

# ONIVYDE®

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### 1. Why am I using ONIVYDE?

ONIVYDE is a nanoliposomal formulation of irinotecan which means that the active substance irinotecan is contained in tiny lipid (fatty) particles called nanoliposomes. ONIVYDE is used to treat Pancreatic Cancer.

For more information, see Section [1. Why am I using ONIVYDE?](#) in the full CMI.

### 2. What should I know before I use ONIVYDE?

Do not use if you have ever had an allergic reaction to ONIVYDE or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use ONIVYDE?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with ONIVYDE and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### **4. How do I use ONIVYDE?**

ONIVYDE must only be given by healthcare professionals trained in administering anticancer medicines.

Your doctor will decide upon the doses you will receive. This depends on your condition, body weight and other factors and other chemotherapy medicines you are being given. Several courses of ONIVYDE therapy may be needed depending on your response to treatment.

More instructions can be found in Section [4. How do I use ONIVYDE?](#) in the full CMI.

## 5. What should I know while using ONIVYDE?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist, pharmacist or nurse you visit that you are using ONIVYDE.</li><li>• Keep all appointments and discuss with your doctor or nurse any problems during or after treatment.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not breastfeed if you are taking ONIVYDE.</li><li>• Do not start taking any other medicines, prescription or not, without first telling your doctor.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• ONIVYDE has moderate influence on a person's ability to drive and use machines. During treatment you should observe caution when driving or using machines.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Treatment will normally take place in a hospital</li></ul>

because of the need for hospital facilities and skilled personnel.

- ONIVYDE is stored in a refrigerator (2-8°C) protected from light. It must not be frozen.

For more information, see Section [5. What should I know while using ONIVYDE?](#) in the full CMI.

## **6. Are there any side effects?**

Very common side effects include but are not limited to increased risk of severe infections, anaemia, and diarrhoea (loose or watery and frequent stools).

Serious side effects include swelling under the skin (angioedema) and/or symptoms of possible anaphylactic/anaphylactoid reactions; fever, chills and signs of an infection; and persistent diarrhoea.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# ONIVYDE®

**Active ingredient(s):** *Nanoliposomal irinotecan* - irinotecan 4.3 mg/mL concentrate for solution for infusion

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using ONIVYDE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ONIVYDE.**

**Where to find information in this leaflet:**

- [1. Why am I using ONIVYDE?](#)
- [2. What should I know before I use ONIVYDE?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ONIVYDE?](#)
- [5. What should I know while using ONIVYDE?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using ONIVYDE?

ONIVYDE is a nanoliposomal formulation of irinotecan which means that the active substance irinotecan is contained in tiny lipid (fatty) particles called nanoliposomes.

Irinotecan is an anticancer medicine that belongs to the group of 'topoisomerase inhibitors'. It blocks an enzyme called topoisomerase I, which is involved in the division of cell DNA. When the enzyme is blocked, the DNA strands break. This prevents the cancer cells from multiplying and growing, and they eventually die.

The nanoliposomes are expected to accumulate within the tumour and release the medicine slowly over time, thereby decreasing the rate at which the irinotecan is removed from the body and allowing it to act for longer duration.

### **ONIVYDE is used to treat Pancreatic Cancer.**

- For patients whose pancreatic cancer has not been previously treated, ONIVYDE is used in combination with other cancer medicines, called oxaliplatin, 5-fluorouracil and leucovorin.
- For patients previously treated by gemcitabine, ONIVYDE is used in combination with other cancer medicines, called 5-fluorouracil and leucovorin.

This medicine belongs to a group of medicines called antineoplastic or cytotoxic medicines. You may also hear of these being called chemotherapy medicines.

ONIVYDE works by killing cancer cells and stopping them from multiplying. It will be given in combination with other anticancer medicines.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Your doctor may have prescribed it for another reason.

There is no evidence that it is addictive.

This medicine is available only with a doctor's prescription.

## **2. What should I know before I use ONIVYDE?**

### **Warnings**

#### **Do not use ONIVYDE if:**

you are allergic to irinotecan, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

#### **Tell your doctor before you are given ONIVYDE if you:**

- have any other medical conditions such as:
- have or have had liver, kidney, lung or heart disease
- have previously been treated with radiation therapy
- have difficulty urinating
- plan to have a vaccination as some vaccinations may not be given during chemotherapy
- have chronic inflammatory bowel disease
- have a bowel obstruction (a blockage that keeps food, liquid, gas, and stool from moving through the intestines in a normal way).

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Like most cytotoxic medicines ONIVYDE is not recommended for use during pregnancy. If there is any need to consider this medicine during your pregnancy, your doctor will discuss with you the benefits and risks of using it.

