

Actrapid® Penfill® ; Protaphane® Penfill® ; Mixtard® 30/70 Penfill®

Insulin (rys)

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Actrapid®, Protaphane®, or Mixtard® Penfill®?

Actrapid®, Protaphane® and Mixtard® contain the active ingredient insulin (rys). Actrapid®, Protaphane® and Mixtard® are used to treat diabetes mellitus. For more information, see Section [1. Why am I using Actrapid®, Protaphane®, or Mixtard® Penfill®?](#) in the full CMI.

2. What should I know before I use Actrapid®, Protaphane® or Mixtard®?

Do not use if you have ever had an allergic reaction to insulin or any of the ingredients listed at the end of the CMI.

Do not use if you are experiencing low blood sugar ("hypo") when your dose is due.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Actrapid®, Protaphane® or Mixtard®?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with insulin and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Actrapid®, Protaphane® and Mixtard® Penfill®?

Carefully follow all instructions given to you by your doctor, nurse educator and pharmacist regarding how to use your medicine, including preparing and injecting it.

More instructions can be found in Section [4. How do I use Actrapid®, Protaphane®, Mixtard® Penfill®?](#) in the full CMI.

5. What should I know while using Actrapid®, Protaphane® or Mixtard® Penfill®?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you have diabetes and are using insulin.Monitor your blood sugar levels regularlyCarry some sugary food or fruit juice with you, in case you experience hypoglycaemia ("a hypo").
Things you should not do	<ul style="list-style-type: none">Do not stop using this medicine unless directed by your doctor to.Do not share your insulin or needles with anyone.
Driving or using machines	<ul style="list-style-type: none">If your blood sugar is low or high, your concentration and ability to react might be affected, and, therefore, also your ability to drive or operate machines.
Drinking alcohol	<ul style="list-style-type: none">Alcohol may mask the symptoms of hypos. If you drink alcohol, your need for insulin may change.
Looking after your medicine	<ul style="list-style-type: none">Store Actrapid®, Mixtard® and Protaphane® Penfill® in the fridge between 2 and 8°CDo not keep in a refrigerator, Penfill® that you are using, or that you are carrying as a spare. You can use them up to 4 weeks after taking them out of the refrigerator. Discard any unused insulin after 4 weeks.

For more information, see Section [5. What should I know while using Actrapid®, Protaphane® or Mixtard® Penfill®?](#) in the full CMI.

6. Are there any side effects?

The most common side effect when using insulin is low blood sugar levels (a hypo). Tell your relatives, friends, close workmates, teachers or carers that you have diabetes. It is important that they can recognise the signs and symptoms of a hypo. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Actrapid® Penfill®

Protaphane® Penfill®

Mixtard® 30/70 Penfill®

Active ingredients: *Insulin (rys)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Actrapid® Penfill®, Protaphane® Penfill® and/or Mixtard® 30/70 Penfill®. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using these medicines.**

Where to find information in this leaflet:

1. [Why am I using Actrapid®, Protaphane®, or Mixtard® Penfill®?](#)
2. [What should I know before I use Actrapid®, Protaphane® or Mixtard®?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use Actrapid®, Protaphane® and Mixtard® Penfill®?](#)
5. [What should I know while using Actrapid®, Protaphane® or Mixtard® Penfill®?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using Actrapid®, Protaphane®, or Mixtard® Penfill®?

Actrapid® Penfill®, Protaphane® Penfill®, Mixtard® 30/70 Penfill® contain the active ingredient insulin (rys).

Insulin (rys) is characterised by being identical to natural human insulin. The abbreviation "rys" indicates the method of genetic engineering used to manufacture the insulin.

Actrapid®, Protaphane®, and Mixtard® Penfill® are used to treat diabetes mellitus.

Diabetes mellitus is a condition where your pancreas does not produce enough insulin to control your blood sugar (glucose) level. Extra insulin is therefore needed.

There are two types of diabetes mellitus:

Type 1 diabetes

Type 2 diabetes

Patients with type 1 diabetes always require insulin to control their blood sugar levels.

Some patients with type 2 diabetes may also require insulin after initial treatment with diet, exercise and tablets is not enough.

Actrapid® is neutral insulin injection, a fast-acting insulin. This means that it will start to lower your blood sugar level about half an hour after you inject it, and the effect will last for approximately 8 hours.

Actrapid® Penfill® can also be used by doctors to treat some people with diabetes in emergency situations. For emergency use, the insulin must first be withdrawn from Penfill® into a syringe.

Actrapid® is often used in combination with longer-acting insulin products.

