

Consumer Medicine Information

PEGASYS RBV[®]

Peginterferon alfa-2a

135 mcg and 180 mcg in 0.5 mL solution for injection in prefilled syringes

Ribavirin

200 mg film coated tablets

What is in this leaflet

This leaflet answers some common questions about PEGASYS RBV combination pack.

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 using PEGASYS RBV against the benefits expected for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What PEGASYS RBV is used for

PEGASYS RBV is a combination pack product that contains two medicines. One is called PEGASYS[®] (peginterferon alfa-2a, solution for injection) and the other is called COPEGUS[®] (ribavirin, film coated tablets).

PEGASYS RBV is used to treat chronic hepatitis C, which is a viral infection of the liver.

PEGASYS belongs to a group of medicines called interferons. PEGASYS is a long-acting interferon. Interferons are proteins that change how the body's immune system fights infections and severe disease.

COPEGUS belongs to a group of medicines called antivirals. These medicines work by preventing the activity of some viruses.

PEGASYS RBV is more effective in chronic hepatitis C than treatment with PEGASYS alone.

People who get hepatitis C will usually carry the virus in their blood for the rest of their lives, unless successfully treated. Most will end up with some liver damage, but not all will feel sick in the earlier stages of the disease. If this viral infection is not managed, in some people, the liver becomes badly damaged and scarred. This is called cirrhosis. Cirrhosis can cause the liver to stop working properly.

Cirrhosis can also be caused by things other than viral infections such as long-term alcoholism.

It is not known if PEGASYS RBV can prevent liver failure or liver cancer that is caused by hepatitis infection.

Ask your doctor if you have any questions about why PEGASYS RBV has been prescribed for you.

PEGASYS RBV is not addictive.

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

Before you use PEGASYS RBV

When you must not use PEGASYS RBV

Do not use PEGASYS RBV if:

- 1. you have had an allergic reaction to alfa interferons, ribavirin, or products derived from a bacteria called *Escherichia coli* (*E. coli*), polyethylene glycol, benzyl alcohol or any of the ingredients listed at the end of this leaflet**
Some symptoms of an allergic reaction include: hives; skin rash; swelling of the face, lips or tongue; wheezing or troubled breathing; faintness
- 2. you or your partner is pregnant**
The baby may absorb this medicine in the womb and there is a possibility of harm to the baby.
- 3. you have autoimmune hepatitis**
- 4. you have severe liver disease (hepatic decompensation)**
- 5. the intended patient is a child less than three years old**
The PEGASYS component contains benzyl alcohol which has been linked with a serious condition in infants up to three years old.
- 6. you have a red blood cell disorder, such as thalassaemia or sickle-cell anaemia**
- 7. the package is torn or shows signs of tampering**
- 8. the expiry date printed on the pack has passed**
If you use this medicine after the expiry date has passed it may not work as well.

If you are not sure if you should be using PEGASYS RBV, talk to your doctor.

Use in children

PEGASYS RBV is not recommended for use in children and adolescents under the age of 18.
The safety and effectiveness of PEGASYS RBV have not been established in children and adolescents under 18 years of age.

Before you start to use PEGASYS RBV

Tell your doctor if:

- 1. you or your female partner are pregnant or plan to become pregnant**

The COPEGUS component of PEGASYS RBV, can cause harm to an unborn baby. You MUST NOT take COPEGUS if you are pregnant. You MUST NOT take COPEGUS if you are the male partner of a woman who is pregnant.

Before starting PEGASYS RBV, female patients and female partners of male patients must have a pregnancy test to show that they are not pregnant.

Extreme care must be taken to avoid pregnancy during treatment and for 6 months after treatment has been completed. Two forms of effective contraception used at the same time are recommended for both males and females while they are taking PEGASYS RBV. Your doctor can discuss the risks of PEGASYS RBV therapy to an unborn baby with you.

2. you are breast-feeding or plan to breast-feed

Because of the potential for harm to the baby, a decision must be made to discontinue breastfeeding or not to start taking PEGASYS RBV. You should not breast-feed if you are taking PEGASYS RBV.

3. you have any other health problems, especially the following:

- mental illness, or a history of mental illness (including depression)
- poor liver function
- kidney disease
- breathing difficulties
- thyroid disease
- autoimmune disease (where the body's immune system attacks the body's own cells), such as psoriasis (a skin disease)
- heart disease or heart problems (including high blood pressure), especially if they are not well controlled, or any previous serious heart condition
- low levels of red blood cells (anaemia), white blood cells or blood clotting cells (platelets)
- diabetes (high blood sugar levels)
- eye or vision problems
- HIV or AIDS

4. you are allergic to any other medicines, foods, dyes or preservatives

If you have not told your doctor about any of the above, tell them before you start taking PEGASYS RBV.

