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.

SELECTED IMPORTANT SAFETY INFORMATION

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 cell count (neutropenic fever, neutropenic sepsis); diarrhea; lung problems (interstitial lung disease, a group of diseases which cause inflammation of the lung tissues leading to scarring); and reactions during administration of ONIVYDE® (including anaphylactic reactions).

Please see Important Safety Information on pages 20-22, and accompanying Full Prescribing Information, including Boxed Warning for ONIVYDE®.
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INTRODUCTION

This brochure is your guide to ONIVYDE® (irinotecan liposome injection), an approved chemotherapy medicine used to treat pancreatic cancer in patients who have already received gemcitabine, alone or in combination with other therapies, for their cancer and whose cancer is metastatic (has spread to other parts of their body). ONIVYDE® is given in combination with 2 other medicines (fluorouracil, also called 5-FU, and leucovorin, also called LV) and is not given alone.

Inside you’ll find:

• Information about ONIVYDE®, including dosing and possible side effects
• Tips for keeping track of possible side effects
• Tips for talking with your treatment team
• Support resources for you and your loved ones

This guide is designed to help you be proactive as you work with your medical team to make the best decisions about your therapy.
WHAT IS ONIVYDE® (irinotecan liposome injection)?

ONIVYDE® contains a chemotherapy drug called irinotecan, which in its active form interrupts cell reproduction. Irinotecan can be built into a container called a liposome. These liposomes are designed to release the medicine slowly over time.

In the clinical trial that led to FDA approval, ONIVYDE® was studied in combination with 2 other drugs called fluorouracil and leucovorin. This combination is referred to as ONIVYDE® + 5-FU/LV.

HOW ONIVYDE® WAS STUDIED

Your doctor may recommend ONIVYDE® to treat your metastatic pancreatic cancer. The effectiveness of ONIVYDE® + 5-FU/LV was demonstrated in a clinical trial.

Patients were split into 3 groups receiving ONIVYDE® + 5-FU/LV, 5-FU/LV alone, or ONIVYDE® alone.

SELECTED IMPORTANT SAFETY INFORMATION

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. When taking ONIVYDE, you may also have abnormal blood test results. The most common blood cell count change seen in ONIVYDE-treated pancreatic cancer patients is a reduction in the number of white blood cells, specifically lower lymphocytes and neutrophils (types of white blood cells), which are important for fighting infections.

Before you receive ONIVYDE, your healthcare provider will give you medications to decrease the potential for allergic reactions to infusion of ONIVYDE. You will also receive anti-nausea medicine to decrease nausea and vomiting, and, possibly, a medicine to decrease immediate diarrhea, called an anti-cholinergic.

The glossary on page 23 contains useful terms and definitions you may want to familiarize yourself with. These terms are highlighted.

Please see Important Safety Information on pages 20-22, and accompanying Full Prescribing Information, including Boxed Warning for ONIVYDE®.
HOW ONIVYDE® (irinotecan liposome injection) WAS STUDIED (CONT’D)

In this trial, ONIVYDE® + 5-FU/LV demonstrated an improvement in median overall survival (OS). An improvement in median OS means patients receiving ONIVYDE® + 5-FU/LV had a greater chance of living longer when compared with the 5-FU/LV alone group (6.1 months [4.8–8.5] median OS vs 4.2 months [3.3–5.3]).

A secondary goal of the trial was to assess progression-free survival (PFS). This means the trial was designed to assess the delay in time to tumor growth and disease progression. The ONIVYDE® + 5-FU/LV group also achieved an increase in median PFS when compared with the 5-FU/LV alone group (3.1 months vs 1.5 months, respectively). In other words, it took more time on average for the disease to progress for patients taking ONIVYDE® + 5-FU/LV than for patients taking 5-FU/LV alone.

ONIVYDE® may not work for every patient. Individual results may vary.

