infusion**

A method of delivering fluids and medicine using a needle or thin tube (called a catheter) inserted into a vein. Often referred to as “IV.”

Irinotecan (*ear-ee-no-TEE-can*)

A chemotherapy drug used to treat certain types of cancer.

Leucovorin (*loo-koh-VOOR-in*)

A drug (also called “folinic acid,” and derived from folic acid) used to treat certain types of cancer, as well as certain types of anemia. Also known as “LV.”

Liposome (*LIPE-oh-sohm*)

A formulation that helps to deliver microscopic substances (such as anti-cancer drugs) to cells in the body.

Lymphocytes (*LIM-foh-sites*)

Cells that originate from stem cells, making up about 20-30 percent of the white blood cells found in normal human blood.

Please see [Important Safety Information](#) on pages 26-30, and accompanying [full Prescribing Information](#), including **IMPORTANT WARNINGS**.

Metastatic (*meh-tuh-STA-tik*)

Cancer that has spread from where it first started (the primary site) to other organs or structures in the body.

NALIRIFOX (*nuh-LEE-ree-fox*)

A treatment regimen given as a first treatment for metastatic pancreatic cancer.

Neutropenia (*noo-troh-PEE-nee-uh*)

A decrease in the number of white blood cells (neutrophils) that respond quickly to an infection. Having neutropenia increases a person’s risk of getting an infection.

Neutrophils (*NOO-troh-fills*)

White blood cells that respond quickly to an infection.

ONIVYDE (*ah-NEE-vied*)

The product name for liposomal encapsulated irinotecan, a chemotherapy drug used to treat metastatic pancreatic cancer.

Oxaliplatin (*aak-sa-lee-PLAT-tn*)

An anti-cancer drug containing platinum that can stop or slow the growth of cancer cells and may cause them to die.

White blood cell count

The number of white blood cells in a blood sample, determined through a laboratory blood test.

INDICATIONS AND IMPORTANT SAFETY INFORMATION ABOUT ONIVYDE

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.

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.

Please see [full Prescribing Information](#), including **IMPORTANT WARNINGS**.

- 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.



IMPORTANT SAFETY INFORMATION ABOUT ONIVYDE (CONTINUED)

What are possible side effects of ONIVYDE? (continued)

- **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.

Please see [full Prescribing Information](#), including **IMPORTANT WARNINGS**.

- 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).

IMPORTANT SAFETY INFORMATION ABOUT ONIVYDE (CONTINUED)

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.

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 [full Prescribing Information](#), including **IMPORTANT WARNINGS**.

In this brochure, patients and caregivers can learn about:



How ONIVYDE® (irinotecan liposome injection) is given



What to know about side effects



Helpful resources

To learn more, visit [ONIVYDE.com](https://www.onivyde.com)



onivyde[®]
(irinotecan liposome injection)

IMPORTANT SAFETY INFORMATION (CONTINUED)

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.

Please see Indications and additional [Important Safety Information](#) on pages 26-30, and accompanying [full Prescribing Information](#), including **IMPORTANT WARNINGS.**



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