Package leaflet: Information for the patient

Zynlonta 10 mg powder for concentrate for solution for infusion
loncastuximab tesirine

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Zynlonta is and what it is used for

Zynlonta is a cancer medicine that contains the active substance loncastuximab tesirine.

Zynlonta is used to treat adults with a certain type of cancer called **diffuse large B-cell lymphoma** (DLBCL) that:
- has come back (relapsed) after two or more treatments, or that
- did not respond to previous treatment (refractory).

Diffuse large B-cell lymphoma is a cancer that develops from a type of white blood cell called B-lymphocyte (also called B-cell).

Talk to your doctor or nurse if you have any questions about how Zynlonta works or why this medicine has been prescribed for you.

How does Zynlonta work?

Loncastuximab tesirine consist of 2 parts; an antibody (a type of protein designed to recognize and attach to a specific target) and a cytotoxic agent (a medicine able to kill cells, including cancer cells). The antibody in this medicine is designed to attach to CD19, a protein that is found on the surface of B cells. When the antibody binds to these cells, including the cancer cells, the medicine enters the cells and kills them.

2. What you need to know before you are given Zynlonta

You must not be given Zynlonta if you are **allergic** to **loncastuximab tesirine** or any of the other **ingredients** of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or nurse before you are given Zynlonta if you:
- have an **active infection** or have had one recently
- have **liver problems;** symptoms may include skin and eyes appearing yellowish (jaundice).Your doctor will monitor you for side effects during treatment.are **pregnant or plan to become pregnant**.
- Zynlonta can harm your unborn baby (see section "Pregnancy and breast-feeding and fertility" for further information).

Tell your doctor or nurse straight away if you have any of the following serious side effects.

Infections
Serious infections, including infections that can cause death, have occurred in people treated with Zynlonta. **Tell your doctor or nurse straight away** if you have new or worsening signs or symptoms of infection, which are listed in section 4, under 'Serious side effects'.

Fluid retention
Your body may hold too much fluid during treatment with Zynlonta. This can be serious. **Tell your doctor or nurse straight away** if you have any signs or symptoms of fluid retention, which are listed in section 4, under 'Serious side effects'. Your doctor will give appropriate treatment for the fluid retention. If you have serious swelling your doctor may stop treatment until the swelling goes down.

Low blood cell counts (platelets, red blood cells, and white blood cells)
Low levels of certain blood cells (low blood cell counts) can be serious or severe. Your doctor or nurse will monitor your blood cell counts during treatment with Zynlonta. **Tell your doctor or nurse straight away** if you have any signs and symptoms of infection, which are listed in section 4, under 'Serious side effects'. Low blood cell counts could be responsible for your infection.

Skin reactions
Serious skin reactions have occurred in people treated with Zynlonta. Exposure to sunlight (including through glass or car windows) may cause severe sunburn. It is important to wear sunscreen and appropriate clothing to ensure you do not burn. **Tell your doctor or nurse straight away** if you get new or worsening severe skin reactions. Signs and symptoms are listed in section 4, under 'Possible side effects'.

Children and adolescents
This medicine should not be given to children or young people under the age of 18. This is because there is no information about its use in this age group.

Other medicines and Zynlonta
Tell your doctor if you are taking, have recently taken or might **take any other medicines**.

Contraception (men and women)
Women of child-bearing potential must use effective contraception during treatment with Zynlonta, and for 10 months after the last dose. **Men** with partners of child-bearing potential **must use effective contraception** during treatment with Zynlonta, and for 7 months after the last dose.
Talk to your doctor about effective contraception.

Pregnancy
You should avoid getting pregnant if you are taking this medicine. **Tell your doctor immediately** if you become pregnant or think that you are pregnant during treatment with Zynlonta. Your doctor may do a pregnancy test before starting treatment with Zynlonta.

Breast-feeding
Do not breast-feed during treatment, and for 3 months after the last dose. It is not known if Zynlonta passes into breast milk.

Fertility
Zynlonta **may cause fertility problems in men**, which may affect their ability to father children. You can seek advice on how to preserve sperm before starting treatment. Talk to your doctor for more information.

Driving and using machines
Zynlonta has no or negligible influence on your ability to drive and use machines. If you get infusion-related reactions or if you feel tired, weak or dizzy (see section 4) do not drive, cycle or use tools or machines until you feel better.

See section 4 for more information about side effects.

