

PRODUCT MONOGRAPH

PrHERCEPTIN[®]

trastuzumab for injection

440 mg trastuzumab/vial

Sterile powder for intravenous infusion only

Pharmaceutical standard professed

Antineoplastic

Hoffmann-La Roche Limited
7070 Mississauga Road
Mississauga, Ontario
L5N 5M8
www.rochecanada.com

Date of Approval:
November 23, 2018

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PART III: CONSUMER INFORMATION

PrHERCEPTIN®

trastuzumab for injection

BREAST CANCER

This leaflet is part III of a three-part “Product Monograph” published when HERCEPTIN was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about HERCEPTIN. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

- HERCEPTIN is a cancer medicine that must be prescribed by a doctor.
- HERCEPTIN is used to slow down the growth of specific breast cancer cells that produce large amounts of HER2 protein. It is used only for patients whose tumours are growing more rapidly than normal because of a genetic problem in the cells. This occurs in about 25 to 30% of breast cancer tumours.
- If your doctor has prescribed PERJETA® (pertuzumab) and chemotherapy drug docetaxel in combination with HERCEPTIN you should also read the leaflet for these medications.
- HERCEPTIN is also approved for the treatment of gastric cancer (a separate Consumer Information insert provides information on the use of HERCEPTIN in gastric cancer).

What it does:

- Our bodies have a natural defence system against cancer cells. When cancer cells appear, our bodies respond by making special proteins called antibodies. The antibodies attach to other proteins on the growing tumour cells. Researchers studied this to learn how to create antibodies that help with cancer treatment.
- Antibodies are now made that can target tumours to try to control the growth of cancer.
- HERCEPTIN belongs to a family of medicines called monoclonal antibodies. It is an antibody that targets the HER2 gene to stop its activity. It attaches to the HER2 receptor on the cancer cell. When it is in place, it works to stop the growth of the cancer cells and may destroy them.

When it should be used:

Patients whose breast cancer tumour cells produce large amounts of the HER2 protein can use HERCEPTIN.

HERCEPTIN is used for certain patients with early breast cancer following surgery and after chemotherapy OR following surgery and with taxane chemotherapy as well as for patients to whom breast cancer has spread to other parts or organs of the body.

When it should not be used:

Do not use HERCEPTIN if you are allergic to trastuzumab, Chinese Hamster Ovary (CHO) cell proteins, or any component of this product (see “What the non-medicinal ingredients are”).

What the medicinal ingredient is:

The medicinal ingredient in HERCEPTIN is trastuzumab. Each vial of HERCEPTIN contains 440 mg trastuzumab.

What the non-medicinal ingredients are:

HERCEPTIN contains the following non-medicinal ingredients: L-histidine, L-histidine HCl, polysorbate 20, and α,α-trehalose dihydrate. The Bacteriostatic Water for Injection supplied with HERCEPTIN contains benzyl alcohol.

What dosage forms it comes in:

HERCEPTIN is a sterile, powder that will be reconstituted and given as an intravenous (IV) administration.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Medication Errors

There is a risk of medication errors between HERCEPTIN (trastuzumab) and KADCYLA (trastuzumab emtansine). Verify with the healthcare provider that the recommended HERCEPTIN (trastuzumab) dose and NOT KADCYLA (trastuzumab emtansine) dose is used.

Cardiotoxicity (harm to the heart)

HERCEPTIN can result in the development of heart problems including heart failure. The appearance of heart failure can be delayed and can occur after treatment with HERCEPTIN is completed. In early breast cancer, the incidence of cardiac dysfunction was higher in patients who received HERCEPTIN plus chemotherapy versus chemotherapy alone, with higher risk when HERCEPTIN was administered together with a taxane following an anthracycline and cyclophosphamide. In patients with breast cancer that has spread to other parts or organs of the body, the incidence and severity of cardiac dysfunction was particularly high in patients who received HERCEPTIN at the same time as anthracyclines and cyclophosphamide.

You should have your heart function evaluated by your doctor before and during treatment with HERCEPTIN.

Infusion Reactions; Lung Problems

Some patients have had serious infusion reactions and lung problems; infusion reactions causing death have been reported. In most cases, these reactions occurred during or within 24 hours of receiving HERCEPTIN. Your HERCEPTIN infusion should be temporarily stopped if you have shortness of breath or very low blood pressure. Your doctor will monitor you until these symptoms go away. If you

have a severe allergic reaction, swelling, lung problems, inflammation of the lung, or severe shortness of breath, your doctor may need to completely stop your HERCEPTIN treatment.

