

Consumer Medicine Information

ONTRUZANT[®]

Trastuzumab

150 mg powder for concentrate, solution for intravenous infusion

What is in this leaflet

This leaflet answers some common questions about Ontruzant infusion.

It does not contain all the available information.

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

All medicines have risks and benefits. Your doctor has weighed the risks of you being given ONTRUZANT against the benefits expected for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What ONTRUZANT is used for

ONTRUZANT contains the active ingredient trastuzumab.

ONTRUZANT belongs to a group of medicines known as antineoplastic (or anti-cancer) agents. There are many different classes of antineoplastic agents. ONTRUZANT belongs to a class called monoclonal antibodies.

Monoclonal antibodies are proteins made in a laboratory. These proteins are designed to recognise and bind to other unique proteins in the body.

ONTRUZANT binds selectively to a protein called human epidermal growth factor receptor 2 (HER2). HER2 is found in large amounts on the surface of some cancer cells. When ONTRUZANT binds to HER2 it stops the growth and spread of the cancer cells.

ONTRUZANT is used to treat breast and gastric cancer. It is only used in patients whose tumours has tested positive to HER2.

ONTRUZANT may be used alone or with other medicines that treat breast cancer, such as an aromatase inhibitor (hormone receptor positive breast cancer) or a taxane (e.g. paclitaxel or docetaxel).

For the treatment of gastric cancer, ONTRUZANT is used with the chemotherapy medicines cisplatin and capecitabine (or 5FU).

For further information about other medicines you are receiving with ONTRUZANT, please ask your doctor, nurse or pharmacist for the Consumer medicine Information (CMI) leaflet.

Ask your doctor if you have any questions why ONTRUZANT has been prescribed for you.

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

Before you are given ONTRUZANT

When you must not be given it

Do not use ONTRUZANT if:

- **you have breast cancer that has not spread (non-metastatic) and**
 - **you have had an LVEF test result (which measures how well your heart can pump blood) of less than 45% or**
 - **you have symptoms of heart failure**

Symptoms of heart failure may include:

- shortness of breath or tire easily after light physical activity (such as walking)
- shortness of breath at night, especially when lying flat
- swelling of the hands or feet due to fluid build up
- abnormal or irregular heartbeat

- **you have had an allergic reaction to:**
 - **ONTRUZANT**
 - **any proteins of Chinese hamster origin, or**
 - **any of the ingredients listed at the end of this leaflet**

Some symptoms of an allergic reaction may include:

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

If you are not sure if you should start receiving ONTRUZANT, talk to your doctor.

Before you are given it

Tell your doctor if:

- **you have a history of:**
 - **coronary artery disease** (also known as CAD, a condition where plaque builds up inside the arteries)
 - **poorly controlled hypertension** (high blood pressure)
 - **heart failure** (where the heart can no longer pump normally)
 - **cardiac arrhythmia** (abnormal or rapid heart beat)
 - **angina** (chest pain)
- **you have previously been treated with chemotherapy medicines known as anthracyclines (e.g. doxorubicin); these medicines can damage heart muscle and increase the risk of heart problems with ONTRUZANT**

Your doctor will monitor your heart function closely before and during your treatment with ONTRUZANT. Your heart function may also be monitored for years after ceasing ONTRUZANT treatment.

- **you have any breathing or lung problems**
- **you are pregnant or plan to become pregnant**

ONTRUZANT may be harmful to an unborn baby. If there is a need for ONTRUZANT treatment when you are pregnant your doctor will discuss the risks and benefits to you and the unborn baby.

You should use effective contraception to avoid becoming pregnant while you are being treated with ONTRUZANT and for 7 months after stopping treatment.
- **you are breast-feeding or plan to breast-feed**

It is not known if ONTRUZANT passes into breast milk. It is recommended that you discontinue breast-feeding while you are being treated with ONTRUZANT and not restart breast-feeding until 7 months after completing ONTRUZANT treatment.
- **you are allergic to any other medicines or any other substances such as foods, preservatives or dyes.**

Allergic or anaphylactic reactions can occur with ONTRUZANT treatment (known as infusion related reactions). Your doctor or nurse will check for side effects during your infusion. See 'Side

effects' for symptoms to look out for.

