onivyde®
(irinotecan liposome injection)

YOUR GUIDE TO STARTING 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.

Please see additional Important Safety Information on pages 26-31 and full Prescribing Information, including IMPORTANT WARNINGS for ONIVYDE.

IPSEN

OVERVIEW

A pancreatic cancer diagnosis can feel overwhelming, and navigating treatment may raise questions. You and your healthcare provider have chosen an ONIVYDE-containing regimen. This brochure was designed to support you with clear information and resources to support you as you begin therapy with ONIVYDE. Although the goal of treatment is to manage your cancer, supporting your experience living with mPDAC while on ONIVYDE is an essential part of the journey as well.

Actor portrayals.

SIGN UP FOR IPSEN CARES®

Now that your healthcare provider has prescribed ONIVYDE, you are encouraged to talk to them about enrolling in **IPSEN CARES®**. **Patient Access Managers** at **IPSEN CARES** are dedicated to:

- Facilitating your access to your ONIVYDE Prescription
- Providing information and support for the interactions among you, healthcare providers' offices, and insurance companies

Help with copays?

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.*

IPSEN CARES also provides access to the **Medication Support Nurse Program,** which allows you to receive individualized support from a nurse contact throughout the duration of your treatment. **Your Medication Support Nurse:**

- Provides education about your condition, treatment, and ONIVYDE
- Helps to identify potential gaps in care throughout your treatment journey

IPSEN CARES 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.

Medication Support Nurses are available Monday – Friday, 9:00 AM – 5:00 PM ET. Please call 866-435-5677.

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

Actor portrayals. ONIVYDE is not indicated for use in pediatric patients.

SIGN UP FOR IPSEN CARES

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

PREPARING FOR YOUR FIRST TREATMENT

A diagnosis of metastatic pancreatic cancer can feel overwhelming. Not only has life taken an unexpected turn, but you've also learned that you're going to start an unfamiliar series of treatments soon.

As preparation before your first treatment, it may help to understand what to expect. Please read this brochure and talk to your healthcare team if you have any questions.

Your healthcare team may include

- Your primary care team
- One or more oncologists
- Nurse Practitioners and Physician Assistants with different specialties
- Infusion center nurses
- Nutritionists
- Pharmacists
- Case managers
- Social workers
- Other specialists

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.

Please see additional Important Safety Information on pages 26-31 and full Prescribing Information, including IMPORTANT WARNINGS for ONIVYDE.

onivyde® (irinotecan liposome injection)

ABOUT THE MEDICINES YOU WILL RECEIVE

ONIVYDE has been used for more than 10 years to treat some types of metastatic pancreatic cancer, and was **studied in more than 1100 patients.***

There are two ONIVYDE-containing regimens for the treatment of pancreatic cancer.

- One regimen, **NALIRIFOX**, is given as a first treatment for adult patients with metastatic pancreatic cancer.
- The other regimen, **ONIVYDE + FU/LV**, is for adult patients with metastatic pancreatic cancer only after they have already received a treatment that contains gemcitabine.

*There were two trials of ONIVYDE in patients with pancreatic cancer. In a first-line trial, 770 total patients were enrolled in two separate arms (383 in the ONIVYDE treatment arm, and 387 in the Gem+NabP treatment arm). In a second-line trial, 417 patients were enrolled in three separate arms (117 in ONIVYDE + FU/LV, 149 in FU/LV, and 151 in ONIVYDE alone).

IMPORTANT SAFETY INFORMATION (continued)

What should I tell my healthcare provider before taking ONIVYDE? (continued)

Before taking ONIVYDE, tell your healthcare provider if you: (continued)

- 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.

Please see additional Important Safety Information on pages 26-31 and full Prescribing Information, including IMPORTANT WARNINGS for ONIVYDE.

onivyde® (irinotecan liposome injection)

Both treatments are given by infusion, a method that uses a needle or thin tube inserted into a vein. This needle or tube may be placed via surgery to make it more comfortable for you to receive the medicines each time you return.

Your treatment will begin at an infusion center.

NALIRIFOX consists of 4 medicines:

- ONIVYDE, oxaliplatin, leucovorin, and fluorouracil.