Protaphane® is isophane insulin injection, an intermediate-acting insulin. This means that it will start to lower your blood sugar level about one and a half hours after you inject it, and the effect will last for approximately 24 hours.

Protaphane® is often used in combination with fast- or rapid-acting insulin products.

Mixtard® 30/70 is two-phase isophane insulin injection, and is a mixture of fast- and longer-acting insulins. Mixtard® 30/70 will start to lower your blood sugar level about half an hour after you inject, and the effect will last for approximately 24 hours.

As with all insulins, the duration of action will vary according to the type of insulin, the dose, injection site, blood flow, temperature and level of physical activity.

Insulin is not addictive. Insulin is available only with a doctor's prescription.

2. What should I know before I use Actrapid®, Protaphane® or Mixtard®?

Warnings

Do not use Actrapid®, Protaphane® or Mixtard® Penfill®:

- if you are allergic to insulin, or any product containing insulin, or any of the ingredients listed at the end of this leaflet.
- if you are experiencing low blood sugar level (a "hypo") when your dose is due.
- if the expiry date printed on the pack has passed, or if the packaging is torn or shows signs of tampering.
- in insulin infusion pumps.

Do not inject Protaphane® or Mixtard® 30/70 into a vein.

Check with your doctor if you:

- are experiencing a lot of hypos, and follow their advice
- have any other medical conditions, such as: kidney liver, adrenal gland, pituitary gland or thyroid gland problems

- take any medicines for any other condition
- have an infection or fever
- are planning to travel.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Pregnancy can make managing your diabetes more difficult, and may require adjustment of how much insulin you need.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Heart disease or a history of stroke

Tell your doctor as soon as possible if you experience signs of heart failure such as unusual shortness of breath or rapid increase in weight or localised swelling (oedema). Some patients with long-standing type 2 diabetes mellitus and heart disease or previous stroke, and who are treated with a class of medicines known as thiazolidinediones in combination with insulin can develop heart failure.

3. What if I am taking other medicines?

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

Some medicines may interfere with insulin and affect how it works.

Medicines that may increase the effect of insulin, and therefore reduce insulin requirements include:

- other medicines used to treat type 2 diabetes
- octreotide - used to treat gastrointestinal endocrine tumours and enlargement of parts of the body (e.g. hands, feet, head) caused by abnormal growth hormone levels
- lanreotide - used to treat enlargement of parts of the body (e.g. hands, feet, head) caused by abnormal growth hormone levels
- monoamine oxidase inhibitors (MAOIs) - used to treat depression
- non-selective beta-blockers - used to treat certain heart conditions and high blood pressure
- alpha-blockers - used to treat high blood pressure and to relieve difficulty in passing urine caused by an enlarged prostate
- angiotensin converting enzyme (ACE) inhibitors - used to treat certain heart conditions, high blood pressure and elevated protein/albumin in the urine
- salicylates, e.g. aspirin - used to relieve pain and lower fever
- anabolic steroids - used to promote growth
- quinine - used to treat malaria and relieve muscle cramps
- quinidine - used to treat heart problems

- sulphonamides - a type of antibiotic used to treat bacterial infections.

Medicines that may reduce the effect of insulin, and increase the insulin requirements include:

- oral contraceptives ("the pill") - used for birth control
- thiazides, frusemide or ethacrynic acid - used to treat high blood pressure or fluid retention (oedema)
- glucocorticoids (except when applied locally) - used to treat inflammatory conditions
- thyroid hormones - used to treat malfunction of the thyroid gland
- sympathomimetics - used to treat asthma
- octreotide - used to treat gastrointestinal endocrine tumours and enlargement of parts of the body (e.g. hands, feet, head) caused by abnormal growth hormone levels
- lanreotide - used to treat enlargement of parts of the body (e.g. hands, feet, head) caused by abnormal growth hormone levels
- growth hormone - used to treat growth disorders
- diazoxide - used to treat high blood pressure
- asparaginase - used to treat leukaemia and lymph gland tumours
- nicotinic acid - used to treat high cholesterol levels in the blood
- oxymetholone - used to treat certain blood disorders
- danazol - used to treat endometriosis, menorrhagia, fibrocystic breast disease and hereditary angioedema.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Actrapid®, Protaphane® or Mixtard®

4. How do I use Actrapid®, Protaphane® and Mixtard Penfill® ?

How much to use

Carefully follow all instructions given to you by your doctor, nurse educator and pharmacist regarding how to use your medicine.

