

# WHEN METASTATIC PANCREATIC CANCER PROGRESSES ON GEMCITABINE

# GO ON

CONSIDER ONIVYDE + 5-FU/LV

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



onivyde<sup>®</sup>  
(irinotecan liposome  
injection)

## IMPORTANT SAFETY INFORMATION

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

ONIVYDE can cause problems that can sometimes become serious or life threatening and can lead to death. Serious side effects may include fever and infection associated with a low white blood count (severe neutropenic fever or neutropenic sepsis) and severe diarrhea.

**Please see Indication and additional Important Safety Information on pages 26-29, and accompanying [full Prescribing Information](#), including Boxed WARNING.**

## WHAT IS ONIVYDE USED FOR?

ONIVYDE is a prescription medicine used to treat pancreatic cancer which has spread to other parts of the body. ONIVYDE can be used in patients who have already received gemcitabine treatment for their pancreatic cancer. ONIVYDE is given in combination with 2 other medicines, fluorouracil (also known as 5-FU) and leucovorin (which is often abbreviated as LV), and is not given alone.

## IMPORTANT SAFETY INFORMATION (CONTINUED)

### What is the most important information I should know about ONIVYDE? (Continued)

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

**Before receiving ONIVYDE, tell your healthcare provider if you:**

- have had a **severe 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 are able to 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 man, you should not father a child during your treatment with ONIVYDE. ONIVYDE can harm the unborn baby of your partner. You should use an effective method of birth control during and for at least 4 months after the last dose of ONIVYDE,
- are breastfeeding or plan to breastfeed. Patients should not breastfeed during treatment with ONIVYDE and for 1 month after the last dose.

Please see additional Important Safety Information on pages 26-29, and accompanying [full Prescribing Information](#), including Boxed WARNING.

## STARTING TREATMENT WITH ONIVYDE



Actor portrayal

People with metastatic pancreatic cancer each have their own treatment journey. If you have received chemotherapy with gemcitabine, and either it did not work or stopped working, your doctor may recommend ONIVYDE.

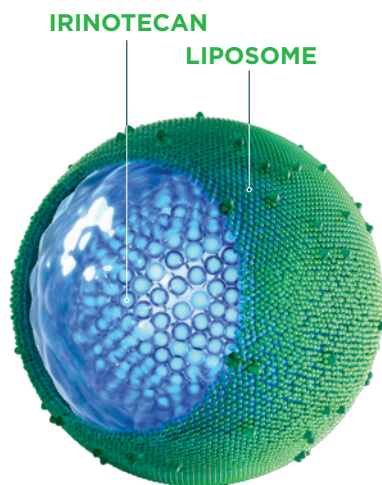
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ONIVYDE is proven to help people with metastatic pancreatic cancer whose disease progressed following gemcitabine-based therapy live longer, when given in combination with 2 other medicines, fluorouracil (5-FU) and leucovorin (LV).

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# HOW ONIVYDE WORKS

ONIVYDE has a design that helps it treat metastatic pancreatic cancer. A protective shell, called a liposome, surrounds an antitumor drug, called irinotecan. The liposome helps ONIVYDE stay in circulation in your body.



## IMPORTANT SAFETY INFORMATION (CONTINUED)

### What are the possible 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.

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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 antitumor medicines to reach the tumor.

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

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## IMPORTANT SAFETY INFORMATION (CONTINUED)

### What are the possible effects of ONIVYDE? (Continued)

- **Diarrhea.** Symptoms of severe diarrhea may include persistent diarrhea; discolored stools (black, green or bloody); or symptoms of dehydration such as lightheadedness, dizziness, or faintness. 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.







Actor portrayal

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## CONSIDERATIONS WITH YOUR TREATMENT

Before you receive ONIVYDE, your doctor may give you medicine to prevent or reduce nausea, vomiting, or diarrhea.

During your therapy, your doctor 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 lymphocytes and neutrophils) that fight infection.



During your treatment with ONIVYDE + 5-FU/LV, you may experience certain side effects that can be serious. See pages 10-15 to learn more about side effects.

### IMPORTANT SAFETY INFORMATION (CONTINUED)

#### What are the possible effects of ONIVYDE? (Continued)

- **Allergic reaction (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.