They are given in 4 steps, all on the same day, every 2 weeks:

Step 01 — ONIVYDE
Given for **90 min**
at the infusion center

Step 02 — Oxaliplatin
Given for **120 min**
at the infusion center

Step 03 — Leucovorin (LV)
Given for **30 min**
at the infusion center

Step 04 — Fluorouracil (FU)
Given for **46 hrs**
Beginning at the infusion center and completed at home

IMPORTANT SAFETY INFORMATION (continued)

What should I tell my healthcare provider before taking ONIVYDE? (continued)

Before taking ONIVYDE, tell your healthcare provider if you: (continued)

- 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.

ABOUT THE MEDICINES YOU WILL RECEIVE (CONTINUED)

ONIVYDE + FU/LV consists of 3 medicines:

- ONIVYDE, fluorouracil, and leucovorin.

They are given in 3 steps, all on the same day, every 2 weeks:

Both of these treatments contain medicines designed for the treatment of metastatic pancreatic cancer, and they may come with side effects. The information on the following pages includes details about some of what you may experience, whether you are taking NALIRIFOX or ONIVYDE + FU/LV.

IMPORTANT SAFETY INFORMATION (continued)

What should I tell my healthcare provider before taking ONIVYDE? (continued)

Before taking ONIVYDE, tell your healthcare provider if you: (continued)

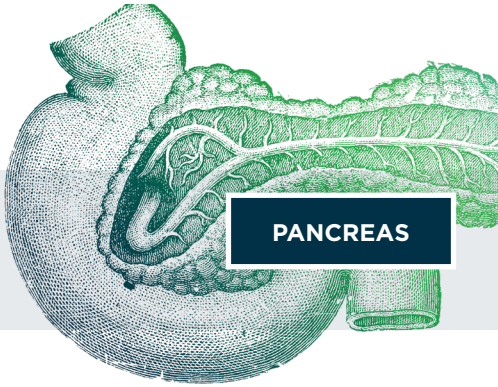
- are breastfeeding or plan to breastfeed. Patients should not breastfeed during treatment with ONIVYDE and for 1 month after the last dose.

HOW ONIVYDE WORKS

ONIVYDE is designed to treat **metastatic** pancreatic cancer. It is made up of a protective shell, called a **liposome**, that surrounds an anti-tumor drug called **irinotecan**. The liposome helps ONIVYDE stay in circulation in your body so that it can reach the tumor.

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

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

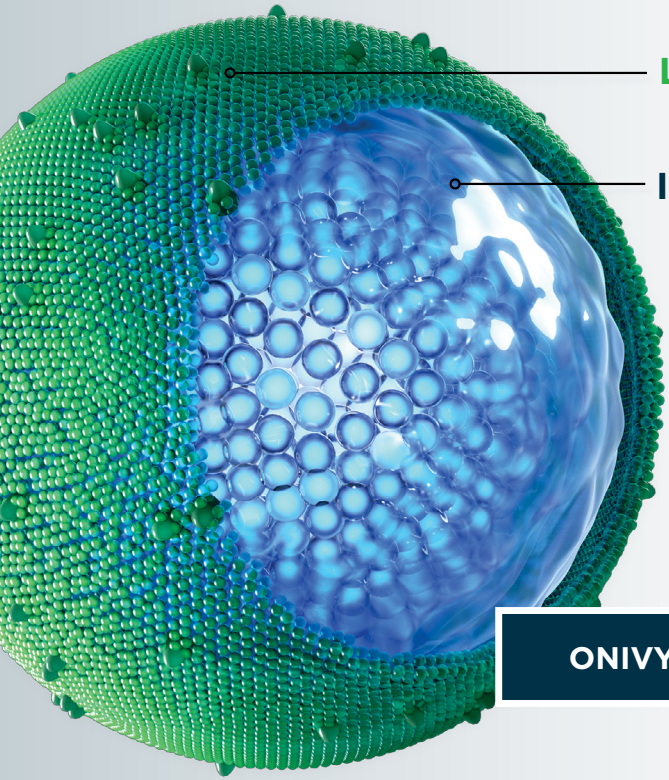


IMPORTANT SAFETY INFORMATION (continued)

What should I tell my healthcare provider before taking ONIVYDE? (continued)

Before taking ONIVYDE, tell your healthcare provider if you: (continued)

- 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.



IMPORTANT SAFETY INFORMATION (continued)

What should I tell my healthcare provider before taking ONIVYDE? (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.

