ZALTRAP®

(ZAL-TRAP)

Aflibercept (rch) (a-flib-er-cept)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Zaltrap.

It does not contain all the available information. It does not take the place of talking to your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Zaltrap against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor.
Keep this leaflet as you may need to read it again.

What Zaltrap is used for

Zaltrap is used to treat advanced large bowel cancer (that is, cancer in the colon or rectum) in combination with chemotherapy agents.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.
Zaltrap contains the active ingredient aflibercept.

Zaltrap is an anti-cancer medicine that blocks the growth of blood vessels that provide nutrients and oxygen to cancer cells. This prevents the growth of the cancer cells.

Your doctor may have prescribed Zaltrap for another purpose.

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

Zaltrap is not addictive.

Before you are given Zaltrap

Do not receive Zaltrap if you are allergic to Zaltrap or any of the ingredients listed at the end of this leaflet.
Some symptoms of an allergic reaction include: skin rash, hives, itching or redness of the skin; shortness of breath, wheezing or difficulty breathing; or swelling of the face, lips, tongue or other parts of the body.

Zaltrap should not be used in your eye, since it may severely damage it.

Do not receive Zaltrap:

- **after the expiry date (EXP) printed on the vial.**
- **if the packaging is damaged or shows signs of tampering.**

Tell your doctor if you are pregnant or are planning on having a baby.
Do not use Zaltrap if you are pregnant unless otherwise advised by your doctor. Zaltrap may harm your unborn baby.

Your doctor will advise you about using effective contraception during treatment with Zaltrap and for at least six months after your last dose of Zaltrap.

Tell your doctor if you plan to start a family in the future.
Zaltrap may affect your ability to become pregnant. Your doctor will advise you of your options prior to starting treatment.

Tell your doctor if you are breast-feeding or plan to breast-feed.
You should not breast-feed while using Zaltrap and for at least six months after the last dose of Zaltrap. Zaltrap may affect the growth and development of your baby.

Zaltrap should not be given to a child or adolescent.

Talk to your doctor if you have any other health problems, especially if:

- you or anyone if your family have a history of bleeding problems
- you have any bleeding problems or if you notice any bleeding after treatment or if you feel extreme tiredness, weakness, dizziness or have changes in the colour of your stool. If the bleeding is severe, your doctor will stop your treatment with Zaltrap. This is because Zaltrap may increase the risk of bleeding
- you have a history of blood clots or stroke, or you are taking medicines to thin the blood to prevent blood clots (e.g. warfarin). The signs of a blood clot may vary depending on where it appears (e.g. lungs, leg, heart or brain) but may include symptoms such as chest pain, coughing, being short of breath or having difficulty breathing. Other signs may include swelling in one or both legs, pain or tenderness in one or both legs, discolouration and warmth of the skin on the affected leg or visible veins. It may also present itself as a sudden numb or weak feeling in the face, arms or legs.

- you have high blood pressure. Zaltrap may increase blood pressure and your doctor will need to monitor your blood pressure and may adjust your blood pressure medicines or dose of Zaltrap.
- you have had heart or circulation problems, such as stroke
- you have conditions causing inflammation or bleeding or the bowel. Symptoms may include fever, vomiting, diarrhoea and stomach pain
- you have stomach ulcers
- you have kidney problems (protein in the urine)
- you have ever had any allergies or are allergic to any other medicines, foods, dyes, or preservatives.
- you have had seizures, or cancer which has spread to your brain or spine
- you are 65 years of age or older and experience diarrhoea, dizziness, weakness, weight loss or severe loss of body fluids (called dehydration). Your doctor should monitor you carefully

Tell your doctor if you are going to have an operation or you have had a dental procedure or any other surgery within the last 4 weeks. Tell your doctor if you have a surgical wound that has not healed. Tell your doctor if you have recently received, or are receiving, radiotherapy.

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

Taking other medicines

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

This is because some medicines can affect the way Zaltrap works or Zaltrap can affect how other medicines work.

How Zaltrap is given

Zaltrap will be given by a drip (infusion) into one of your veins (intravenous use) in hospital by a doctor or nurse for about an hour.

Zaltrap will be administered to you in combination with other chemotherapy medicines.

Zaltrap should not be used if you notice the solution is cloudy and/or visible particles are present in the vial or in the infusion bag.

Zaltrap must not be injected into the eye, since it may severely damage it.