# HOW ONIVYDE IS GIVEN TO YOU

ONIVYDE is given to you in combination with 2 other medicines, fluorouracil (5-FU) and leucovorin (LV). You are given ONIVYDE + 5-FU/LV by intravenous infusion (IV), which is when medicine is injected into your vein. Your treatment will be given to you in an infusion center by a healthcare professional who is trained to administer chemotherapy.

You'll start fluorouracil (5-FU) in an infusion center, and may be able to continue at home using a portable infusion pump.

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ONIVYDE + 5-FU/LV is given in 3 steps, known as a treatment cycle, that lasts for 2 weeks.

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## IMPORTANT SAFETY INFORMATION (CONTINUED)

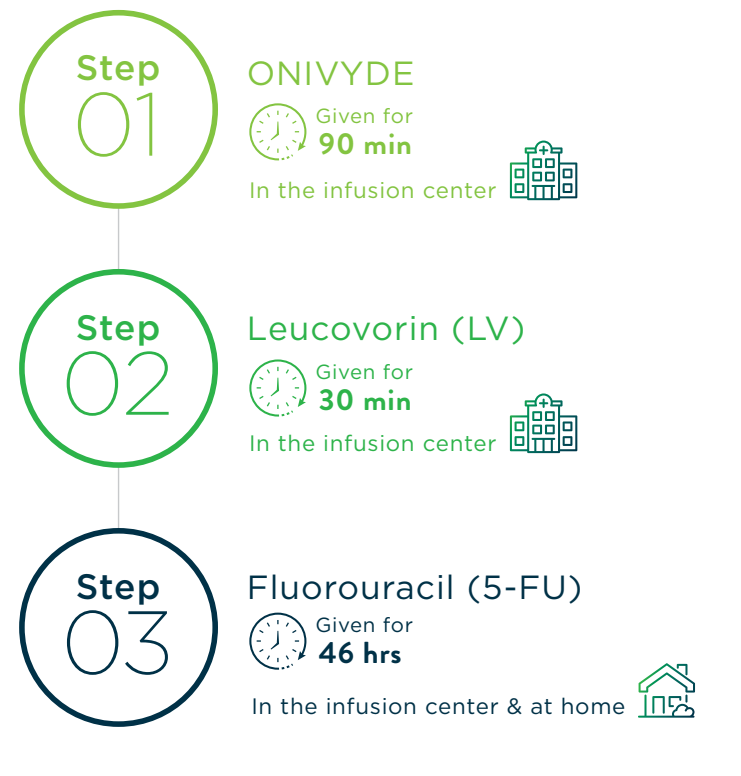
### What are the most common side effects of ONIVYDE?

- The most common side effects which were seen in people with pancreatic cancer treated with ONIVYDE include: diarrhea, feeling tired, vomiting, nausea, loss of appetite, inflammation in the mouth, fever, and dehydration.
- The most frequent side effects resulting in **discontinuation** of ONIVYDE were diarrhea, vomiting, and infection caused by low white blood cells (neutropenic sepsis).

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## Treatment cycle at a glance

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No further chemotherapy until the next treatment cycle begins



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## WHAT TO KNOW ABOUT SIDE EFFECTS



The most common side effects include diarrhea, tiredness/weakness, vomiting, nausea, decreased appetite, mouth sores, and fever. The most common blood count change seen is a reduction in the number of white blood cells, which are

important for fighting infections.

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

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

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If you experience certain serious side effects during treatment with ONIVYDE + 5-FU/LV, your doctor may choose to delay or withhold your dose, or stop your treatment. More than half of the patients in the clinical study that led to the approval of ONIVYDE had a dose delayed or withheld.

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# MANAGING DIARRHEA DURING TREATMENT

Diarrhea is a common—and sometimes serious—side effect of chemotherapy. If you experience diarrhea during your treatment, your doctor may give you anti-diarrhea medicine, such as loperamide or atropine. If you experience diarrhea that is serious, your doctor 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 doctor 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 doctor and treatment team. To do so, you can **use the side effects/symptoms log that's included with this brochure on pages 22 and 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.

**In addition to your doctor's advice, there 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)
- Food 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 doctor 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 (if you are lactose intolerant)

Please see Indication and Important Safety Information on pages 26-29, and accompanying [full Prescribing Information](#), including Boxed WARNING.