POSSIBLE SIDE EFFECTS WITH NALIRIFOX OR ONIVYDE + FU/LV

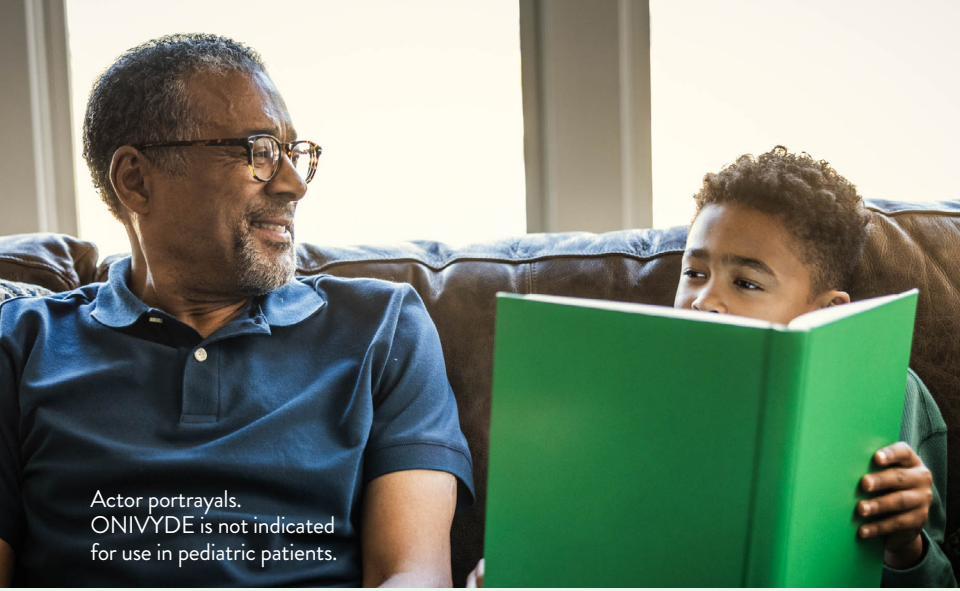
Any treatment for any illness can cause side effects, also called adverse events. Understanding which side effects might occur, how you can recognize them, and how you and your healthcare team might handle them is an important part of starting treatment.

IMPORTANT!

Be sure to let your healthcare team know about any side effects you may experience as soon as they occur.

Not all patients will experience all side effects, and the severity of side effects can change over time for each patient, so it is important to carefully pay attention to how you feel and be sure to talk to your healthcare team whenever you have concerns.

Also, be sure to tell your healthcare provider about all of the prescriptions, over-the-counter medicines, vitamins, and herbal supplements you take. They may cause side effects when taken with NALIRIFOX or ONIVYDE + FU/LV or they may affect how well the treatment works.



To help you and your loved ones keep track of all your questions and discussions you've had with your healthcare providers, consider using *MY TREATMENT JOURNEY: Care Team Discussion Guide*. You can also use this to write down any symptoms you may have and take it with you to each office visit.

The most common adverse events that people who have taken ONIVYDE have experienced were

- Moderate to severe fatigue or lack of energy
- Nausea
- Vomiting
- Decreased appetite
- Abdominal pain
- Decreased weight
- Diarrhea
- Constipation
- Swelling of the mouth or lips
- Inflammation of the intestinal lining
- Abnormal blood test results
- Fever

POSSIBLE SIDE EFFECTS WITH NALIRIFOX OR ONIVYDE + FU/LV (CONTINUED)

Your treatment team can help you know what to expect, when to expect it, and how to manage it. Some of these, however, can become quite serious. They are:

SEVERE AND LIFE-THREATENING NEUTROPENIA

- Neutropenia is an abnormally low number of neutrophils, and severe and life-threatening neutropenia can include fatal neutropenic sepsis and fatal neutropenic fever
- Neutrophils, or white blood cells, are responsible for fighting infections in your body. Without enough white blood cells for defense, infections that the body could usually fight off can spread throughout the body and may cause death
  - Your blood will be routinely checked for anything that is not normal
  - If you develop neutropenia, your doctor may temporarily stop (withhold) ONIVYDE to allow your white blood cell count to increase

If you develop neutropenia, you will need to watch for signs of infections, such as fever, chills, dizziness, or shortness of breath, and contact your healthcare team if you think you might be developing an infection, even a minor one.

SEVERE DIARRHEA

- Severe diarrhea can cause dehydration, decreased nutrient absorption, electrolyte imbalances, and kidney problems, and can even become life-threatening
- Diarrhea can also make infections associated with neutropenia harder to treat

IMPORTANT!