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

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you have bought from a pharmacy, supermarket or health food shop.

Treatment with ONTRUZANT and gemcitabine, vinorelbine, a taxane or radiation therapy can increase the chance of lung problems (interstitial lung disease).

Your doctor and pharmacist may have information on medicines to be careful with or avoid while undergoing treatment with ONTRUZANT.

Tell your doctor or pharmacist that you have received ONTRUZANT therapy, if you start any new medication within seven months of stopping ONTRUZANT treatment.

It may take up to seven months for ONTRUZANT to be removed from your body.

Use in children

The safety and effectiveness of ONTRUZANT in children under 18 years of age have not been established.

How ONTRUZANT is given

Your doctor will perform a test to check that your cancer is HER2 positive before starting treatment with ONTRUZANT.

Follow all directions given to you by your healthcare professional (doctor, nurse or pharmacist).

They may differ from the information contained in this leaflet.

ONTRUZANT must be prepared by a healthcare professional before treatment and will be given in a hospital or clinic by a doctor or nurse.

ONTRUZANT is given by "drip" into a vein (intravenous or IV infusion).

The first ONTRUZANT infusion is given over 90 minutes. If the first infusion is well tolerated, your drip time may be shortened to 30 minutes.

For the treatment of breast cancer, ONTRUZANT may be given either once a week or once every three weeks. It may be given alone, or in combination with other medicines used to treat breast cancer.

For the treatment of gastric cancer, ONTRUZANT is given once every three weeks in combination with other medicines used to treat gastric cancer.

Your doctor will decide how long you should receive ONTRUZANT; this will depend on your response to ONTRUZANT and the state of your disease.

If you miss a dose

As ONTRUZANT is given to you under the supervision of your doctor, you are unlikely to miss a dose. However, if you forget or miss an appointment to receive ONTRUZANT, make another appointment as soon as possible. Your doctor will decide when and how much your next dose of ONTRUZANT will be.

If you are given too much (overdose)

As ONTRUZANT is given to you under the supervision of your doctor it is unlikely that you will be given too much. However, if you experience any side effects after being given ONTRUZANT, tell your doctor or nurse immediately.

While you are receiving ONTRUZANT

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are receiving ONTRUZANT.

Tell your doctor or nurse immediately if you have any signs or symptoms of an allergic reaction or anaphylactic reaction.

Some signs and symptoms include:

- swelling of your face, lips, tongue or throat with difficulty breathing,
- swelling of other parts of your body
- shortness of breath, wheezing or trouble breathing
- rash, itching or hives on the skin
- feeling sick (nausea)
- fever, chills
- feeling tired
- headache

Tell your doctor or nurse immediately if you have any signs and symptoms of heart problems.

Some signs and symptoms of heart problems are:

- shortness of breath or getting tired easily after light physical activity (such as walking)
- shortness of breath at night, especially when lying flat
- swelling of the hands or feet due to fluid build up
- cough
- abnormal or irregular heartbeat.

Please follow all your doctor's instructions if any of these symptoms require medication.

Tell your doctor if you become pregnant or plan to become pregnant while receiving ONTRUZANT or if you intend to start a family while receiving ONTRUZANT.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.
Your doctor should perform regular tests.

Things you must not do

Do not stop your ONTRUZANT treatment without talking to your doctor first.

Tell your doctor if you feel that ONTRUZANT is not helping your condition.

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

Things to be careful of

Ontruzant may cause dizziness and have a minor effect on the ability to drive or use machinery.

Be careful driving or operating machinery until you know how ONTRUZANT affects you.

If you experience symptoms during your treatment with ONTRUZANT you should not drive or operate machinery.