Toxicity to Fetus (Unborn Baby)

HERCEPTIN can cause harm to the fetus (unborn baby), in some cases death of the fetus, when taken by a pregnant woman. Women who could become pregnant need to use effective birth control methods during HERCEPTIN treatment and for at least 7 months after treatment with HERCEPTIN. Nursing mothers treated with HERCEPTIN should discontinue nursing or discontinue HERCEPTIN.

BEFORE you use HERCEPTIN talk to your doctor or pharmacist if:

- you have ever had a bad reaction to HERCEPTIN, benzyl alcohol, or any of the inactive ingredients;
- you are allergic to other medicines, food and dyes;
- you are taking any other medicines, including those not prescribed by your doctor;
- you have any other illness or diseases, such as heart problems, heart disease, breathing problems or lung disease; the risk of heart problems may be increased in geriatric patients in both early breast cancer and breast cancer that has spread to other parts or organs of the body; the risk of lung disease may increase if you have taken chemotherapy drugs which are toxic for the lungs;
- you have already been treated with chemotherapy drugs (especially anthracyclines such as doxorubicin, epirubicin or related drugs such as mitoxantrone) or radiation therapy;
- you are pregnant, plan to become pregnant or are breast-feeding a child. Please note that a reduction in the amount of [amniotic] fluid that surrounds the developing fetus within the amniotic sac has been observed in pregnant women receiving HERCEPTIN;
- you have difficulty breathing at rest.

This information will help your doctor and you decide whether you should use HERCEPTIN and what extra care may need to be taken while you are on the medication.

Driving and using machines

We do not know whether HERCEPTIN could affect your ability to drive a car or operate machines. If you experience unwanted effects related to the infusion (such as itching, wheezing, dizziness, racing heart) you should not drive or operate machinery until symptoms resolve completely.

INTERACTIONS WITH THIS MEDICATION

Formal drug interaction studies with HERCEPTIN have not been done in humans. Important interactions with other medications were not seen during clinical trials with HERCEPTIN.

PROPER USE OF THIS MEDICATION

Your doctor has prescribed HERCEPTIN after carefully studying your condition. Other people may not benefit from taking this medicine, even though their problems may seem similar to yours.

Verify with the healthcare provider that the recommended HERCEPTIN (trastuzumab) dose and NOT KADCYLA (trastuzumab emtansine) dose is used.

Usual Dose:

The usual dose of HERCEPTIN depends on your body weight. Your doctor will calculate the dose for you.

How long you need to take HERCEPTIN will depend on your response to the treatment. Your doctor will check your response regularly and decide how many treatments you will receive.

A Registered Nurse in the hospital or outpatient clinic will give you HERCEPTIN at regular intervals determined by your physician. HERCEPTIN is not taken by mouth, but given through an intravenous line. An intravenous line, or IV, is a thin, plastic tube with a needle placed in a vein in your hand or arm. When HERCEPTIN is given intravenously, it is called an infusion.

Your first infusion of HERCEPTIN will take about 90 minutes. If you tolerate this infusion well, your next infusions may be given in less time, usually about 30 minutes.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

For information on the risk of KADCYLA overdose due to medication errors, see the KADCYLA Product Monograph.

Missed Dose:

If you miss a dose, your doctor will advise you on when your next administration of HERCEPTIN will be.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Unwanted effects are possible with all medicines. Talk to your doctor, nurse or pharmacist if you are worried about side effects or find them very bothersome, and report any new or continuing symptoms to your doctor immediately. Your doctor will be able to tell you what to do and may be able to help you with these side effects.

Some unwanted effects happen during the first infusion or shortly after it is completed. The effects usually do not last long but may need treatment. The infusion may be stopped, and may be restarted and/or given over a longer time.

These unwanted effects related to the infusion may include:

- Itching
- Wheezing
- Dizziness
- Racing heart

Giving certain medications before the next infusion of HERCEPTIN may prevent these unwanted effects.

In clinical studies, the most common unwanted effects were fever and chills, nausea, vomiting, diarrhea, pain, and headache. The symptoms can easily be treated. Giving certain medications before HERCEPTIN can prevent some unwanted effects.