3. How you are given Zynlonta

Zynlonta is given under supervision of a doctor experienced in giving such treatments. It is given **into a vein** as a drip (infusion) **over a period of 30 minutes**.

The dose of this medicine depends on your body weight. The usual starting dose is 0.15 mg for each kg of body weight.

The table below shows the recommended dose in each treatment cycle.

Recommended dose	Cycle
0.15 mg per kg every 21 days	1st cycle
0.15 mg per kg every 21 days	2nd cycle
0.075 mg per kg every 21 days	3rd cycle onwards

Your doctor may lower your dose if you experience any serious side effects.

Taking dexamethasone with Zynlonta
During your treatment with Zynlonta you will also be given another medicine called dexamethasone to help reduce side effects as a result of treatment.
You will be given 4 mg of dexamethasone either by mouth or into your vein twice a day for three days, beginning the day before you receive Zynlonta treatment.
If you do not receive dexamethasone the day before your treatment, then it must be given at least 2 hours before you are given Zynlonta.

How often will you be given Zynlonta
Zynlonta is usually given every 3 weeks (on day 1 of a 21-day cycle).
- Your doctor will give you medicines before each infusion to lower your chance of side effects.
- Your doctor may stop your treatment, delay your treatment, or change your dose of Zynlonta if you have severe side effects (see section 4 possible side effects).
- Your doctor will do regular blood tests to check for side effects of Zynlonta.
- Your doctor will decide how many treatment cycles you need.

If you are given more Zynlonta than you should
Since the infusion is given to you by your doctor or other appropriately trained staff, an overdose is unlikely. If you inadvertently receive too much medicine, your doctor will monitor you and give you additional treatment as required.

If you miss a dose of Zynlonta
If you miss a dose of Zynlonta, it should be given as soon as possible. You might need to reschedule receiving the next planned dose to ensure that it is given 21 days after the missed dose. The 21-day interval between doses should be maintained.

If you stop receiving Zynlonta
You should not stop the therapy early without talking with your doctor first.

The therapy for lymphoma with Zynlonta usually requires a number of infusions. The number of infusions that you receive will depend on how you are responding to treatment. Therefore, even if you see your symptoms improve, you should continue to take Zynlonta until your doctor decides that your medicine should be stopped. If the treatment is stopped too early, your symptoms may return.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects have been reported with this medicine:

Serious side effects

Infections
Serious infections, including infections that can cause death, have occurred in people treated with Zynlonta. **Tell your doctor or nurse straight away** if you notice any of the following signs and symptoms:
- fever
- chills
- flu-like symptoms (cough, tiredness or weakness, and body aches)
- severe headache
- cuts or scrapes that are red, warm, swollen, or painful

Fluid retention
Your body may hold too much fluid during treatment with Zynlonta. This can be serious. You can get swelling in various parts of your body including your hands, feet (very common) and abdomen (common), or around internal organs such as your heart (common) and lungs (very common).
Tell your doctor or nurse straight away if you notice any of the following signs and symptoms:
- have chest pain (common)
- difficulty breathing (very common)
- swelling in any part of your body (very common)

Low blood cell counts
Low blood cell counts (very common) can be serious or severe. Your doctor or nurse will monitor your blood counts during treatment with Zynlonta. **Tell your doctor or nurse straight away** if you notice any bruising or bleeding, or any of the signs and symptoms of infections above.

Skin reactions
Skin reactions (common) have occurred in people treated with Zynlonta. Some of these can be serious.
Tell your doctor or nurse straight away if you get new or worsening severe skin reactions, including:
- sensitivity to sunlight including sunburn-like reactions such as skin peeling and irritation following exposure to light
- itchy rash
- blistering of skin
- darker skin patches
- irritation, swelling, pain, and/or skin damage at the injection site.

Other side effects
Tell your doctor or nurse if you notice any of the following side effects:

Very common: may affect more than 1 in 10 people
- tiredness and pale skin
- abnormal blood tests showing:
  - low levels of neutrophils, a type of white blood cell that fight infection, sometimes with fever
  - low blood platelet count which can lead to bleeding and bruising
  - liver problems
- loss of appetite
- feeling sick or vomiting
- diarrhoea
- stomach pain
- constipation
- reddening of the skin
- rash
- itching.

Common: may affect up to 1 in 10 people
- infection of the lungs including bronchitis or pneumonia
- nose and throat infection
- rash characterised by a flat, red area on the skin that is covered with small, raised bumps
- muscle pain
- joint pain
- back and neck pain
- pain in the arms and legs
- lack of energy.