Prior to taking this medicine talk with your doctor about the possible risk with this medicine and the options that may preserve your ability to have children.

During treatment with ONIVYDE and for seven months after you cease treatment with ONIVYDE, you should choose a suitable effective birth control method to prevent pregnancy during this period. Males should use condoms during treatment with ONIVYDE and for 4 months thereafter.

### **Do not breastfeed if you are taking this medicine.**

The active ingredient in ONIVYDE may pass into breast milk and there is a possibility that your baby may be affected.

**The safety and effectiveness of ONIVYDE in children (under 18 years) has not been established.**

- **If you are not sure whether you should be given this medicine, talk to your doctor.**

### **3. What if I am taking other medicines?**

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Tell your doctor, pharmacist or nurse if you are already having, or have recently had chemotherapy and/or radiotherapy or treatment with the antifungal medicine flucytosine.

**Some medicines may interfere with ONIVYDE and affect how it works.**

**Medicines that may increase the effect of ONIVYDE include:**

- grapefruit juice
- ketoconazole, itraconazole or voriconazole (medicines used to treat fungal infections)
- clarithromycin (an antibiotic medicine used to treat bacterial infections)
- indinavir, lopinavir, nelfinavir, ritonavir, saquinavir, atazanavir (medicines against HIV infection)
- telaprevir (a medicine used to treat a liver disease called hepatitis C)

- nefazodone (a medicine used to treat depression, sad mood)
- gemfibrozil (medicine used to treat high fat levels in the blood).

**Medicines that may reduce the effect of ONIVYDE include:**

- phenytoin, phenobarbital or carbamazepine (medicines used to treat convulsions and falls)
- rifampicin and rifabutin (medicines used to treat tuberculosis)
- St. John's wort (a medicine used to treat depression and sad mood).
- **Other medicines to be careful of:**
- laxatives - as they may increase the chance of having diarrhoea with ONIVYDE
- fluid pills for blood pressure - as they may increase the chance of dehydration due to vomiting or diarrhoea with ONIVYDE.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ONIVYDE.**

You may need to take different amounts of your medicines, or you may need to use different medicines.

Your doctor, or pharmacist or nurse will have more information to be careful with or avoid while taking this medicine.

## **4. How do I use ONIVYDE?**

### **How much to take / use**

You should be treated with ONIVYDE by a doctor who is experienced in treating patients with cancer. Treatment will normally take place in a hospital because of the need for hospital facilities and skilled personnel.

Before you start treatment with ONIVYDE pegylated liposomal, if you have been previously treated with a medicine called gemcitabine, your doctor will perform blood tests (or other medical examinations) to determine the best starting dose for you.

You will need to have (blood or other) tests during treatment so that your doctor can monitor your blood cells and assess how you are responding to the treatment. Your doctor may need to adjust the dose or your treatment.

It is likely that your doctor will give you one or more medicines before administering ONIVYDE, to help stop you vomiting or feeling sick after the treatment. You will probably also have blood tests before each treatment.

### **How much to take / use**

Your doctor will decide upon the doses you will receive. This depends on your condition, body weight and other factors and other chemotherapy medicines you are being given.

## **When to take / use ONIVYDE**

ONIVYDE must only be given by healthcare professionals trained in administering anticancer medicines.

ONIVYDE may be given in combination with other medicines.

Several courses of ONIVYDE therapy may be needed depending on your response to treatment.

Additional treatment may not be repeated until your blood cell numbers return to acceptable levels and any uncontrolled effects have been controlled.

## **How ONIVYDE is administered**

ONIVYDE is diluted with saline or dextrose and usually given as an infusion (drip) into a vein over 90 minutes and is followed by an infusion of other medicines.

If your cancer has not been previously treated, after you have been given ONIVYDE you will be given three other medicines called: oxaliplatin, leucovorin and 5-fluorouracil.

If your cancer has been previously treated with a medicine called gemcitabine, after you have been given ONIVYDE you will be given two other medicines called: leucovorin and 5-fluorouracil.

The treatment will be repeated every two weeks.

You may receive premedication against nausea and vomiting. If you have experienced sweating, abdominal cramping, and salivation together with early frequent and liquid stools in previous treatments with ONIVYDE, you may receive additional medicines before ONIVYDE to prevent or reduce this in the following treatment cycles.

Ask your doctor if you want more information about the dose of ONIVYDE and the other medicines you will be receiving and how they are given while you are being treated with ONIVYDE.