If you have any symptoms of diarrhea, such as loose stools, you should contact your healthcare provider and treatment team right away.

- Your healthcare team will ask you about the consistency of your stools and frequency of your bowel movements to monitor for diarrhea. Your doctor may stop (withhold) ONIVYDE if your diarrhea becomes severe. Depending on when in the treatment cycle you experience diarrhea, you may receive atropine or loperamide to help manage your diarrhea
- It's important to notice whether you are having more bowel movements per day or week compared with what is normal for you
  - If you are having 4-6 more bowel movements than normal per day, your healthcare team may have you stop taking ONIVYDE until your diarrhea is less frequent, and you may restart ONIVYDE at a lower dose
  - If you are having 7 or more bowel movements than normal per day, your healthcare team will need to keep a close eye on you while they take steps to control the diarrhea

POSSIBLE SIDE EFFECTS WITH NALIRIFOX OR ONIVYDE + FU/LV (CONTINUED)

SEVERE DIARRHEA (continued)

- If you have vomiting, black or bloody stools, or feel dehydrated, lightheaded, dizzy, or faint, your healthcare provider may give you some medicine to control symptoms or, depending on the severity of your symptoms, they may reduce your dose or stop your treatment
- 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. It's also a good idea to track how much fluid you're taking in, since diarrhea can cause dehydration. A smart water bottle or an app that tracks fluid intake can help with this and with keeping you hydrated

TALK TO YOUR HEALTHCARE TEAM

If a side effect is bothering you, don't keep it to yourself. Your doctor might be able to adjust the dose, change the schedule, or offer medications to help, but only if they know what you're experiencing.

INTERSTITIAL LUNG DISEASE

- Your doctor will check you at each visit for changes in your breathing and will permanently stop ONIVYDE if you develop early signs of scarring of the lungs, a condition called interstitial lung disease

REACTIONS TO THE INFUSION

- You will stop taking ONIVYDE if you have a strong reaction during or after infusions

OTHER SIDE EFFECTS

- Other side effects, while not life-threatening, can affect your work or home life and make staying on treatment unpleasant or difficult. Your healthcare team will have helpful suggestions for feeling your best while on treatment. If side effects from your treatment are too severe, you and your doctor may decide to pause ONIVYDE and then continue ONIVYDE at a lower dose to help keep you on treatment but help reduce the severity of side effects

SEEK MEDICAL ATTENTION IMMEDIATELY IF YOU DEVELOP

- 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
- New coughing, difficulty breathing, fever

These are not all the possible side effects that may occur with treatment. **Please talk to your healthcare provider about the other side effects that can occur.**

To help you and your loved ones keep track of all your questions and discussions you've had with your healthcare providers, consider using *MY TREATMENT JOURNEY: Care Team Discussion Guide*.

Actor portrayals. ONIVYDE is not indicated for use in pediatric patients.

NUTRITION IS IMPORTANT

Fighting cancer is hard. One of the challenges with pancreatic cancer is maintaining a nutritious diet. You may need to change your diet while you are undergoing treatment in order to get the nutrients you need. Talk to your healthcare provider about an optimal diet for your lifestyle.

If you experience weight loss because you are not able to get enough nutrients, you may feel tired, find it challenging to receive treatment, and become likely to get infections.

The goals of maintaining a nutritious diet are to help you

- Maintain healthy food intake so that you can continue to receive nutrients important for your body
- Avoid unintended weight loss
- Prevent potential problems with food digestion

SCAN THE QR CODE
for additional resources on nutrition.

A healthy pancreas helps break down carbohydrates and secretes enzymes to help digest protein and fats. With pancreatic cancer, food may be more difficult to digest. To help you get the nutrients you need from digestion, consider the following tips:

- Eat small, frequent meals with nutrient-dense foods throughout the day
- Chew slowly and well
- Drink plenty of fluids by sipping small amounts of liquid often. Even sucking on ice cubes may help increase your water intake

For more information, see the *ONIVYDE Patient Nutrition Guide for Pancreatic Cancer*.

Actor portrayals.

HOW MOVEMENT CAN HELP FIGHT FATIGUE

People who have cancer often feel tired and overwhelmed, which may be caused by the cancer, surgery, or the treatment.

Certain types of exercise may help reduce fatigue and can have additional benefits:

- A combination of light aerobic exercise (such as walking) and resistance exercise (using weights) may help people feel less tired from cancer or cancer treatment
- Exercise can also improve muscle strength, the ability to walk safely, and balance, which are important for maintaining independence

Consult with your healthcare provider before starting any new exercise regimen.

