MEDICINE INFORMATION

Zolbetuximab (Vyloy)

Patient information about zolbetuximab with chemotherapy for selected stomach and gastro-oesophageal junction cancers.

At a glance

Zolbetuximab is a targeted antibody given through a drip into a vein alongside chemotherapy. It can be used when a stomach cancer or a cancer at the junction of the stomach and food pipe has the right test results. Feeling sick and being sick are common. Your team plans medicines to help prevent this.

How it is given. You receive zolbetuximab as a drip into a vein, alongside the chemotherapy in your plan.

How it works

Zolbetuximab attaches to claudin 18.2, also written CLDN18.2. This is a protein found on some stomach and gastro-oesophageal junction cancer cells. The antibody helps the immune system damage cells carrying that protein.

Is this treatment suitable for me?

Zolbetuximab is approved in India, the US and the EU for use with chemotherapy as the first treatment for adults with locally advanced cancer that cannot be removed by surgery or cancer that has spread. The cancer must test positive for CLDN18.2 and negative for human epidermal growth factor receptor 2 (HER2), a different protein. Your team checks a sample of the cancer for these results. Ask how the test results affect your choices and which product and treatment plan are available where you receive care.

CLDN18.2 is tested on tumour tissue. The laboratory looks at how strongly the cells stain for the protein and how many cells stain. Ask your team whether the existing biopsy is suitable for testing, and what the result means for your treatment choices.

Before treatment starts

Tell your team about nausea, vomiting, difficulty eating, weight loss and any previous reaction to a drip. They will assess your nutrition and check your blood tests. Ask which anti-sickness medicines you should have before the drip and what to take at home if sickness returns.

If you are already vomiting or struggling to keep drinks down, call before coming in. The team may need to treat these symptoms before the first drip. Ask for a written plan showing which anti-sickness medicines to take on schedule, which to take if symptoms break through, and when to call.

How treatment is given

You receive zolbetuximab in the treatment unit with a combination such as FOLFOX or CAPOX. Both contain oxaliplatin. FOLFOX uses fluorouracil by drip and may involve going home with a pump. CAPOX uses capecitabine tablets for part of the cycle. Ask for a written calendar for the combination you are receiving.

The team gives anti-sickness medicines before the zolbetuximab infusion. Staff can slow or pause the drip if you become unwell. Tell the nurse as soon as nausea, chills, a rash or chest discomfort begins. Allow time for monitoring afterwards, and ask how long to plan for at your hospital.

Monitoring your treatment

The team checks symptoms, weight and blood tests, including blood counts and tests relevant to your chemotherapy. Scans help assess how the cancer is responding. Bring a record of vomiting, difficulty eating and any fluids you were unable to keep down.

Vomiting and poor intake can affect the kidneys and levels of salts such as potassium. Blood tests help the team decide if you need fluids, replacement salts or a delay before the next treatment.

Side effects

Common side effects

- **Nausea and vomiting.** These are often most noticeable in the first cycle. They can begin during the drip or after you go home. Call if the medicines in your plan are failing to control them.
- **Appetite and weight loss.** Tell the team if you feel full quickly, can only eat small amounts or keep losing weight. Ask about seeing a cancer dietitian early.
- **Bowel changes and tiredness.** Diarrhoea, constipation and fatigue can occur. Tell the team which bowel symptoms you have and which medicines you have taken so they can advise you safely.
- **Low blood counts.** The combination can reduce white cells that fight infection, red cells that carry oxygen and platelets that help stop bleeding. Report fever, unusual bruising or a marked change in tiredness or breathing.

Other reported side effects

Your chemotherapy may cause tingling in the fingers or toes. Oxaliplatin can make cold drinks, air or objects uncomfortable, especially soon after treatment. Follow the team’s cold-sensitivity advice and report tingling that lasts or interferes with walking, writing or using buttons. Report new swelling so the team can check its cause.

Serious effects to recognise

A severe allergic reaction needs immediate treatment. Tell staff immediately if you develop wheezing, a rash, chest discomfort, dizziness or swelling during or after the drip. Vomiting that you cannot control can cause dehydration and may need urgent treatment.

When to seek urgent help

Call your hospital's 24-hour cancer care number straight away for repeated vomiting, inability to keep fluids down, very little urine, fever, shaking chills or feeling suddenly unwell. Follow the temperature instructions given by your team for the chemotherapy combination. If you have no written threshold, call at 37.5°C (99.5°F) or above, or below 36°C (96.8°F). Call if you feel very unwell even without a fever.

Seek emergency care if you have severe breathing difficulty, swelling of your mouth or throat, or collapse. Tell staff you are receiving zolbetuximab and chemotherapy.

Practical advice for this treatment

Make a plan for nausea before each visit

Zolbetuximab can cause pronounced nausea or vomiting, particularly during early infusions. Ask which medicines to take before treatment and which to use after leaving hospital. Tell the infusion team when nausea starts so it can assess you and decide whether to pause or adjust the drip.