## **5. What should I know while using ONIVYDE?**

### **Things you should do**

**Keep all appointments with your doctor and always discuss with your doctor any problems during or after treatment with ONIVYDE.**

### **Call your doctor straight away if you:**

- experience diarrhoea

Diarrhoea is a common side effect of ONIVYDE. If untreated, severe diarrhoea can be life-threatening.

Your doctor will prescribe loperamide (a medicine to treat diarrhoea) for you to take in case you get diarrhoea after treatment. You should start taking loperamide, when you first have poorly formed or loose stools or

have more frequent bowel movements than you would normally expect.

**You must tell your doctor if you cannot get diarrhoea under control within 24 hours after taking loperamide.**

You should not take loperamide for more than 48 hours.

**Also tell your doctor if you develop a fever in addition to the diarrhoea.**

In these cases, your doctor may give you antibiotics. If the diarrhoea or fever persists you may become dehydrated and need to go to Accident and Emergency at your nearest hospital for treatment.

This medicine can lower the number of white blood cells and platelets in your blood. This means that you have an increased chance of getting an infection or bleeding. You may need to take antibiotics if there are changes in your blood tests indicating a lack of white blood cells. Symptoms of this may include frequent infections such as fever, severe chills, sore throat or mouth ulcers. If this persists, you may need to go to Accident and Emergency at your nearest hospital for treatment.

If you have severe stomach cramps, you may need to be treated with antibiotics.

**If you become pregnant while you are being treated with this medicine, tell your doctor immediately.**

Talk to your doctor if you need more information about this.

Remind any doctor, dentist or pharmacist you visit that you are using ONIVYDE.

## **Things you should not do**

- Do not start taking any other medicines, prescription or not, without first telling your doctor.

## **Driving or using machines**

Be careful before you drive or use any machines or tools until you know how ONIVYDE affects you.

## **Looking after your medicine**

ONIVYDE is stored in a refrigerator (2-8°C) protected from light.

It must not be frozen.

**Keep it where young children cannot reach it.**

## **When to discard your medicine**

**Do not use ONIVYDE after the expiry date which is printed on the label after the word 'EXP'.**

The expiry date refers to the last day of that month.

## **6. Are there any side effects?**

**Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are being given ONIVYDE.**

ONIVYDE, like all other medicines, may cause unwanted side effects. Side effects are very common with anti-cancer medicines such as ONIVYDE and they may be serious. You may need medical treatment if you get some of the side effects.

**Do not be alarmed by the following lists of side effects. You may not experience any of them.**

**Tell your doctor as soon as possible if you experience any side effects, including any effects not listed below.**

**Tell your doctor immediately if you get any of the following side effects:**

**Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Immune system</b></p> <ul style="list-style-type: none"><li>• swelling under the skin (angioedema) and/or symptoms of possible anaphylactic/anaphylactoid reactions such as sudden shortness of breath, flushing, headache, tightness in the chest or throat during the infusion or shortly after it. Severe allergic reactions may be life threatening. The</li></ul>	<p><b>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p>infusion may need to be stopped and you may need to be treated or observed</p> <p><b>Infections</b></p> <ul style="list-style-type: none"> <li>• fever, chills and signs of an infection (as this might require immediate treatment)</li> </ul> <p><b>Gastro-intestinal</b></p> <ul style="list-style-type: none"> <li>• severe persistent diarrhoea (liquid and frequent stools)</li> </ul> <p><b>The above side effects may be serious. You may need urgent medical attention.</b></p>	

**Tell your doctor immediately if you get any of the following side effects:**

## Less serious side effects

Less serious side effects	What to do
<p data-bbox="204 432 432 477"><b>Infections</b></p> <ul data-bbox="204 510 774 1413" style="list-style-type: none"><li data-bbox="204 510 659 674">● Increased risk of infections including severe infections</li><li data-bbox="204 696 724 797">● Fungal infection of the mouth</li><li data-bbox="204 819 727 987">● Infection related to the administration of the product into a vein</li><li data-bbox="204 1010 770 1167">● Whole body inflammation, caused by infection</li><li data-bbox="204 1189 774 1346">● Infection of the parts of the body that collect and pass out urine</li><li data-bbox="204 1368 373 1413">● Fever</li></ul> <p data-bbox="204 1447 341 1491"><b>Blood</b></p> <ul data-bbox="204 1525 774 1989" style="list-style-type: none"><li data-bbox="204 1525 695 1738">● Anaemia, which may make you weak and light-headed or may cause you to faint</li><li data-bbox="204 1760 774 1861">● Reduction in white blood cell numbers</li><li data-bbox="204 1883 692 1989">● Low platelets in your blood</li></ul>	<p data-bbox="817 432 1374 651"><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
<p><b>Metabolism related</b></p> <ul style="list-style-type: none"> <li>● Loss of body fluid (dehydration)</li> <li>● Low blood sugar</li> <li>● Decrease in some salts (electrolytes) in the body</li> </ul> <p><b>Gastro-intestinal</b></p> <ul style="list-style-type: none"> <li>● Diarrhoea (loose or watery and frequent stools)</li> <li>● Nausea and vomiting</li> <li>● Dry mouth</li> <li>● Difficulty in swallowing</li> <li>● Disease where stomach acid rises up into the oesophagus (gastroesophageal reflux disease)</li> <li>● Inflammation of the stomach and the gut (gastroenteritis)</li> <li>● Pain and inflammation of the bowel causing diarrhoea (enterocolitis), gas, swelling in belly</li> <li>● Indigestion</li> <li>● Constipation</li> </ul>	

