

ONIVYDE

Nanoliposomal irinotecan - Irinotecan 4.3 mg/mL concentrate for solution for infusion

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ONIVYDE.

It does not contain all of the available information. All medicines have risks and benefits. Your doctor has weighed the risks of using your medicine against the benefit that it will have for you.

It does not take the place of talking to your doctor or pharmacist.

If you have any concerns about having this medicine, ask your doctor or pharmacist.

Please read this leaflet carefully and keep it for future reference.

Please also note that this leaflet is subjected to change, therefore, ask your doctor whether this is the latest information regarding this medicine.

What is 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.

What ONIVYDE is used for

This medicine is used to treat Pancreatic Cancer.

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.

Before being treated with ONIVYDE

When ONIVYDE must not be given

ONIVYDE must not be given if you:

- are allergic to irinotecan or any of the ingredients listed at the end of this leaflet

Tell your doctor if you are pregnant or plan to become pregnant.

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.

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.

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

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

Before treatment with ONIVYDE

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.

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.

You should tell your doctor if:

- you have or have had liver, kidney, lung or heart disease
- you have previously been treated with radiation therapy
- you have difficulty urinating
- you plan to have a vaccination as some vaccinations may not be given during chemotherapy

If you have not told your doctor about any of the above, tell your doctor before you are given ONIVYDE.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including:

- all prescription medicines
- all medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a pharmacy, supermarket, naturopath or health food shop.

Some medicines and ONIVYDE may interfere with each other. In particular, tell your doctor if you are taking:

- phenytoin, phenobarbital or carbamazepin (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)

Since they reduce the availability of the active substance of ONIVYDE in your body.

It is especially important that you tell your doctor if you are also taking:

- 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)

Since they increase the availability of the active substance of Onivyde in your body.

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.

Ask your doctor or other healthcare professional if you are not sure about this list of medicines.

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

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

How ONIVYDE is given

How much is given

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.

ONIVYDE may be given in combination with other drugs.

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 given

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.

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.

Overdose

As ONIVYDE is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you experience severe side effects after being given this medicine, tell your doctor or nurse immediately.

You may need urgent medical attention.

Symptoms of an ONIVYDE overdose include the side effects listed below in the 'Side Effects' section, but are usually of a more severe nature.

While being treated with ONIVYDE

Things you must do

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

Tell your doctor as soon as possible if diarrhoea occurs.

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.

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

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 immediately if you get any of the following side effects:

- sudden shortness of breath, flushing, headache, tightness in the chest or throat during the infusion or shortly after it (as the infusion may need to be stopped and you may need to be treated or observed)
- fever, chills and signs of an infection (as this might require immediate treatment)
- severe persistent diarrhoea (liquid and frequent stools)

The above side effects may be serious. You may need urgent medical attention.

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

Very common side effects (may affect more than 1 in 10 people)

- Increased risk of infections including severe infections
- Anaemia, which may make you weak and light-headed or may cause you to faint
- Diarrhoea (loose or watery and frequent stools)
- Nausea and vomiting
- Sore mouth and lips

- Loss of appetite and loss of weight
- Loss of body fluid (dehydration)
- Unusual hair loss
- Tiredness
- Dizziness
- Fluid retention which results in swelling
- Pain and swelling in the stomach or the gut area
- Fever
- Generalised weakness

Common side effects (may affect up to 1 in 10 people)

- Fungal infection of the mouth
- Infection related to the administration of the product into a vein
- Inflammation of the stomach and the guts (gastroenteritis)
- Whole body inflammation, caused by infection
- Decrease in some salts (electrolytes) in the body
- Low blood sugar
- Sleeplessness
- A change in the sense of taste
- A syndrome called cholinergic syndrome with sweating, salivation and abdominal cramping
- Low blood pressure
- Blood clots
- Voice impairment and shortness of breath
- Swollen and/or inflamed veins in the low gut area
- Increased or decreased liver enzymes in laboratory tests
- Sudden problems with the kidney function (Abnormal fluid retention)

Your doctor has information on monitoring for such side effects and their treatment.

Storage

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

It must not be frozen.

Keep out of the reach and sight of children.

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.

Product Description

What ONIVYDE looks like?

ONIVYDE is a white to slightly yellow opaque dispersion in a glass vial and needs to be diluted prior to use.

Active ingredient:

Irinotecan hydrochloride trihydrate.

One vial contains 43 mg irinotecan (as sucrofosate salt).

ONIVYDE also contains:

Distearoylphosphatidylcholine (DSPC), cholesterol, Sodium methoxy PEG-40-carbonyl-distearoyl-phosphatidylethanolamine (MPEG-2000-DSPE), 4 - (2-hydroxyethyl)-1-piperazineethanesulfonic acid (HEPES), sodium chloride, sucrofosate and water for injections.

Name and address of the sponsor

ONIVYDE is distributed in Australia by:

Servier Laboratories (Aust.) Pty Ltd
8 Cato Street
PO Box 196
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