The OS data from this study supported the approval of ONIVYDE® + 5-FU/LV for use in patients with metastatic pancreatic cancer whose disease has progressed following treatment with gemcitabine or gemcitabine in combination with another therapy. ONIVYDE® is not approved for use as a single drug without 5-FU/LV.

SELECTED IMPORTANT SAFETY INFORMATION

When should ONIVYDE® not be taken?

You should not receive ONIVYDE® if:

• you have had a severe allergic reaction to ONIVYDE® or irinotecan HCl,
• your white blood cell count is low (neutrophil white blood cell count below the level of 1,500 cells/mm³),
• you have a fever and your neutrophil white blood cell count is low (also called neutropenic fever), or
• you have a problem in your bowel that prevents food, fluids or gas from moving through your intestines.

POTENTIAL PATIENTS* FOR ONIVYDE®

The following examples show a few potential patients for whom ONIVYDE® in combination may be appropriate. It is important to talk to your doctor about treatments that may be right for you.

Marc, 63
When Marc was diagnosed with metastatic pancreatic cancer, his doctor prescribed gemcitabine. When his disease began to progress again, Marc and his doctor discussed treatment options and decided to switch to ONIVYDE® + 5-FU/LV.

Jane, 72
Jane received gemcitabine in combination with another therapy in the locally advanced setting, but after receiving the news that her pancreatic cancer had metastasized, she and her doctor elected to start therapy with ONIVYDE® + 5-FU/LV.

Todd, 66
Todd has received two treatments for his metastatic pancreatic cancer—one containing 5-FU/LV and another containing gemcitabine. With his cancer now progressing, Todd’s doctor has chosen to switch him to ONIVYDE® + 5-FU/LV.

*Not actual patients.
**SELECTED IMPORTANT SAFETY INFORMATION TO KNOW ABOUT SERIOUS SIDE EFFECTS**

Serious side effects may occur while taking ONIVYDE® (irinotecan liposome injection). Call or see your healthcare provider right away if you develop any of the following or if these get worse.

**Serious side effects may include:**

- **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.** Diarrhea can be early (beginning within 24 hours of receiving ONIVYDE) or late (beginning more than 24 hours after ONIVYDE administration). 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.

**The following side effects may occur:**

<table>
<thead>
<tr>
<th>Very common</th>
<th>Common</th>
<th>Uncommon</th>
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<tbody>
<tr>
<td>• Low levels of white blood cells (neutropenia and leukopenia)</td>
<td>• Infections—for example, fungal infections in the mouth (oral candidiasis), fever with low counts of white blood cells (febrile neutropenia), infections related to the administration of the product into a vein</td>
<td>• Systemic body inflammation, caused by infection of the gall bladder and bile ducts (biliary sepsis)</td>
</tr>
<tr>
<td>• Diarrhea (loose or watery and frequent stools)</td>
<td>• Inflammation of the stomach and the guts (gastroenteritis)</td>
<td>• Allergic reaction to ONIVYDE® (the active substance or the excipients)</td>
</tr>
<tr>
<td>• Nausea and vomiting</td>
<td>• Unusual hair loss</td>
<td>• Diminished availability of oxygen to the body tissues</td>
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<tr>
<td>• Pain in the stomach or in the gut area</td>
<td>• Tiredness</td>
<td>• Inflammation of the esophagus (food pipe)</td>
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<tr>
<td>• Loss of weight</td>
<td>• Fever</td>
<td>• Inflammation of the lining of the rectum (the end of the large intestine)</td>
</tr>
<tr>
<td>• Loss of appetite</td>
<td>• Generalized weakness</td>
<td>• Type of rash, characterized by appearance of a flat, red area on the skin covered with bumps (maculopapular rash)</td>
</tr>
<tr>
<td>• Loss of body fluid (dehydration)</td>
<td></td>
<td>• Change in the color of the nail plates</td>
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</table>

**Getting medical treatment right away may keep these problems from becoming more serious.**

Please see Important Safety Information on pages 20–22, and accompanying Full Prescribing Information, including Boxed Warning for ONIVYDE®.
WHAT TO EXPECT WHEN RECEIVING ONIVYDE® (irinotecan liposome injection)

How is ONIVYDE® administered?