Less common unwanted effects are:

- Shortness of breath and water retention, which are symptoms of heart problems. These are caused by an effect on the heart muscle that reduces the strength of the pumping action of the heart. This unwanted effect is more common in women who have previously had anthracycline chemotherapy (e.g. doxorubicin, epirubicin). Heart failure as a result of HERCEPTIN treatment can vary in severity and may require treatment with heart medications and/or HERCEPTIN treatment may need to be stopped..
- Shortness of breath, fatigue, or a racing heart, which are symptoms of anemia. This is caused by a temporary decrease in the number of red blood cells.
- A temporary decrease in the number of white blood cells may increase your risk of infection and diarrhea.

Difficulty breathing, fatigue and weight loss are commonly seen with lung disease.

Call your doctor immediately if you notice any of the following:

- Shortness of breath;
- Increased cough;
- Swelling of the legs as a result of water retention;
- Diarrhea – if you have an extra four bowel movements each day or any diarrhea at night;
- Symptoms of infection that include:
 - fever: a temperature of 38°C or greater
 - sore throat
 - cough
 - any redness or swelling
 - pain when you pass urine
- Symptoms of an allergic reaction include:
 - closing of the throat
 - swelling of lips and tongue
 - hives
 - rash
 - dizziness
 - fast heartbeat

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
MOST COMMON (≥10%)	Diarrhea Where you have an extra four bowel movements each day or any diarrhea at night		✓	
LESS COMMON (≥ 1 AND ≤ 10%)	Heart problems: Symptoms include shortness of breath, water retention (swelling of the lower legs)		✓	
	Anemia (reduced number of red blood cells of the blood): Symptoms include: shortness of breath, racing heart, dizziness, light headedness		✓	
	Reduced number of white blood cells may lead to an increase chance of infection: Symptoms of infection include: fever (temperature above 38°C or 101°F), chills, sore throat, cough, any redness or swelling, pain when you pass your urine		✓	
	Lung problems: Symptoms include shortness of breath, wheezing or coughing		✓	

This is not a complete list of side effects. For any unexpected effects while taking HERCEPTIN, contact your doctor, nurse or pharmacist.

HOW TO PREPARE IT

The hospital pharmacy will prepare HERCEPTIN so it can be used.

If you are sensitive to benzyl alcohol, the HERCEPTIN powder should be mixed with sterile water.

HOW TO STORE IT

The hospital pharmacy will store HERCEPTIN in a refrigerator. HERCEPTIN can be at room temperature when the infusion is given.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

Reminder: This medicine has been prescribed only for you. Do not give it to anybody else. If you have any further questions, please ask your doctor or pharmacist.

This document plus the full product monograph, prepared for health professionals can be found at:

www.rochecanada.com

or by contacting the sponsor, Hoffmann-La Roche Limited, at: 1-888-762-4388.

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Last revised:

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Hoffmann-La Roche Limited
Mississauga, ON L5N 5M8

PART III: CONSUMER INFORMATION

HERCEPTIN®

trastuzumab for injection

GASTRIC CANCER

This leaflet is part III of a three-part “Product Monograph” published when HERCEPTIN was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about HERCEPTIN. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

- HERCEPTIN is a cancer medicine that must be prescribed by a doctor.
- HERCEPTIN is used for certain patients with gastric cancer that has spread to other parts or organs of the body to slow down the growth of specific gastric cancer cells that produce large amounts of HER2 protein
- HERCEPTIN is used in combination with chemotherapy (capecitabine or intravenous 5-fluorouracil and in combination with cisplatin) for the treatment of gastric cancer that has spread to other parts or organs of the body.
- HERCEPTIN is also approved for the treatment of breast cancer (a separate Consumer Information insert provides information on the use of HERCEPTIN in breast cancer)

What it does:

- Our bodies have a natural defence system against cancer cells. When cancer cells appear, our bodies respond by making special proteins called antibodies. The antibodies attach to other proteins on the growing tumour cells. Researchers studied this to learn how to create antibodies that help with cancer treatment.
- Antibodies are now made that can target tumours to try to control the growth of cancer.
- HERCEPTIN belongs to a family of medicines called monoclonal antibodies. It is an antibody that targets the HER2 gene to stop its activity. It attaches to the HER2 receptor on the cancer cell. When it is in place, it works to stop the growth of the cancer cells and may destroy them.