- Other types of exercise, such as yoga, tai chi, and stretching, can also help reduce tiredness
- It may be helpful to do some type of exercise on a regular basis, and it's also important not to overdo it
- You may find it helpful to plan your day to allow time for some type of exercise and some rest

TIPS FOR GETTING STARTED

Talk to your healthcare team about your medications, your current activity level, and your goals

Start slow and keep it simple. You may not be quite as fit as you were

Keep it interesting. Consider wearable fitness or fitness apps to help track progress. Mix up the types of exercise you do, and try new things

Celebrate the small things. If you're not feeling well, commit to doing something small and rewarding

Take your time, focus on comfort, and keep your doctor up to date on your activities

Consider working with a professional; ask your doctor to refer you to an exercise specialist to create a custom exercise program

Actor portrayals. ONIVYDE is not indicated for use in pediatric patients.

YOUR EMOTIONAL AND MENTAL HEALTH ARE A PRIORITY

With a diagnosis of pancreatic cancer, it can be easy to center your time and energy on caring for yourself physically. However, it's also very important to focus on your emotional and mental well-being.

You can start by paying attention to your emotions. If you are feeling depressed, anxious, or stressed, let your care team members know. They can direct you to people who know how to support you.

In addition, there are a number of tools you can try to find out which ones help you feel better emotionally and mentally:

Take time during your day to **practice deep breathing exercises.** This can help you feel more calm and reduce stress, anxiety, and depression.

A DEEP-BREATHING EXERCISE YOU CAN DO IS CALLED "4-7-8 BREATHING"

- **Breathe** in through your nose while you count to **4**
- Then **hold that breath** while you count to **7**
- Then **exhale** through your mouth slowly while you count to **8**

Note: If you become breathless or dizzy, return to normal breathing.

Spend time creating moments that have meaning for you and those that give you feelings of awe.

Let others know what you are needing. It's important for you to be honest with your family, friends, and healthcare team about what you need from them. This can be anything from what they talk about with you, especially around your cancer diagnosis, to how you want to spend your time.

Keep hope alive. Even if having pancreatic cancer doesn't leave you feeling hopeful, you can hope for other things, such as quality time with your family and friends and having meaning in your life.

ADVOCACY GROUPS

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

Pancreatic Cancer Action Network®
(877) 272-6226
PanCAN.org

PanCAN Patient Services is a lifeline for anyone impacted by a pancreatic cancer diagnosis. Case Managers offer ongoing support with free, personalized resources for any question related to pancreatic cancer.

Scan the QR code for quick access to the PanCAN website.

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.

Scan the QR code for quick access to the Let's Win Pancreatic Cancer Initiative website.

This information 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.

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 make 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.

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*) A type of white blood cell 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.

Overall survival How long a person lives for after starting treatment.

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.

Progression-free survival The length of time a person lives after starting treatment before the person's cancer starts to grow or spread again.

Stroma (*STROH-muh*) A dense wall of tissue that surrounds a tumor and can make it harder for some treatments to reach it.

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

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.
- 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.

IMPORTANT SAFETY INFORMATION (CONTINUED)

What are possible side effects of ONIVYDE?

ONIVYDE can cause serious side effects, including:

- **Very low white blood cell counts.** ONIVYDE can cause severe or life-threatening low white blood cell counts and fatal infections due to low white blood cell counts. 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.

IMPORTANT SAFETY INFORMATION (CONTINUED)

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

- 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.

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.

NOTES

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SUMMARY

- The ONIVYDE-containing regimens NALIRIFOX and ONIVYDE + FU/LV are designed for the treatment of metastatic pancreatic cancer
- The most severe potential side effects of these regimens are neutropenia, diarrhea, and fatigue. **If you experience these or any other side effects, contact your healthcare provider right away**
- Following a modified diet, exercising regularly, and taking care of your mental well-being may be helpful while you are receiving treatment. Be sure to scan the QR code on page 21 for additional resources
- IPSEN CARES® can help you with access to your treatment, understand your insurance coverage for ONIVYDE, and provide financial assistance to eligible patients

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 additional Important Safety Information on pages 26-31 and full Prescribing Information, including IMPORTANT WARNINGS for ONIVYDE.

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onivyde® (irinotecan liposome injection)

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