# ABOUT SERIOUS SIDE EFFECTS

During your treatment with ONIVYDE + 5-FU/LV, you may experience certain side effects that are serious, and which could be fatal, such as diarrhea, an infection, a lung problem, or a severe allergic reaction.

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

## IMPORTANT SAFETY INFORMATION (CONTINUED) What are the most common side effects of ONIVYDE? (CONTINUED)

- The most frequent side effects requiring **dose reductions** of ONIVYDE were 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 called thrombocytopenia (platelets are important for clotting to stop bleeding).

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## Serious and potentially fatal side effects of treatment with ONIVYDE

Serious side effects	Common symptoms	What you should do
<b>Diarrhea</b> 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, green, or bloody), symptoms of dehydration (feeling dizzy, lightheaded, or faint).	<b>Contact your doctor or care team.</b> Your doctor may give you anti-diarrhea medicine, such as loperamide or atropine, or reduce your dose or stop your treatment.
<b>Serious infections</b> can occur during your treatment with ONIVYDE, especially if your white blood cell count is low.	Fever, chills, feeling dizzy, feeling short of breath.	<b>Contact your doctor or care team.</b> Your doctor will monitor your white blood cell count from time to time during your treatment, to be sure you don't get neutropenia.
<b>Serious lung problems</b> (interstitial lung disease) can occur during your treatment with ONIVYDE.	New coughing, difficulty breathing, fever.	<b>Contact your doctor or care team.</b>
<b>A severe allergic reaction</b> (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.	<b>SEEK MEDICAL ATTENTION IMMEDIATELY.</b>



## SIGN UP FOR IPSEN CARES<sup>®</sup>

Once the provider has prescribed ONIVYDE, the IPSEN CARES Patient Access Specialists are fully dedicated to:

- Facilitating patients' access to their prescribed medications
- Providing information and support for the interactions among offices, patients, and insurance companies for Ipsen medications



### Help with copays?

Check for copay coverage. Considering that some patients need financial assistance, our copay assistance programs may help eligible\* patients with the cost of their treatment.



### Free medication

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

To learn more, call (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](http://www.ipsencares.com).

\*For eligible patients. See the full Terms and Conditions at [www.ipsencares.com](http://www.ipsencares.com).

Actor portrayal

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# 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.



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**Pancreatic Cancer Action Network®**

**(877) 272-6226**

[pancan.org](https://pancan.org)

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



**National Comprehensive Cancer Network®  
(NCCN®)**

**(215) 690-0300**

[nccn.org](https://nccn.org)

The NCCN is dedicated to improving the quality of cancer care, so patients can lead better lives.\*



**Let's Win! Pancreatic Cancer Initiative**

[letswinpc.org](https://letswinpc.org)

Let's Win! Pancreatic Cancer is changing the narrative around pancreatic cancer. Instead of sharing dismal statistics, Let's Win! breaks down the barriers between patients, doctors, and researchers through a dynamic website and robust social media program in both English and Spanish. With a mission based on information and outreach, Let's Win! focuses on unmet needs in the pancreatic cancer world. Its message is simple: Everyone who is diagnosed with pancreatic cancer should have easy access to information about the best treatment options available.

\*Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Pancreatic Adenocarcinoma V.1.2022. © National Comprehensive Cancer Network, Inc. 2022. All rights reserved. Accessed May 5, 2022. To view the most recent and complete version of the guideline, 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.

# GUIDE FOR TALKING WITH YOUR DOCTOR



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

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

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Here are some questions you may want to ask your doctor:

- 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 Indication and Important Safety Information on pages 26-29, and accompanying [full Prescribing Information](#), including Boxed WARNING.

# TRACK YOUR SYMPTOMS AND SIDE EFFECTS

All the symptoms and side effects you experience are important. Use this log to record them and discuss with your doctor 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](http://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 Indication and Important Safety Information on pages 26-29, and accompanying [full Prescribing Information](#), including Boxed WARNING.



# GLOSSARY OF COMMON TERMS

The following is a list of common terms relating to pancreatic cancer and your treatment with ONIVYDE + 5-FU/LV.

**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 “5-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 anticancer 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.

**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.

**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.

**White blood cell count**

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

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# INDICATION AND IMPORTANT SAFETY INFORMATION ABOUT ONIVYDE

## What Is ONIVYDE Used For?

ONIVYDE is a prescription medicine used to treat pancreatic cancer which has spread to other parts of the body. ONIVYDE can be used in patients who have already received gemcitabine treatment for their pancreatic cancer. ONIVYDE is given in combination with 2 other medicines, fluorouracil (also known as 5-FU) and leucovorin (which is often abbreviated as LV), and is not given alone.