Before you receive ONIVYDE®, your healthcare provider will give you medication to decrease the potential for allergic reactions to infusion of ONIVYDE®. You will also receive an anti-nausea medicine to decrease nausea and vomiting, and possibly a medicine to decrease immediate diarrhea.

ONIVYDE® + 5-FU/LV is administered through intravenous infusion (IV). It will be given to you by a healthcare professional who is trained to administer chemotherapy.

- You’ll most likely receive ONIVYDE® and leucovorin (LV) in the healthcare setting over the course of a couple of hours (see sample recommended dosing regimen on page 11).

- After that, your doctor will probably give you a portable infusion pump for the fluorouracil (5-FU). This pump should be worn over about 46 hours, allowing you to receive 5-FU outside of the healthcare setting. You do not need to stay home during this time.

What do I need to plan for when receiving ONIVYDE® treatment?

The most common starting regimen of ONIVYDE® + 5-FU/LV is explained in the graphic below. The recommended schedule is to receive this therapy every 2 weeks, but your doctor may adjust that based on your response to treatment and any side effects you may experience.

When receiving ONIVYDE® + 5-FU/LV, you may experience abnormal blood test results. The most common blood count change seen in pancreatic cancer patients includes a reduction in the number of white blood cells, specifically lower lymphocytes and neutrophils. In order for your doctor to monitor your white blood cell count, you’ll need to have your blood drawn once a week (on Days 1 and 8 of each cycle of therapy with ONIVYDE®).

Sample Recommended Dosing Regimen

![Example of infusion pump used to administer 5-FU](image)

1. ONIVYDE® OVER 90 MINUTES
2. LEUCOVORIN OVER 30 MINUTES
3. FLUOROURACIL OVER 46 HOURS

Individualized Dosing Information

Your doctor will determine the appropriate dosing regimen for you. Dosing of ONIVYDE® may be adjusted based on a patient’s genes (genetic makeup) and/or liver function.

Dose Modifications

You should be aware that your doctor may choose to reduce, delay, or discontinue your dose of ONIVYDE® if you experience certain side effects while receiving ONIVYDE®.

Delaying a dose or having a dose withheld is not uncommon; over half of the patients in the ONIVYDE® + 5-FU/LV combination arm of the clinical trial experienced something similar. Be sure to talk to your doctor about options for managing side effects.

For a list of some important items to discuss with your treatment team before receiving ONIVYDE®, please see page 15 of this brochure.
OTHER CONSIDERATIONS BEFORE RECEIVING ONIVYDE® (irinotecan liposome injection)

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®.

KEEPING TRACK OF POSSIBLE SIDE EFFECTS

This tear-out log provides a space for you to keep track of any side effects you may experience. You can write down the date and time of each event, and record how you’re feeling. Bring this page into the doctor’s office at your next appointment.

Be sure to write down any other questions you may have, and any side effects you may be experiencing, even if they seem minor, to discuss with your doctor during your next visit.

<table>
<thead>
<tr>
<th>DATE</th>
<th>I’ve generally been feeling...</th>
<th>My appetite has been...</th>
<th>My energy level has been...</th>
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</tbody>
</table>

On the next page, we’ve included a tear-out log where you can keep a record of any side effects you may experience during treatment. Be sure to bring this log to your next doctor’s appointment.
DATE | I've generally been feeling... | My appetite has been... | My energy level has been...

Notes:

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TALKING WITH YOUR TREATMENT TEAM

You and your treatment team are working together to treat your cancer. Asking questions will keep you informed, and keeping track of the way you are feeling will help you communicate effectively with your treatment team.