How much is given

The recommended dose of Zaltrap is 4 mg per kilogram of your body weight.

How often is Zaltrap given

You will usually have an infusion once every 2 weeks. Each 2 week period is called one cycle of chemotherapy. Your doctor will decide how many of these cycles you will need.

Your doctor will decide how often you will receive Zaltrap and if you need adjustment in the dose.

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

If you take too much (overdose)

As Zaltrap is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you experience any unexpected or worrying side effects after being given Zaltrap immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26) or go to Accident and Emergency at your nearest hospital.

While you are using it

Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Zaltrap.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Zaltrap.

Men and women of childbearing potential should use effective contraception during treatment with Zaltrap and up to 6 months after the last dose of treatment.

Continue using Zaltrap until your doctor tells you to stop. If your condition gets worse, you must tell your doctor.

Things you must not do

Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting a pharmacist.

Things to be careful of

Be careful driving or operating machinery until you know how Zaltrap affects you. Zaltrap has not been shown to affect your ability to drive or operate machinery.

Side effects

Zaltrap helps most people with advanced large bowel cancer (that is, cancer of the colon or rectum) but like all medicines it can cause side effects, although not everybody gets them.

Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

The side effects listed below were seen when Zaltrap was given together with chemotherapy.

Do not be alarmed by the list of possible list effects. You may not experience any of them.

If any of the following happen while you are being given Zaltrap in the hospital/clinic, tell your doctor or nurse immediately:

- skin rash
- hives
- itching
- redness of skin
- shortness of breath, wheezing or difficulty breathing or swelling of the face, lips tongue or other parts of the body.

If you are outside of the hospital/clinic go to Accident and Emergency at your nearest hospital.
These are very serious side effects although they are uncommon.

If you have them, you may have had a serious allergic reaction to Zaltrap and you may need urgent medical attention or hospitalisation.

Tell your doctor immediately if you notice any of the serious side effects below:

- Stomach cramps or pains
- Severe or bloody diarrhoea
- Bleeding from the stomach or bowel which may look like coffee grounds or black, sticky bowel motions (stools)
- Vomiting blood or material that looks like coffee grounds
- Coughing or spitting blood
- Blocking of the arteries or veins by a blood clot
- Problems with your wounds healing after surgery
- Headache, vision changes, confusion and/or seizures

Other side effects are described below.

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

- Decrease in the number of white blood cells
- Decrease in the number of cells in the blood that help the blood to clot
- Decrease in appetite
- Headache
- Nose bleeds
- Difficulty in speaking or hoarseness
- Difficulty in breathing
- Painful sores in the mouth
- Stomach pain
- Swelling and numbness of the hands and feet that occurs with chemotherapy
- Feeling tired or weak
- Loss of weight
- Changes in liver or kidney function
- High blood pressure

Common (may affect up to 1 in 10 people)

- Fever
- Dehydration
- Urinary tract infection
- Inflammation of the nasal passages
- Pain in the mouth and/or throat
- Runny nose
- Haemorrhoids, rectal bleeding, pain at the anus or in the rectum
- Inflammation of the mouth
- Toothache
- Changes in the colour of skin

Other side effects not listed above may occur in some patients.

Ask your doctor or pharmacist to answer any questions you may have.

After taking it

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor, nurse or pharmacist.

Storage

Store at 2°C to 8°C (Refrigerate. Do not freeze). Protect from light.

Product description

What Zaltrap looks like

Zaltrap is a clear, colourless to pale yellow solution.

Availability

Zaltrap is available as 4mL and 8mL vials.

Ingredients

Active ingredient
Aflibercept (25mg/mL)

Inactive ingredients

- sucrose
- sodium chloride
- sodium citrate (dihydrate)
- citric acid monohydrate
- polysorbate 20
- sodium phosphate dibasic (heptahydrate)
- sodium phosphate monobasic monohydrate
- sodium hydroxide
- hydrochloric acid and
- water for injections.

Manufacturer/Sponsor

Zaltrap is made in Germany.

Zaltrap is supplied in Australia by:
Sanofi-Aventis Australia Pty Ltd
12-24 Talavera Road
Macquarie Park NSW 2113

This leaflet was prepared in June 2013.

Australian Register Number(s):
Zaltrap 100mg/4mL AUST R 195234
Zaltrap 200mg/8mL AUST R 195974