- Your doctor or diabetes education nurse will tell you how much of this medicine you need to use each day.
- It is very important that you manage your diabetes carefully. Too much or too little insulin can cause serious effects.

When to use Actrapid®, Protaphane®, Mixtard® Penfill® ?

- Your doctor or diabetes education nurse will tell you when and how often to inject your insulin.

How to inject Actrapid®, Protaphane®, Mixtard® Penfill® ?

- Penfill® cartridges are designed to be used with Novo Nordisk insulin delivery devices (such as NovoPen®), and NovoFine® needles.
- Make sure you are using the correct type and strength of insulin.

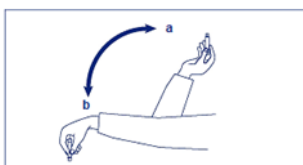
- Carefully follow the instructions on how to use your Penfill® in the Novo Nordisk insulin delivery device.
- If you use more than one type of insulin in a Penfill®, you must use a separate insulin delivery device for each type.
- Do not use the insulin level indicator on the device to measure your dose of insulin.
- Inject insulin under the skin (subcutaneous injection) as shown to you by your doctor or diabetes education nurse.
- Take care not to drop or knock the device that contains Penfill®.

Checking your Penfill® before injection

- Check your Penfill® every time you are preparing your injection to make sure you are using the correct type and strength of insulin.
- Disinfect the rubber membrane with a medicinal swab.
- **Do not use your Actrapid® Penfill® unless the insulin appears clear and colourless. Do not use it if the insulin appears thickened or has bits in it.**
- **Do not use your Protaphane® or Mixtard® 30/70 Penfill® if the insulin is no longer a cloudy, white suspension after mixing, or if it has bits in it.**
- Do not use your Penfill® if you notice any damage, including any damage to the rubber plunger (stopper) or if there is a gap between the plunger and the white label band.

Preparing your Penfill® for injection

- On the Penfill® cartridge is a coloured band. Do not start an injection with a Penfill® cartridge if you have emptied beyond the coloured band.
- The glass ball must have adequate space to resuspend the insulin. Resuspending is easier when the insulin has reached room temperature.
- Before you put Penfill® into the Novo Nordisk insulin delivery device, move it up and down between positions a and b - see picture below - so that the glass ball in the cartridge moves from one end to the other at least 20 times. The movement must always be repeated until the liquid appears uniformly white and cloudy.
- If Penfill® is already inside the Novo Nordisk insulin delivery device, turn the delivery device upside-down at least 10 times with the cartridge inside it. Do this again before every injection.
- Complete the remaining stages of injection without delay.



Checking for insulin flow (priming):

- Always check your Novo Nordisk insulin delivery device for insulin flow (priming) before each injection, as described in the device user manual.
- The priming procedure may highlight a malfunction with your insulin delivery device. Priming also removes any air bubbles and helps indicate whether or not a needle is broken.
- Only dial up your required dose after you see a drop of insulin at the needle tip.
- After priming, if you need to put the insulin delivery device down, make sure the needle does not touch anything.

Choose a site for injection

- **Inject the medicine into the abdomen, thighs, upper arms or buttocks.** Note that your insulin will work more quickly if you inject into the abdomen.
- Change the injection site so that the same position is not used more often than once a month. This reduces the risk of developing lumps or skin pitting.
- Pinch the skin between two fingers, push the needle into the raised skin, and inject the full dose of insulin under the skin.
- Slowly count to 6 before pulling the needle out.
- Keep the push button fully depressed until the needle has been withdrawn.
- Apply gentle pressure over the injection site for several seconds
- Do not rub the area

After injecting:

- **Dispose of your used needle safely into a yellow plastic sharps container after each injection.**
- If you are using Actrapid® or Mixtard®, it is recommended that you eat a meal or a snack containing carbohydrate within 30 minutes of the injection.
- **Do not share needles, insulin cartridges or insulin delivery devices.**

If you forget to inject your insulin - hyperglycaemia

Actrapid®, Protaphane® and Mixtard Penfill® must be used strictly as advised by your doctor or nurse educator.

If you forget your insulin dose, test your blood sugar level as soon as possible.

If you are not sure what to do, talk to your doctor, diabetes education nurse or pharmacist.

Do not use a double dose of your insulin.

If it is almost time for your next dose, skip the dose you missed and inject your next dose when you are meant to.

Otherwise, use it as soon as you remember and then go back to using it as you would normally.

If you are using Actrapid® or Mixtard®, make sure you eat some carbohydrate within 30 minutes of the injection.