Taking other medicines

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

Some medicines may interfere with PEGASYS RBV.

You must tell your doctor if you are taking:

- theophylline (Nuelin[®]), a medicine used to treat asthma, bronchitis, emphysema and related conditions, as you may need to take a different dose of PEGASYS. Your doctor will advise you.
- telbivudine (Sebivo[®]), a medicine used to treat chronic hepatitis B
- methadone, a medicine used to treat opioid dependence
- antacids (Gaviscon[®], Mylanta[®], Titralac[®], Acidex[®]), a group of medicines used to treat heartburn and indigestion
- azathioprine (Azamun[®], Imuran[®]), a medicine used to suppress the immune system.

You must tell your doctor if you are being treated for Human Immunodeficiency Virus (HIV) infection or Acquired Immune Deficiency Syndrome (AIDS) with:

- zidovudine (Retrovir[®], Combivir[®])
- didanosine (Videx[®])
- stavudine (Zerit[®])

It is not certain whether the COPEGUS component of PEGASYS RBV will change the way these medicines work. Therefore, your doctor may check your blood regularly to be sure that the HIV infection is not getting worse. If it gets worse, your doctor will decide whether or not your PEGASYS RBV treatment needs to be changed.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using PEGASYS RBV.

Ask your doctor or pharmacist if you are not sure about this list of medicines.

How to use PEGASYS RBV

Follow all directions given to you by your doctor, nurse or pharmacist carefully.

They may differ from the information contained in this leaflet.

How much PEGASYS to inject

Inject PEGASYS exactly as your doctor has prescribed.

Your doctor will tell you how much PEGASYS to inject according to your individual needs.

PEGASYS is usually administered as a 180 mcg injection once a week for between 24 and 72 weeks.

If necessary, your dose may be changed by your doctor during treatment, or PEGASYS may be stopped altogether, according to your response.

How to inject PEGASYS

PEGASYS is administered by subcutaneous injection. PEGASYS is injected with a short needle into the fatty tissue just under the skin in the stomach or thigh.

Your doctor may discuss whether it would be more convenient for you to receive your injection at home, in which case you, or a family member, would be instructed on how to give the injection. This is a simple procedure and many patients prefer it.

If you are using PEGASYS by subcutaneous injection at home, please follow the instructions below. Your doctor or nurse will usually show you how to inject PEGASYS.

Directions for self-administration

You should read these directions from beginning to end before starting so that each step of the procedure becomes familiar. These instructions must be carefully followed. Consult your doctor, nurse or pharmacist if you require further instructions.

Remember that cleanliness is vital.

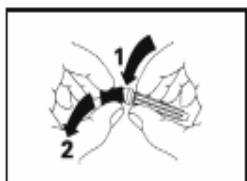
I. Before subcutaneous injection

- Check the expiry date. Do not use PEGASYS after the expiry date shown on the prefilled syringe label.
- Check the dose that you have been prescribed.
- Check the liquid has no discolouration, cloudiness or particles. The liquid should look clear and colourless to slightly yellow.
- To allow the solution to reach room temperature, leave it out of the fridge for 10 – 15 minutes.
- Wash your hands thoroughly.

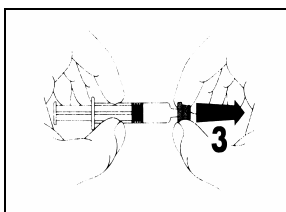
- Place everything you need within easy reach on a cleaned surface: the prefilled syringe, the injection needle, several alcohol swab packets and container for disposal of needle and syringe.

II. How to prepare the syringe

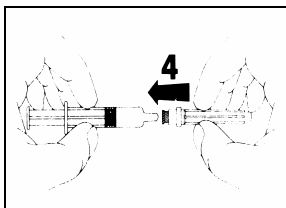
- A. Take the sealed needle in both hands and snap the cap backwards. Remove the cap. *Do not* remove the plastic needle shield.



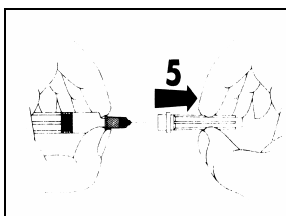
- B. Remove the rubber tip from the syringe. Do not touch the tip of the syringe.



- C. Attach the needle with the plastic shield firmly to the syringe.