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• Loss of appetite</li> </ul> <p><b>Nervous system / psychiatric</b></p> <ul style="list-style-type: none"> <li>• Headache</li> <li>• Pain, numbness, burning and tingling in the arms and/or legs (peripheral neuropathy)</li> <li>• Numbness, tingling, pins and needles of the hands and/or feet (paraesthesia)</li> <li>• A syndrome called cholinergic syndrome with sweating, salivation and abdominal cramping</li> <li>• Sleeplessness</li> <li>• Toxicity altering the nervous system</li> <li>• Unpleasant and abnormal feeling when touched</li> <li>• Shaking</li> <li>• A change in the sense of taste</li> </ul> <p><b>Eye</b></p> <ul style="list-style-type: none"> <li>• Blurry vision</li> </ul>	

<b>Less serious side effects</b>	<b>What to do</b>
<p><b>Ear</b></p> <ul style="list-style-type: none"> <li>• Dizziness</li> </ul> <p><b>Heart</b></p> <ul style="list-style-type: none"> <li>• Rapid heartbeat</li> </ul> <p><b>Vascular</b></p> <ul style="list-style-type: none"> <li>• Low blood pressure</li> <li>• Blood clots</li> <li>• Swollen and/or inflamed veins in the low gut area</li> </ul> <p><b>Respiratory</b></p> <ul style="list-style-type: none"> <li>• Hiccups</li> <li>• Inflammation of the nose and throat</li> <li>• Nosebleed</li> <li>• Voice impairment and shortness of breath</li> </ul> <p><b>Skin</b></p> <ul style="list-style-type: none"> <li>• Hand foot syndrome - redness, swelling, and/or pain on the palms of the hands and/or the soles of the feet</li> <li>• Dry skin</li> <li>• Skin eruption</li> <li>• Darkened areas of skin (hyperpigmentation)</li> </ul>	

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• Itching</li> <li>• Sore mouth and lips</li> <li>• Unusual hair loss</li> </ul> <p><b>Musculoskeletal</b></p> <ul style="list-style-type: none"> <li>• Muscular weakness, muscle pain, abnormal muscle contractions</li> </ul> <p><b>Kidney related</b></p> <ul style="list-style-type: none"> <li>• Sudden problems with the kidney function</li> </ul> <p><b>Test results</b></p> <ul style="list-style-type: none"> <li>• Increased or decreased liver enzymes in laboratory tests</li> <li>• Abnormal changes in blood protein levels in laboratory tests</li> </ul> <p><b>General</b></p> <ul style="list-style-type: none"> <li>• Tiredness and generalised weakness</li> <li>• Weight loss</li> <li>• Abnormal fluid retention which results in swelling</li> </ul>	

**Tell your doctor, nurse or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What ONIVYDE contains

<b>Active ingredient (main ingredient)</b>	Irinotecan hydrochloride trihydrate.  One vial contains 43 mg irinotecan (as sucrosolate salt).
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• distearoylphosphatidylcholine (DSPC)</li><li>• cholesterol</li></ul>

- sodium methoxy PEG-40-carbonyl-distearoyl-phosphatidylethanolamine (MPEG-2000-DSPE), 4 - (2-hydroxyethyl)-1-piperazineethanesulfonic acid (HEPES)
- sodium chloride
- sucrosolate; and
- water for injections.

**Do not take this medicine if you are allergic to any of these ingredients.**

## **What ONIVYDE looks like**

ONIVYDE is a sterile white to slightly yellow opaque dispersion in a glass vial and needs to be diluted prior to using a needle no larger than 21 gauge.

ONIVYDE is registered on the Australian register of Therapeutic Goods (AUST R 263184).

## **Who distributes ONIVYDE**

ONIVYDE is distributed in Australia by:

Servier Laboratories (Aust.) Pty Ltd

Level 4, Building 9,

588A Swan Street

Burnley Victoria 3121.

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