

YONDELIS

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.

1. Why am I using YONDELIS?

YONDELIS contains the active ingredient trabectedin. YONDELIS is used for the treatment of patients with liposarcoma or leiomyosarcoma, which are types of soft tissue sarcoma, when previous medicines have been unsuccessful, or the patients are unsuited to receive them.

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

2. What should I know before I use YONDELIS?

Do not use if you have ever had an allergic reaction to trabectedin 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. Women of childbearing potential must use effective contraception during and for 3 months after YONDELIS treatment. Men of fertile age must use effective contraception during and for 5 months after YONDELIS treatment.

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

3. What if I am taking other medicines?

Some medicines may interfere with YONDELIS 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 is YONDELIS given?

- The usual dose is 1.5 mg/m² of body surface area.
- YONDELIS will be given to you as an infusion (a drip) into a vein (intravenously) over a period of 24 hours.

More instructions can be found in Section [4. How is YONDELIS given?](#) in the full CMI.

5. What should I know while using YONDELIS?

Things you must do	<ul style="list-style-type: none">• If you are about to be started on any new medicine, remind your doctor that you are being given YONDELIS• Remind any doctor dentist or pharmacist you visit that you are using YONDELIS.• If you become pregnant while being given this medicine, tell your doctor immediately.
Things you must not do	<ul style="list-style-type: none">• Do not take this medicine if you are pregnant or breastfeeding.• Do not take this medicine if you have any serious infections.• Do not take this medicine if you have problems with your liver, kidney or heart.• Do not take this medicine if you will receive yellow fever vaccine.
Driving or using machines	<ul style="list-style-type: none">• During your treatment with YONDELIS you may feel tired and experience loss of strength. Do not drive or use any tools or machines if you are experiencing any of these side effects.
Drinking alcohol	<ul style="list-style-type: none">• Alcohol consumption must be avoided during treatment with YONDELIS as this may harm the liver.

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

6. Are there any side effects?

The most common side effect is the increased levels of the yellow pigment bilirubin in the blood which might cause jaundice (a yellowing of the skin, mucous membranes and eyes). Serious side effects include fever, severe muscle pain or weakness, reaction at the site of injection, allergic reaction (when your body reacts to the medicine) and capillary leak syndrome (excessive accumulation of fluid in your tissues). 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.

YONDELIS

Active ingredient(s): *trabectedin*

Consumer Medicine Information (CMI)

This leaflet provides important information about using YONDELIS. **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 YONDELIS.**

Where to find information in this leaflet:

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

1. Why am I using YONDELIS?

YONDELIS contains the active ingredient trabectedin. YONDELIS is an anti-cancer medicine that works by preventing the tumour cells from multiplying.

YONDELIS is used for the treatment of patients with liposarcoma or leiomyosarcoma, which are types of soft tissue sarcoma, when previous medicines have been unsuccessful, or the patients are unsuited to receive them. Soft tissue sarcoma is a malignant disease that starts somewhere in the soft tissues, such as the muscles, fat or other tissues (for example cartilages or vessels).

2. What should I know before I use YONDELIS?

Warnings

Do not use YONDELIS if:

- you are allergic to trabectedin, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you have liver, kidney or heart problems
- you have any serious infections
- you are pregnant or plan to become pregnant
- you are breast-feeding
- you will receive yellow fever vaccine
- you are a child or adolescent

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- have liver or kidney problems

- cardiac problems or a history of cardiac problems
- left ventricular ejection fraction (LVEF) under the lower limit of normal
- received high anthracycline dose treatment in the past

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. YONDELIS must not be used during pregnancy.

Tell your doctor immediately if you become pregnant. Genetic counselling is recommended since YONDELIS can cause genetic damage.

Adequate contraceptive precautions must be used by:

- women of childbearing potential when receiving YONDELIS and for 3 months following the end of treatment.
- men in fertile age when receiving YONDELIS and for 5 months following the end of treatment.

Tell your doctor if you are planning to have children.

Patients should seek advice on ovules or sperm conservation prior to treatment because of the risk of irreversible infertility due to therapy with YONDELIS. Genetic counselling is also recommended for patients wishing to have children after therapy.

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

YONDELIS must not be given to patients who are breast-feeding. Therefore you must stop breast-feeding before you start your treatment and you must not begin breast-feeding again until your doctor has confirmed that it is safe to do so.

YONDELIS contains potassium

This medicine contains potassium, less than 1 mmol (39 mg) per vial, and can therefore be considered as essentially “potassium-free”.

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.

You must not use YONDELIS if you will receive yellow fever vaccine. It is not recommended that you use YONDELIS if you will receive a vaccine containing live virus particles. The effect of medicines containing phenytoin (for epilepsy) may be decreased if given together with YONDELIS and this is therefore not recommended.

Some medicines may interfere with YONDELIS and affect how it works, therefore you should avoid the use of YONDELIS together with the medicines listed below.