**When should ONIVYDE® (irinotecan liposome injection) not be taken?**

You should not receive ONIVYDE® if:

- you have had a severe allergic reaction to ONIVYDE® or irinotecan HCl
- your white blood cell count is low (neutrophil white blood cell count below the level of 1,500 cells/mm$^3$),
- you have a fever and your neutrophil white blood cell count is low (also called neutropenic fever), or
- you have a problem in your bowel that prevents food, fluids, or gas from moving through your intestines

**Medications and supplements**

Be sure to tell your healthcare provider about all the medicines you take, including:

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

This will help your medical team understand any potential drug interactions between your medicines and ONIVYDE®.

---

The more openly you discuss your therapy with your doctor and medical team, including any side effects you experience, the better they can help you and manage any concerns you may have.

Please see Important Safety Information on pages 20-22, and accompanying Full Prescribing Information, including Boxed Warning for ONIVYDE®.
GENERAL NUTRITION TIPS

While your treatment team is the best source for advice to manage any side effects, some general nutritional tips are below.

Eat smaller meals slowly and more often, to avoid feeling too full.

Drink cool liquids (water, ginger ale, apple juice) slowly and at least an hour before or after mealtime.

Avoid
- Sweets or fatty, fried foods
- Smells such as smoke, perfume, or cooking odors that may bother you

There may be times during therapy that you don’t feel well. Even if you don’t feel like it, it’s important to keep eating—as appetite loss can lead to a loss of weight, muscle mass, and strength.

Diarrhea and vomiting can cause dehydration, so remember to drink plenty of water and other clear liquids.
If you are nauseated and can’t keep water down, try sucking on ice chips. Staying hydrated is important during therapy. Make sure to tell your doctor if you aren’t drinking water or notice symptoms of dehydration.

If you experience diarrhea...

Eat
- Smaller amounts of food, but eat more often
- Foods low in fiber, including white rice and white bread
- Canned or cooked, skinless fruit and pureed vegetables
- Potassium-rich foods like bananas, oranges, and potatoes (without the skin)

Drink
As soon as the first liquid stool occurs, start drinking large volumes of rehydration fluids (eg, water, soda water, soup) to avoid losing too much liquid and salt from your body.

Avoid
- Coffee, tea, alcohol
- Greasy, fried foods, or spicy foods
- Dairy products (if they make your diarrhea worse)
- Whole-grain breads, raw vegetables, and fresh or dried fruit

If loose stools persist, contact your doctor immediately.

Always report side effects or dietary changes to your doctor, even if they seem minor, so that together you can make appropriate decisions about your therapy experience.
QUESTIONS YOU MAY WANT TO ASK

These questions can help you start a discussion with your doctor. Be sure to write down any other questions you want to ask before your appointment.

- What should I do to be ready for treatment?
- What can I expect from therapy?
- What are common goals for treatment in this setting?
- Will I need to adjust my daily activities and responsibilities?
- What other lab tests or procedures do I need during therapy?
- What risks or side effects might I expect? How long are they likely to last?
- What will you do to manage my side effects? What can I do by myself?
- Are there any drugs I am currently taking that might interact with this new therapy?
- How can I tell if my therapy is working?
- What is the best way to contact you if I have a question? Who should I contact?
- Who will be part of my cancer care team, and what does each member do?
- What support services are available to me? To my family?
- Who can help me with managing costs for my therapy?
- Who handles health insurance concerns in your office?

The goal of IPSEN CARES® is to help simplify processes between you, your insurance company, and your doctor’s office.

With a wide range of services, IPSEN CARES® supports your treatment process every step of the way:

- Help you navigate the insurance process to determine out-of-pocket costs for treatment
- Help with copay assistance for eligible patients*
- Provide free medication through the Patient Assistance Program†
- Help keep any treatment delays or interruptions to a minimum
- Make sure your medication gets to you through specialty pharmacies
- Provide injection training for select medications, for you and your caregiver

To learn more, visit IPSENCARES.com or call (866) 435-5677.