Check the timing of the partner medicines

Zolbetuximab is used with chemotherapy. Ask which medicines are in your plan, whether it includes capecitabine tablets or a fluorouracil pump, and which instructions apply if you cannot keep tablets down. Get written contact details before going home with a pump.

Plan for keeping fluids down

Tell the team if drinking or eating was already difficult because of the cancer. Ask about a dietitian. Call if you keep vomiting, pass much less urine, or become faint when standing. Symptoms may need treatment even if you are between visits.

Other medicines and vaccinations

Give the team a list of everything you take, including vitamins and herbal remedies. Check before starting new medicines or having a vaccination. Ask which advice applies to your chemotherapy as well as zolbetuximab.

Everyday life

Try small amounts of food and drink as tolerated, using any fluid limits your team has given. Ask a dietitian for help if you are losing weight or are struggling to eat. Keep your anti-sickness plan and hospital phone number handy.

Fertility, pregnancy and breastfeeding

Tell your team if you are pregnant, planning a pregnancy or breastfeeding. Ask what contraception to use and for how long with your full combination. The US Vyloy label advises avoiding breastfeeding during treatment and for eight months after the last zolbetuximab dose. Ask your team to confirm the dates for all the medicines you receive and discuss fertility preservation before treatment if it matters to you.

After treatment

Keep follow-up appointments and continue reporting problems with eating, drinking or weight. Your team will explain which medicines continue and how they will monitor your recovery.

Frequently asked questions

Can I have it without chemotherapy?

The approved use described in the US and EU prescribing information pairs zolbetuximab with chemotherapy. Your oncologist will discuss which combination is suitable for you.

Are HER2 and CLDN18.2 the same test?

They look for different proteins. Ask your team to show you both results and explain what they mean for treatment.

What if I feel sick as soon as the drip starts?

Tell the nurse immediately. They can assess you, give treatment for symptoms and adjust or pause the drip if needed.

Is zolbetuximab the same as immunotherapy?

It is a targeted antibody that attaches to CLDN18.2. The medicines often called immunotherapy in stomach cancer discussions work differently. Ask which medicines are included in your plan.

Do I need another biopsy for CLDN18.2 testing?

The laboratory may be able to test tissue already taken. Ask whether there is enough suitable tissue and whether another sample would help.

Why is my chemotherapy different from another patient's?

FOLFOX and CAPOX use different forms of part of the chemotherapy. Your team considers your health, previous treatment, ability to take tablets and what the schedule involves.

How long will I be at the hospital?

Allow for medicines before treatment, the zolbetuximab and chemotherapy drips, and time for observation. Ask your unit for an estimate for your first visit.

What if I am already vomiting on treatment day?

Call before travelling. The team will assess your symptoms and may need to treat nausea or vomiting before the first zolbetuximab infusion can go ahead. Take only the extra anti-sickness medicine your team has advised.

Can I take extra anti-sickness medicine at home?

Use the plan from your team. If it is unclear or symptoms continue, call for advice before taking extra doses.

How can I tell if I am getting dehydrated?

Passing less urine, dizziness and a dry mouth can be signs. Call the unit promptly if you are repeatedly vomiting or cannot keep drinks down.

How do I manage if I am eating very little?

Ask about a dietitian, especially if your weight is falling. Bring a short record of what you can eat and drink so the advice fits your situation.

Can I take cold drinks after treatment?

Oxaliplatin can make cold drinks uncomfortable. Try room-temperature drinks if cold triggers symptoms and follow your unit’s advice.

What if I vomit after taking capecitabine?

Do not take an extra tablet to replace it. Call your team if vomiting continues and follow the instructions for your next dose.

Does a slower drip mean I received less medicine?

The drip rate is how quickly the medicine goes in. Ask the nurse whether the infusion was completed or whether the team changed your treatment.

How do I know whether treatment is helping?

Your team considers scans, symptoms and how you are managing treatment. Ask when they expect to review these together.

How long do pregnancy and breastfeeding precautions continue?

Ask for the date that applies to your whole combination. Different medicines can have different requirements after the last dose.

Does a positive CLDN18.2 result tell me which chemotherapy I will have?

It helps the team decide whether zolbetuximab is an option alongside chemotherapy. Your oncologist also considers the other test results, your health and the chemotherapy regimen suitable for you.

Sources and further reading

Read this guide alongside your hospital's plan. Ask your pharmacist to confirm the exact product dispensed in India and follow the instructions for that product.

Summary of Product Characteristics (SmPC) and prescribing information

- Zolbetuximab (Vyloy) - EU SmPC
- Oxaliplatin infusion - UK SmPC
- Fluorouracil injection - UK SmPC
- Folinic acid (calcium folinate) injection - UK SmPC
- Capecitabine (Xeloda) - EU SmPC
- Vyloy FDA prescribing information

Clinical protocols and other references

- SPOTLIGHT trial of zolbetuximab with modified FOLFOX
- CDSCO import approvals, including zolbetuximab

Additional sources

- FDA approval summary for zolbetuximab

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