If you use too much insulin - hypoglycaemia

If you think that you have used too much insulin, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Actrapid®, Protaphane® or Mixtard® Penfill®?

Hypoglycaemia

Your blood sugar level may become too low (you may experience hypoglycaemia (a hypo) if you:

- accidentally use too much of this medicine
- have too much or unexpected exercise
- delay eating meals or snacks
- eat too little food
- are ill.

The first symptoms of mild to moderate hypos can come on suddenly. They may include:

- cold sweat, cool pale skin
- fatigue, drowsiness, unusual tiredness and weakness
- nervousness, feeling anxious, tremor, rapid heart beat
- confusion, difficulty concentrating
- excessive hunger
- vision changes
- headache, nausea.

Always carry some sugary food or fruit juice with you.

Do not inject any insulin if you feel a hypo coming on.

Tell your relatives, friends, close workmates or carers that you have diabetes. It is important that they recognise the signs and symptoms of a hypo.

Make sure they know to give you some sugary food or fruit juice for mild to moderate symptoms of a hypo.

If you lose consciousness, make sure they know:

- to turn you on your side and get medical help immediately
- not to give you anything to eat or drink as you may choke.

An injection of the hormone glucagon may speed up recovery from unconsciousness. This can be given by a relative, friend, workmate or carer who knows how to give it.

- If glucagon is used, eat some sugary food or have a sugary
- drink as soon as you are conscious again.

If you do not feel better after this, contact your doctor, diabetes education nurse, or the closest hospital.

See your doctor if you keep having hypo reactions, or if you have ever become unconscious after using insulin.

Your insulin dose may need to be changed.

If a severe hypo is not treated, it can cause convulsions, brain damage and even death.

Hyperglycaemia

Your blood sugar levels may become high (hyperglycaemia) if you:

- miss doses of insulin or use less insulin than you need
- have uncontrolled diabetes
- exercise less than usual
- eat more carbohydrates than usual
- are ill or stressed.

High blood sugar levels over a long period of time can lead to too much acid in the blood (diabetic ketoacidosis).

Contact your doctor immediately if your blood sugar level is high or you recognise any of the following symptoms.

Symptoms of mild to moderate hyperglycaemia include:

- drowsy feeling
- flushed face
- thirst, loss of appetite
- fruity odour on the breath
- blurred vision
- passing larger amounts of urine than usual
- getting up at night more often than usual to pass urine
- high levels of glucose and acetone in the urine.

Symptoms of severe hyperglycaemia include:

- heavy breathing
- fast pulse
- nausea, vomiting
- dehydration
- loss of consciousness.

Severe hyperglycaemia can lead to unconsciousness and in extreme cases death if untreated.

Things you should do

Measure your blood sugar levels regularly.

Make sure all friends, relatives, workmates or carers know that you have diabetes.

If your child has diabetes, it is important to tell their teachers and carers.

Keep using your insulin even if you feel well. It helps to control your diabetes, but does not cure it.

Always carry some sugary food or fruit juice with you.

Tell your doctor if you are feeling sick, especially if you are experiencing nausea or vomiting.

Tell your doctor if you have trouble recognising the symptoms of hypos.

Remind any doctor, dentist or pharmacist you visit that you have diabetes and are using insulin.

Tell your doctor if your diet changes or you are exercising more.

Tell your doctor if you notice any skin changes at the injection site.

The injection site should be rotated to help prevent changes to the fatty tissue under the skin, such as skin thickening, skin shrinking or lumps under the skin. The insulin may not work very well if you inject into a lumpy, shrunken or thickened area. Change the injection site with each injection to help prevent these skin changes.

Things you should not do

- **Do not stop using your insulin unless your doctor tells you to.**
- **Do not give your insulin to anyone else, even if they have diabetes.**
- **Do not share needles.**

Driving or using machines

Be careful before you drive or use any machines or tools until you know how the insulin affects you.

If your blood sugar is low or high your concentration and ability to react might be affected, and therefore also your ability to drive or operate a machine.

Bear in mind that you could endanger yourself or others. Please ask your doctor whether you can drive a car, especially if:

- you have frequent hypos
- you find it hard to recognise hypos.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may mask the signs of a hypo. Carefully monitor your blood sugar levels when drinking.