When it should be used:

Patients whose gastric cancer tumour cells produce large amounts of the HER2 protein can use HERCEPTIN. HERCEPTIN is used in combination with chemotherapy (capecitabine or intravenous 5-fluorouracil and cisplatin) for the treatment of gastric cancer that has spread to other parts or organs of the body in patients that have not received prior anti-cancer treatment for their disease.

When it should not be used:

Do not use HERCEPTIN if you are allergic to trastuzumab, Chinese Hamster Ovary (CHO) cell proteins, or any component of this product (see “What the non-medicinal ingredients are”).

What the medicinal ingredient is:

The medicinal ingredient in HERCEPTIN is trastuzumab. Each vial of HERCEPTIN contains 440 mg trastuzumab.

What the non-medicinal ingredients are:

HERCEPTIN contains the following non-medicinal ingredients: L-histidine, L-histidine HCl, polysorbate 20, and α,α -trehalose dihydrate. The Bacteriostatic Water for Injection supplied with HERCEPTIN contains benzyl alcohol.

What dosage forms it comes in:

HERCEPTIN is a sterile, powder that will be reconstituted and given as an intravenous (IV) administration.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Medication Errors

There is a risk of medication errors between HERCEPTIN (trastuzumab) and KADCYLA (trastuzumab emtansine). Verify with the healthcare provider that the recommended HERCEPTIN (trastuzumab) dose and NOT KADCYLA (trastuzumab emtansine) dose is used.

Cardiotoxicity (harm to the heart)

HERCEPTIN can result in the development of heart problems including heart failure. The appearance of heart failure can be delayed and can occur after treatment with HERCEPTIN is completed. In early breast cancer, the incidence of cardiac dysfunction was higher in patients who received HERCEPTIN plus chemotherapy versus chemotherapy alone, with higher risk when HERCEPTIN was administered together with a taxane following an anthracycline and cyclophosphamide. In patients with breast cancer that has spread to other parts or organs of the body, the incidence and severity of cardiac dysfunction was particularly high in patients who received HERCEPTIN at the same time as anthracyclines and cyclophosphamide.

You should have your heart function evaluated by your doctor before and during treatment with HERCEPTIN

Infusion Reactions; Lung Problems

Some patients have had serious infusion reactions and lung problems; infusion reactions causing death have been reported. In most cases, these reactions occurred during or within 24 hours of receiving HERCEPTIN. Your HERCEPTIN infusion should be temporarily stopped if you have shortness of breath or very low blood pressure. Your doctor will monitor you until these symptoms go away. If you have a severe allergic reaction, swelling, lung problems, inflammation of the lung, or severe shortness of breath, your doctor may need to completely stop your HERCEPTIN treatment.

Toxicity to Fetus (Unborn Baby)

HERCEPTIN can cause harm to the fetus (unborn baby), in some cases death of the fetus, when taken by a pregnant woman. Women who could become pregnant need to use effective birth control methods during HERCEPTIN treatment and for at least 7 months after treatment with HERCEPTIN. Nursing mothers treated with HERCEPTIN should discontinue nursing or discontinue HERCEPTIN.

BEFORE you use HERCEPTIN talk to your doctor or pharmacist if:

- you have ever had a bad reaction to HERCEPTIN, benzyl alcohol, or any of the inactive ingredients;
- you are allergic to other medicines, food and dyes;
- you are taking any other medicines, including those not prescribed by your doctor;
- you have any other illness or diseases, such as heart problems, heart disease, breathing problems or lung disease;
- you are pregnant, plan to become pregnant or are breast-feeding a child. Please note that a reduction in the amount of [amniotic] fluid that surrounds the developing fetus within the amniotic sac has been observed in pregnant women receiving HERCEPTIN;
- you have difficulty breathing at rest.

This information will help your doctor and you decide whether you should use HERCEPTIN and what extra care may need to be taken while you are on the medication.

Driving and using machines

We do not know whether HERCEPTIN could affect your ability to drive a car or operate machines. If you experience unwanted effects related to the infusion (such as itching, wheezing, dizziness, racing heart) you should not drive or operate machinery until symptoms resolve completely.

INTERACTIONS WITH THIS MEDICATION

Formal drug interaction studies with HERCEPTIN have not been done in humans. Important interactions with other medications were not seen during clinical trials with HERCEPTIN.

PROPER USE OF THIS MEDICATION

Your doctor has prescribed HERCEPTIN after carefully studying your condition. Other people may not benefit from taking this medicine, even though their problems may seem similar to yours.