Side effects

Tell your doctor as soon as possible if you do not feel well while you are receiving ONTRUZANT.

ONTRUZANT helps most people with HER2 positive breast cancer and gastric cancer, but it may have some unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

Because ONTRUZANT may be used with other medicines that treat breast and gastric cancer, it may be difficult for your doctor to tell whether the side effects are due to ONTRUZANT or due to the other medicines.

For further information about the side effects of any other medicines you are receiving, please ask your doctor, nurse or pharmacist.

During an infusion

Tell your doctor or nurse immediately if you notice any of the following during, or soon after your infusion (particularly during the first infusion):

- swelling of your face, lips, tongue or throat with difficulty breathing
- swelling of other parts of your body such as your hands or feet
- shortness of breath, difficulty breathing or wheezing
- abnormal or rapid beating of the heart
- hives, skin rashes or itching skin
- feeling sick (nausea) or vomiting, diarrhoea
- pain or discomfort (including stomach, back, chest or neck pain)
- fever or chills
- headache and/or dizziness
- weakness or fatigue
- cough

These may be serious side effects. You may require urgent medical attention.

Your doctor may prescribe medication to prevent the side effects from occurring while receiving your ONTRUZANT infusion.

After an infusion

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- swelling of your face, lips, tongue or throat with difficulty breathing
- severe shortness of breath, wheezing or trouble breathing
- severe chest pain spreading out to the arms, neck, shoulder and/or back
- rash, itching or hives on the skin
- fever or chills
- abnormal or irregular beating of the heart
- severe swelling of the hands, feet or legs
- severe coughing.

These may be serious side effects. You may require urgent medical attention.

Tell your doctor or nurse as soon as possible if you notice any of the following:

- any of the side effects listed above
- getting tired more easily after light physical activity, such as walking
- shortness of breath, especially when lying down or if it disturbs your sleep
- runny or blocked nose, or nose bleeds
- insomnia (difficulty sleeping), anxiety or depression
- confusion
- weakness, soreness in muscles and/or joints
- increased cough
- feeling dizzy, tired, looking pale
- flu and/or cold like symptoms, frequent infections such as fever, severe chills, sore throat or mouth ulcers
- hot flushes

- diarrhoea
- changes in weight (gain or loss)
- decrease in or loss of appetite
- redness, dryness or peeling of the hands or feet (hand-foot syndrome)
- unusual hair loss or thinning
- nail problems
- eye problems such as producing more tears, swollen runny eyes or conjunctivitis (discharge with itching of the eyes and crusty eyelids).

This is not a complete list of all possible side effects. Your doctor or pharmacist has a more complete list. Other side effects may occur in some people and there may be some not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

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

Product description

Storage

ONTRUZANT will be stored in the pharmacy or on the hospital ward in a refrigerator at a temperature between 2°C and 8°C.

Availability

ONTRUZANT 150 mg vial is supplied in a single pack.

ONTRUZANT is available in one type (formulation);

- Powder for intravenous infusion (drip into the vein). Supplied as a single dose vial and available in one strength, 150 mg.

What ONTRUZANT looks like

ONTRUZANT is a white to pale yellow powder which is dissolved in sterile water before use.

After dissolving, the ONTRUZANT solution should appear as a clear colourless to pale yellow solution.

Ingredients

Each vial of ONTRUZANT contains 150 mg of the active ingredient, trastuzumab.

ONTRUZANT powder also contains histidine hydrochloride monohydrate, histidine, trehalose dihydrate and polysorbate 20.

The trastuzumab protein is made using chinese hamster ovary cells.

Distributor

ONTRUZANT is distributed by:

Sponsor:

SAMSUNG BIOEPIS NZ LIMITED

TMF Group, Level 11, 41 Shortland Street, Auckland 1010

New Zealand

Distributor:

Organon New Zealand Limited

Quigg Partners, Level 7, 36 Brandon Street, Wellington, 6011
New Zealand
Telephone: 0800 111 700

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