Looking after your medicine

- Penfill® cartridges that are not being used should be stored between 2°C and 8°C in the refrigerator (away from the cooling element).
- Penfill® cartridges that you are using, or that you are carrying as a spare, should not be kept in a refrigerator.
- **Protect the insulin in Penfill® from light by keeping the cartridges in the carton when not in use.**
- Do not allow cartridges to be frozen, or exposed to excessive heat and light.
- **Never use Actrapid® Penfill® if the solution is not clear and colourless.**
- **Never use Protaphane® or Mixtard® Penfill® if the suspension does not become white and uniformly cloudy after resuspending.**

Keep it where young children cannot reach it.

In an emergency Actrapid® is suitable for injection into a muscle (intramuscular administration) or into a vein (intravenous administration) but only by a doctor. It must be withdrawn from the cartridge and given by a needle and syringe.

Discard any insulin left after emergency use.

When to discard your medicine

You can use Actrapid®, Mixtard® and Protaphane® Penfill® for up to 4 weeks after taking it out of the refrigerator if kept below 25°C.

Discard Penfill® cartridges after 4 weeks even if there is still some insulin left in them.

Getting rid of unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Never use insulin after the expiry date printed on the Penfill® label and carton after 'Expiry'. The expiry date refers to the last day of that month.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Hypoglycaemia (mild to moderate): <ul style="list-style-type: none">• cold sweat, cool pale skin• fatigue, drowsiness, unusual tiredness and weakness• nervousness, anxious feeling, tremor, rapid heart beat• confusion, difficulty concentrating• excessive hunger• vision changes• headache, nausea. Injection site reactions: <ul style="list-style-type: none">• redness, swelling or itching at the injection site• a depression or thickening of the skin around the injection site. <p>Other effects when you first start using insulin:</p> <ul style="list-style-type: none">• visual problems• swelling of your hands• swelling of your feet.	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Hypoglycaemia (severe): <ul style="list-style-type: none">• disorientation• seizures, fits, convulsions	Call your doctor straight away, or go straight to the

Serious side effects	What to do
<ul style="list-style-type: none"> loss of consciousness. Severe allergy - anaphylaxis: <ul style="list-style-type: none"> skin rashes over a large part of the body shortness of breath, wheezing swelling of the face, lips or tongue fast pulse sweating. 	Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Actrapid® Penfill® contains

Active ingredient (main ingredient)	Insulin (rys) 100 IU/mL
Other ingredients (inactive ingredients)	glycerol metacresol zinc chloride Water for Injection. hydrochloric acid and sodium hydroxide to adjust the pH.

Do not take this medicine if you are allergic to any of these ingredients.

What Protaphane® Penfill® contains

Active ingredient (main ingredient)	Isophane insulin (rys) 100 IU/mL
Other ingredients (inactive ingredients)	glycerol metacresol phenol dibasic sodium phosphate dihydrate zinc chloride protamine sulfate

	Water for Injection. hydrochloric acid and sodium hydroxide to adjust the pH.
Potential allergens	protamine sulfate is derived from fish

Do not take this medicine if you are allergic to any of these ingredients.

What Mixtard® 30/70 Penfill contains

Active ingredient (main ingredient)	a pre-mixed neutral suspension of insulin (rys) 100 IU/mL, consisting of neutral insulin injection (30%) and isophane insulin injection (70%)
Other ingredients (inactive ingredients)	glycerol metacresol phenol dibasic sodium phosphate dihydrate zinc chloride protamine sulfate Water for Injection. hydrochloric acid and sodium hydroxide to adjust the pH.
Potential allergens	protamine sulfate is derived from fish

Do not take this medicine if you are allergic to any of these ingredients.

What Actrapid®, Protaphane® and Mixtard® Penfill® look like

A coloured band is located on the Penfill® cartridge. The colour of the band is specific for the insulin preparation.

Actrapid® is a clear, colourless solution for subcutaneous injection. Actrapid® Penfill® 3 mL is a glass cartridge (AUST R 169623)

Protaphane® Penfill® is a white, cloudy suspension for subcutaneous injection. Protaphane® Penfill® 3 mL is a glass cartridge (AUST R 169635)

Mixtard® 30/70 is a white, cloudy suspensions for subcutaneous injection. Penfill® 3mL is a glass cartridge (AUST R 169629)

Who distributes these medicines?

Actrapid® Penfill®, Protaphane® Penfill® and Mixtard® 30/70 Penfill® are supplied in Australia by:

Novo Nordisk Pharmaceuticals Pty Ltd

Level 10

118 Mount Street

North Sydney NSW 2060

Australia

Further information

For further information call Novo Nordisk Medical
Information on 1800 668 626.

www.novonordisk.com.au

You can also get more information about diabetes from

Diabetes Australia:

- freecall helpline 1300 136 588
- www.diabetesaustralia.com.au

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