*Patient Eligibility & Terms and Conditions: Only patients with commercial insurance and “cash-pay” patients are eligible. “Cash-pay” patients are defined for purposes of this program as patients without insurance coverage or who have commercial insurance that does not cover the Ipsen product in question. Medicare Part D enrollees who are in the prescription drug coverage gap (the “donut hole”) are not considered cash-pay patients, and are not eligible for the copay benefit. Patients are not eligible if prescriptions are paid in part or full by any state or federally funded programs, including, but not limited to, Medicare, Medicaid, or Medicaid Waivered programs (collectively, “Government Programs”).


Please see Important Safety Information on pages 20–22, and accompanying Full Prescribing Information, including Boxed Warning for ONIVYDE®.
IMPORTANT SAFETY INFORMATION ABOUT ONIVYDE® (irinotecan liposome injection) (CONT’D)

Serious side effects may occur while taking ONIVYDE. Call or see your healthcare provider right away if you develop any of the following or if these get worse.

Serious side effects may include:

• **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.

Getting medical treatment right away may keep these problems from becoming more serious.

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.

• 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).
**IMPORTANT SAFETY INFORMATION ABOUT ONIVYDE® (irinotecan liposome injection)**

**(CONT’D)**

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

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

**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.

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

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**GLOSSARY**

**Blood cell counts**—A count of the number of cells in a given sample of blood. Red blood cells, white blood cells, and platelets are most often counted in this lab test.

**Chemotherapy (kee-moh-THER-uh-pee)**—Medicines or drugs used to treat cancer. Often called chemo.

**Fluorouracil (5-FU) (flure-oh-YOOR-a-sil)**—A type of chemotherapy used in the treatment of certain cancers.

**Gemcitabine (jem-SITE-a-been)**—A chemotherapy drug used in the treatment of certain cancers.

**Intravenous (IV) (in-truh-VEE-nus) infusion**—Often shortened to IV. A method of giving fluids and medicines using a needle or a thin tube (called a catheter) that is put into a vein.

**Irinotecan (eye-rye-no-TEE-can)**—Irinotecan is an anti-cancer chemotherapy drug.

**Leucovorin (LV) (loo-koe-VOR-in)**—Also called folinic acid. Derived from folic acid and used in medicine in the treatment of certain anemias and certain cancers.

**Liposome (LIP-uh-sohm)**—An artificial sac that is used to deliver microscopic substances (DNA or drugs) to cells.

**Locally advanced (LOH-kuh-lee ad-VANST)**—Cancer that has not yet spread to distant organs but cannot be removed completely with surgery.

**Lymphocytes (LIM-fuh-sahyts)**—Cells originating from stem cells, constituting 20–30 percent of white blood cells of normal human blood.

**Metastatic (meh-Tuh-stak)**—Used to describe cancer that has spread from where it started (the primary site) to other structures or organs.

**Neutropenia (noo-trop-ee-nee-uh)**—A decrease in the number of white blood cells (neutrophils) that respond quickly to infection, which increases a person’s risk of infection.

**Neutrophils (NOO-tro-fils)**—Type of white blood cell.

**Sepsis (SEP-sis)**—Complication of an infection that occurs when chemicals released into the bloodstream trigger an inflammatory response in the body.
UNDERSTANDING THERAPY WITH ONIVYDE® (irinotecan liposome injection)

Inside this guide you’ll find:

• Information on what to expect when receiving treatment with ONIVYDE®, including dosing and possible side effects
• Space and guidance for keeping track of possible side effects
• Tips for talking with your treatment team
• A list of resources and advocacy groups for you and your loved ones
• A glossary of useful terms

Please see Important Safety Information on pages 20-22, and accompanying Full Prescribing Information, including Boxed Warning for ONIVYDE®.

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