Medicines that may increase the effect of YONDELIS include medicines that contain:

- ketoconazole or fluconazole (for fungal infections),
- ritonavir (for human immunodeficiency virus [HIV] infection),
- clarithromycin (for bacterial infections),
- aprepitant (to prevent nausea and vomiting),
- cyclosporin (inhibit the defensive system of the body) or
- verapamil (for high blood pressure and heart conditions).

Medicines that may reduce the effect of YONDELIS include medicines that contain:

- rifampicin (for bacterial infections),
- phenobarbital (for epilepsy) or
- St. John's Wort (*Hypericum perforatum*, an herbal medicine for depression).

If you are given YONDELIS together with a medicine that might cause damage to the liver or to the muscles (rhabdomyolysis), you may need to be closely monitored, as there could be an increased risk of liver or muscle damage. Medicines containing statins (for lowering cholesterol levels and preventing cardiovascular disease) is an example of medicines that may cause muscle damage.

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

4. How is YONDELIS given?

YONDELIS is given to you in the hospital or clinic under the supervision of a physician experienced in the use of chemotherapy. Its use should be confined to qualified oncologists or other health professionals specialised in the administration of cytotoxic medicines.

How much is given

- The usual dose is 1.5 mg/m² of body surface area.
- During the treatment period, your doctor will carefully monitor you and decide the most appropriate dosage of YONDELIS to give to you.
- The recommended dose in Japanese patients is lower than the usual dose for all other races and is 1.2 mg/m² of body surface area.

How it is given

- Before YONDELIS is given to you, it will be reconstituted and diluted for intravenous use.
- YONDELIS will be given to you as an infusion (a drip) into a vein (intravenously) over a period of 24 hours.
- In order to avoid irritation at the site of injection it is recommended that YONDELIS is given to you through a central venous line.
- You will be given a medicine before and as needed during the treatment with YONDELIS in order to protect your liver and to reduce the risk of side effects such as feeling sick (nausea) and vomiting.

How long it will be given for

- The infusion is given to you every 3 weeks, although occasionally your doctor may recommend dose delays to ensure that you receive the most appropriate dose of YONDELIS.
- The length of your whole treatment period will depend on your progress and how well you feel. Your doctor will tell you how long your treatment lasts.

If too much is given (overdose)

As this medicine is being given by your doctor or nurse, it is unlikely that you will be given too much. In the unlikely event of an overdose, your doctor will monitor you for side effects treat any of your symptoms as required.

If you have any further questions on the use of this medicine, ask your doctor.

5. What should I know while using YONDELIS?

If you receive YONDELIS and feel any of the symptoms mentioned **under Section 6. Are there any side effects?** during your treatment, your doctor or nurse must be informed. In case you suffer these symptoms, the YONDELIS dose may be omitted temporarily or reduced depending on the severity.

Things you must do

- If you are about to be started on any new medicine, remind your doctor that you are being given YONDELIS.
- Remind any doctor, dentist or pharmacist you visit that you are using YONDELIS.
- Tell your doctor or nurse straight away if you experience an allergic reaction or feel unwell during the infusion.

Typical symptoms associated with allergic reactions are redness of the face or chest, itching, coughing, shortness of breath, chest discomfort, etc. Other symptoms may occur as well.

These side effects mostly occur during or after the infusion of the first dose. You will be monitored for signs of these effects during and after the infusion.

Depending on the seriousness of the allergic reactions, your infusion of YONDELIS may be interrupted. You may require additional treatment to prevent complications and reduce your symptoms.

When the symptoms go away or improve, the infusion can be continued more slowly, and speeded up gradually if the symptoms do not recur. Your doctor may decide not to continue YONDELIS treatment if you have a strong infusion reaction.

Your doctor may want to take additional precautions.

Call your doctor straight away if you become pregnant while being given this medicine.

Things you must not do

- Do not take this medicine if you are pregnant or breastfeeding.
- Do not take this medicine if you have any serious infections.
- Do not take this medicine if you have problems with your liver, kidney or heart.
- Do not take this medicine if you will receive yellow fever vaccine.

Driving or using machines

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

During your treatment with YONDELIS you may feel tired and experience loss of strength. Do not drive or use any tools or machines if you are experiencing any of these side effects.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol consumption must be avoided during treatment with YONDELIS as this may harm the liver.

Storage

YONDELIS will be stored in the pharmacy or on the ward. The medicine is kept in its original packaging in the refrigerator where the temperature stays between 2°C and 8°C.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Your doctor will perform certain checks periodically to test for side effects that may affect the blood, liver, kidneys, heart and muscle.