Uncommon: may affect less than 1 in 10 people
- pus filled raised bumps on the skin
- limb discomfort
- muscle and bone discomfort
- inflammation of the membrane around the heart.

Not known: frequency cannot be estimated from the available data
- spider veins (broken blood vessels located near surface of skin)
- blisters
- rash consisting of tiny-to-small fluid-filled blisters

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme. Website www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zynlonta

Zynlonta will be stored by the doctor and pharmacist at the hospital or clinic where you are treated. Your doctor, pharmacist or nurse is responsible for storing this medicine and disposing of any unused product correctly. The following information is intended for healthcare professionals.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the vial after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C). Do not freeze.

Keep the vial in the outer carton in order to protect from light.
Both the reconstituted solution and the diluted solution for infusion should not be frozen or exposed to direct sunlight.

Zynlonta is a cytotoxic medicine. Applicable special handling and disposal procedures must be followed.

Your doctor or pharmacist is responsible for disposing of any unused Zynlonta correctly. These measures will help protect the environment.

6. Contents of the pack and other information

What Zynlonta contains
- The **active substance** is loncastuximab tesirine. Each vial contains 10 mg of loncastuximab tesirine. After reconstitution, each mL contains 5 mg of loncastuximab tesirine.
- The **other ingredients** are: L-histidine, L-histidine monohydrochloride, polysorbate 20, sucrose.

What Zynlonta looks like and contents of the pack
This medicine is a white to off-white powder, which has a cake-like appearance. It comes in a glass vial and is for single use only. The powder needs to be reconstituted and diluted before infusion.

Each pack contains 1 vial.

Marketing Authorisation Holder
Swedish Orphan Biovitrum AB (publ)
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Manufacturer
Cilatus Manufacturing Services Ltd.
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This leaflet was last revised in 04/2023.

This medicine has been given ‘conditional approval’. This means that there is more evidence to come about this medicine.

The MHRA will review new information on this medicine at least every year and this leaflet will be updated as necessary.

The following information is intended for healthcare professionals only:

Procedures for proper handling and disposal of anticancer medicinal products should be considered.

Reconstitution of powder for concentrate

- Reconstitute each vial of powder for concentrate using 2.2 mL of sterile water for injections with the stream directed toward the inside wall of the vial to obtain a final concentration of 5 mg/mL.
- Swirl the vial gently until the powder is completely dissolved. Do not shake.
- Inspect the reconstituted solution for particulate matter and discolouration. The solution should appear clear to slightly opalescent, colourless to slightly yellow. Do not use if the reconstituted solution is discoloured, is cloudy, or contains visible particulates.
- Discard unused vial after reconstitution if the recommended storage time is exceeded.

Dilution in intravenous infusion bag

- Withdraw the required volume of reconstituted solution from the vial using a sterile syringe. Discard any unused portion left in the vial.
- Add the calculated dose volume of Zynlonta reconstituted solution into a 50 mL intravenous infusion bag of **5% glucose**.
- Gently mix the intravenous infusion bag by slowly inverting the bag. Do not shake.
- No incompatibilities have been observed between Zynlonta and intravenous infusion bags with product-contacting materials of polyvinylchloride (PVC), polyolefin (PO), and PAB (copolymer of ethylene and propylene).
- Zynlonta must be administered using a dedicated infusion line equipped with a sterile, non-pyrogenic, low-protein binding in-line or add-on filter (0.2 or 0.22 micrometre pore size) and catheter.

Reconstituted solution

From a microbiological point of view, the reconstituted solution should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and should not be longer than 4 hours refrigerated (2°C - 8°C) or 4 hours at room temperature (20°C - 25°C), unless reconstitution has taken place in controlled and validated aseptic conditions. Chemical and physical in-use stability of the reconstituted solution has been demonstrated for up to 4 hours refrigerated (2°C - 8°C) or 4 hours at room temperature (20°C - 25°C).

Diluted solution

From a microbiological point of view, the prepared solution for infusion should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and should not be longer than 24 hours refrigerated (2°C - 8°C) or 8 hours at room temperature (20°C - 25°C), unless dilution has taken place in controlled and validated aseptic conditions. Chemical and physical in-use stability of the prepared solution for infusion has been demonstrated for up to 24 hours at room temperature (20°C - 25°C).