Verify with the healthcare provider that the recommended HERCEPTIN (trastuzumab) dose and NOT KADCYLA (trastuzumab emtansine) dose is used.

Usual Dose:

The usual dose of HERCEPTIN depends on your body weight. Your doctor will calculate the dose for you.

How long you need to take HERCEPTIN will depend on your response to the treatment. Your doctor will check your response regularly and decide how many treatments you will receive.

A Registered Nurse in the hospital or outpatient clinic will give you HERCEPTIN at regular intervals (usually every 3 weeks) determined by your physician. HERCEPTIN is not taken by mouth, but given through an intravenous line. An intravenous line, or IV, is a thin, plastic tube with a needle placed in a vein in your hand or arm. When HERCEPTIN is given intravenously, it is called an infusion.

Your first infusion of HERCEPTIN will take about 90 minutes. If you tolerate this infusion well, your next infusions may be given in less time, usually about 30 minutes.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

For information on the risk of KADCYLA overdose due to medication errors, see the KADCYLA Product Monograph.

Missed Dose:

If you miss a dose, your doctor will advise you on when your next administration of HERCEPTIN will be.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Unwanted effects are possible with all medicines. Talk to your doctor, nurse or pharmacist if you are worried about side effects or find them very bothersome, and report any new or continuing symptoms to your doctor immediately. Your doctor will be able to tell you what to do and may be able to help you with these side effects.

Some unwanted effects happen during the first infusion or shortly after it is completed. The effects usually do not last long but may need treatment. The infusion may be stopped, and may be restarted and/or given over a longer time.

These unwanted effects related to the infusion may include:

- Itching
- Wheezing
- Dizziness
- Racing heart

Giving certain medications before the next infusion of HERCEPTIN may prevent these unwanted effects.

In the main clinical study in gastric cancer, the most common unwanted effects which are known to be associated with both the chemotherapy drugs used in the study and with trastuzumab administration were:

- stomach disorders such as nausea, vomiting, diarrhea and constipation

- blood disorders such as neutropenia (reduced number of white blood cells) anemia (reduced number of red blood cells) and thrombocytopenia (reduced number of platelet cells (colorless blood cells that play an important role in blood clotting)).

Giving certain medications before HERCEPTIN can prevent some unwanted effects.

Call your doctor immediately if you notice any of the following:

- Shortness of breath;
- Increased cough;
- Swelling of the legs as a result of water retention;
- Diarrhea – if you have an extra four bowel movements each day or any diarrhea at night;
- Symptoms of infection that include:
 - fever: a temperature of 38°C or greater
 - sore throat
 - cough
 - any redness or swelling
 - pain when you pass urine
- Symptoms of an allergic reaction include:
 - closing of the throat
 - swelling of lips and tongue
 - hives
 - rash
 - dizziness
 - fast heartbeat

In the main clinical study in gastric cancer, serious side effects that appeared with higher frequency in HERCEPTIN plus chemotherapy arm versus chemotherapy arm alone are listed in the table below.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

	Infections - Infection of the lungs (pneumonia) Symptoms may include symptoms of a cold followed by high fever.		✓	
	General Disorders - Fever		✓	
	Metabolism Disorders - Anorexia		✓	
	Kidney problems -Kidneys fail to function adequately Symptoms may include: decreased or normal urine output, fluid retention, causing swelling in your legs, ankles or feet, drowsiness shortness of breath, fatigue.		✓	

This is not a complete list of side effects. For any unexpected effects while taking HERCEPTIN, contact your doctor, nurse or pharmacist.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
LESS COMMON (≥ 1 and ≤ 10%)	Stomach problems - Diarrhea, - Vomiting -Difficulty swallowing.		✓
	Blood disorders - Reduced number of white blood cells leading to increased chance of infection; fever.		✓

HOW TO PREPARE IT

The hospital pharmacy will prepare HERCEPTIN so it can be used.

If you are sensitive to benzyl alcohol, the HERCEPTIN powder should be mixed with sterile water.

HOW TO STORE IT

The hospital pharmacy will store HERCEPTIN in a refrigerator. HERCEPTIN can be at room temperature when the infusion is given.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

Reminder: This medicine has been prescribed only for you. Do not give it to anybody else. If you have any further questions, please ask your doctor or pharmacist.

This document plus the full product monograph, prepared for health professionals can be found at:

www.rochecanada.com

or by contacting the sponsor, Hoffmann-La Roche Limited, at: 1-888-762-4388.

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