## IMPORTANT SAFETY INFORMATION

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

ONIVYDE can cause problems that can sometimes become serious or life threatening and can lead to death. Serious side effects may include fever and infection associated with a low white blood 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.**

**Before receiving ONIVYDE, tell your healthcare provider if you:**

- have had a **severe 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 are able to 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 man, you should not father a child during your treatment with ONIVYDE. ONIVYDE can harm the unborn baby of your partner. You should use an effective method of birth control during and for at least 4 months after the last dose of ONIVYDE,

Please see accompanying **full Prescribing Information**, including **Boxed WARNING**.

- are breastfeeding or plan to breastfeed. Patients should not breastfeed during treatment with ONIVYDE and for 1 month after the last dose.

### 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.
- **Diarrhea.** Symptoms of severe diarrhea may include persistent diarrhea; discolored stools (black, green or bloody); or symptoms of dehydration such as lightheadedness, dizziness, or faintness. 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.
- **Allergic reaction (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?

- The most common side effects which were seen in people with pancreatic cancer treated with ONIVYDE include: diarrhea, feeling tired, vomiting, nausea, loss of appetite, inflammation in the mouth, fever, and dehydration.



## IMPORTANT SAFETY INFORMATION ABOUT ONIVYDE (CONTINUED)

### What are the most common side effects of ONIVYDE? (Continued)

- The most frequent side effects resulting in **discontinuation** of ONIVYDE were diarrhea, vomiting, and infection caused by low white blood cells (neutropenic sepsis).
- The most frequent side effects requiring **dose reductions** of ONIVYDE were 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 called thrombocytopenia (platelets are important for clotting to stop bleeding).

### Tell your healthcare provider about all the medicines you take, including:

- prescriptions
- over-the-counter medicines
- vitamins
- herbal supplements

### These are not all the possible side effects of ONIVYDE.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. To learn more, talk to your healthcare provider. You can ask your doctor or pharmacist for information about ONIVYDE that is written for health professionals, and it can be found at [ONIVYDE.com](http://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](http://www.fda.gov/medwatch).

### Pregnancy and Nursing

If you are a female, tell your healthcare provider if you are pregnant or plan to become pregnant. ONIVYDE can harm your unborn baby. Females who are able to become pregnant should use an effective method of birth control during and for at least 1 month after the last dose of ONIVYDE. Talk to your healthcare provider about birth control methods that you can use during this time. Tell your healthcare provider right away if you become pregnant during treatment with ONIVYDE. Before receiving ONIVYDE, tell your healthcare provider if you are breastfeeding or plan to breastfeed. It is not known if ONIVYDE passes into your breast milk. Do not breastfeed during treatment with ONIVYDE and for at least 1 month after the last dose of ONIVYDE.

If you are a man, you should not father a child during your treatment with ONIVYDE. ONIVYDE can harm the unborn baby of your partner. You should use an effective method of birth control during and for at least 4 months after the last dose of ONIVYDE.

### These are not all the possible side effects of ONIVYDE.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. To learn more, talk to your healthcare provider. You can ask your doctor or pharmacist for information about ONIVYDE that is written for health professionals, and it can be found at [ONIVYDE.com](http://ONIVYDE.com).

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [fda.gov/medwatch](http://fda.gov/medwatch) or call 1-800-FDA-1088.

Please see accompanying [full Prescribing Information](#), including **Boxed WARNING**.

In this brochure, patients and caregivers  
can learn about:



**How ONIVYDE is given**



**What to know  
about side effects**



**Helpful resources**

To learn more, visit [\*\*ONIVYDE.com\*\*](https://ONIVYDE.com)



**onivyde<sup>®</sup>**  
(irinotecan liposome  
injection)

## **IMPORTANT SAFETY INFORMATION (CONTINUED)**

### **When Should ONIVYDE Not Be Given?**

You should not receive ONIVYDE if:

- you have had a **severe allergic reaction to ONIVYDE or irinotecan HCl**

**Please see Indication and additional Important Safety Information on pages 26-29, and accompanying [full Prescribing Information](#), including Boxed WARNING.**