Less serious side effects

Less serious side effects	What to do
<p>General or affecting different parts of the body:</p> <ul style="list-style-type: none"> • Tiredness • More likely to get infections • Headache • Sleeping problems • Hair loss (alopecia) • Dizziness, low blood pressure and flushing or skin rash <p>Muscle or pain related:</p> <ul style="list-style-type: none"> • Pain in back and joints <p>Stomach and digestive system related:</p> <ul style="list-style-type: none"> • Stomach pain including cramps and aches • Loss of appetite • Nausea. Symptoms include stomach discomfort, feeling sick or the feeling that you are going to vomit • Vomiting • Constipation • Diarrhoea • Mucosal inflammation as a swelling redness of the inside of the mouth leading to painful ulcers, mouth sores and inflammation of the mouth (stomatitis) • Loss of water from the body, weight loss, digestive discomfort and a change in your sense of taste 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>General or affecting different parts of the body:</p> <ul style="list-style-type: none"> • Fever which may cause side-effects affecting your blood and liver • YONDELIS infusion leaks out of your vein while you are being given it. It could lead to damage and death of your tissue cells around the injection site (tissue necrosis) which may require surgery • Allergic reaction (hypersensitivity). Symptoms include fever, difficulty in breathing, redness or flushing of skin or a rash, feeling sick (nausea) or being sick (vomiting) • Unexplained partial or general swelling (oedema), with possible 	<p>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.</p>

<p>lightheadedness, dizziness or thirst (low blood pressure). It could be a sign of a condition (capillary leak syndrome) that can cause excessive accumulation of fluid in your tissues</p> <ul style="list-style-type: none"> • Infusion leaks out of your vein while you are being given it (extravasation). Symptoms include some redness, swelling, itchiness and discomfort at the injection site. This could lead to damage and death of your tissue cells around the injection site (tissue necrosis) which may require surgery. Some of the symptoms or signs of extravasation may not be visible until several hours after it occurred. There may be blistering, peeling and darkening of the skin over the site. It is possible for it to take a few days before the full extent of tissue damage is visible. • Excess of fluid in the body (oedema). You may experience an abnormal build-up of fluid in the lungs, which leads to swelling (pulmonary oedema) • Difficulty breathing and coughing <p>Infection related:</p> <ul style="list-style-type: none"> • Serious blood infections (sepsis) if your immune system is greatly compromised due to low white blood cell counts <p>Blood related:</p> <ul style="list-style-type: none"> • Decreased white blood cell count, sometimes associated with blood infections, which could lead to severe infections and death • Decreased platelet count. Symptoms include difficulty in breathing, irregular heartbeat, decreased urine output, abrupt change in mental status, areas of mottled skin or extremely low blood pressure. • Decreased red blood cell count or abnormal red blood cells. This results in reduced oxygen flow to the body's organs. Symptoms include feeling tired and weak, shortness of breath, dizziness or lightheadedness <p>Liver related:</p> <ul style="list-style-type: none"> • Increased levels of the yellow pigment bilirubin in the blood which might cause jaundice (a yellowing of the skin, mucous 		<p>membranes and eyes), pain in the upper right area of your abdomen, nausea, vomiting, a general sense of not feeling well, difficulty in breathing, disorientation or confusion, or sleepiness could be signs that indicate the inability of the liver to perform its normal function</p> <ul style="list-style-type: none"> • Liver damage. If you are given YONDELIS together with a medicine that might cause damage to the liver, there could be an increased risk of liver damage <p>Heart related:</p> <ul style="list-style-type: none"> • Heart muscle problems including heart failure. Symptoms include chest pain, shortness of breath, tiredness, swelling of your legs, ankles, or feet, or you feel like your heart is beating too hard or too fast in your chest (palpitations) <p>Stomach and digestive system related:</p> <ul style="list-style-type: none"> • Feel sick, vomit or unable to drink fluids and therefore pass less urine despite being given anti-sickness medicines <p>Muscle or pain related:</p> <ul style="list-style-type: none"> • Severe muscle aches and pain, stiffness, muscle weakness or darkening of the urine colour could be a sign of damage to your muscles (rhabdomyolysis). In very severe cases this could lead to kidney failure. 	
<p>Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.</p> <p>Other side effects not listed here may occur in some people.</p> <p>Reporting side effects</p> <p>After you have received medical advice for any side effects you experience, you can report side effects to Medsafe online at https://medsafe.govt.nz/profs/adverse/reactions.asp and to Specialised Therapeutics at drugsafety@sta@stbiopharma.com. By reporting side effects, you can help provide more information on the safety of this medicine.</p> <p>Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.</p>			

7. Product details

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

What YONDELIS contains

Active ingredient (main ingredient)	Trabectedin
Other ingredients (inactive ingredients)	Sucrose Potassium dihydrogen phosphate Phosphoric acid Potassium hydroxide

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

What YONDELIS looks like

YONDELIS is a powder for solution for intravenous infusion.

The powder has a white to off-white colour.

1 mg powder (1 vial): AUST R 332001

Who distributes YONDELIS

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This leaflet was prepared in June 2024.