- D. Remove the plastic cover from the needle while holding the syringe. Avoid pushing the plunger.

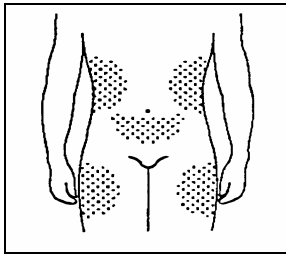


To remove air bubbles from the syringe, hold the syringe with the needle pointing up. Tap the syringe gently to bring the bubbles to the top. Push up the plunger slowly to the correct dose. Replace the needle guard and place the syringe on a clean flat surface.

The syringe is now ready for use.

III. Performing subcutaneous injection

- E. Select an injection site in the stomach or thigh area (except your navel or waistline, see diagram). Change your injection site each time.

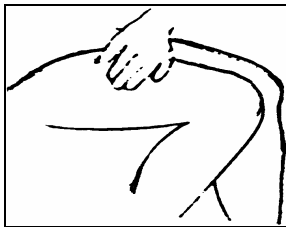


- F. Remove an alcohol swab from one packet and clean and disinfect the site by wiping with the swab.

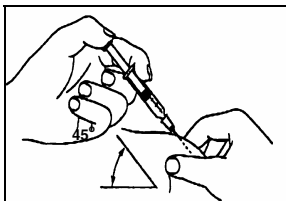


- G. Remove the alcohol swab from the site. Allow the injection site to dry for 10 seconds.

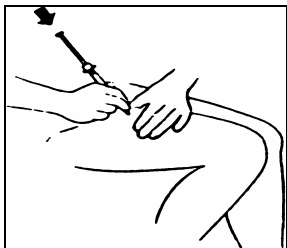
- H. Grasp the skin firmly between the thumb and forefingers (without squeezing) to elevate the subcutaneous tissue.



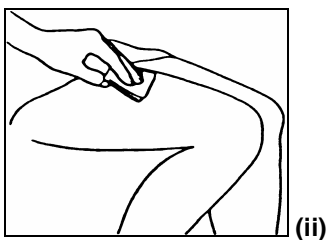
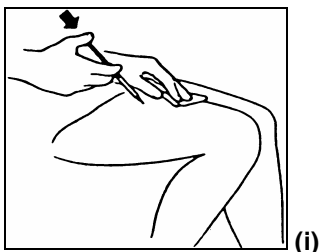
- I. Insert the needle into the grasped skin at an angle of 45° to 90°.



- J. Inject the solution by gently pushing the plunger all the way down, while keeping the skin grasped.



- K. After injecting, remove the needle and release the skin. Immediately disinfect the site with a new alcohol swab and apply finger pressure for a minute or so.



Remember: Most people can learn to give themselves a subcutaneous injection, but if you experience difficulty, please do not be afraid to ask for help and advice from your doctor, nurse or pharmacist.

IV. How to dispose of used needles and syringes

The needle and syringe are to be used **once** only. Dispose of the needle and syringe immediately after injection into a sturdy glass or hard plastic container away from children. Do not replace the needle cover.

Never put used needles and syringes into your normal household waste bin.

If you are not sure how to dispose of the needles and syringes, consult your doctor, pharmacist or nurse on how to properly dispose of them.

Please note that the needle supplied with the PEGASYS prefilled syringe is for subcutaneous injection only and is **not** suitable for any other type of injection (e.g. intravenous or intramuscular injection).

When to inject PEGASYS

Your doctor will tell you how often to use this medicine. PEGASYS is usually given as a single injection once a week.

If you are injecting this medicine yourself, use it at bedtime, as PEGASYS may make you very tired or cause flu-like symptoms.

How much COPEGUS to take

Take COPEGUS exactly as your doctor has prescribed.

Your doctor will tell you how many COPEGUS tablets to take each day.

The usual dose is between four and six 200 mg COPEGUS tablets per day. The dose depends on your weight and the type of hepatitis C disease you have. The daily dose is usually divided so that some tablets are taken in the morning and some in the evening.

Your doctor may do regular blood tests to see if COPEGUS is working or if it is causing side effects. Your dose and the length of time you take COPEGUS may be adjusted, or COPEGUS may be stopped altogether, according to your response.

How to take COPEGUS

Swallow the tablets whole with a glass of water.

Do not chew the tablets.

When to take COPEGUS

Take COPEGUS during or immediately after a meal, at about the same time each day.

Taking COPEGUS at the same time every day will help its effect and help you to remember to take your tablets.

How long to use PEGASYS RBV

Continue using PEGASYS RBV until your doctor tells you to stop.

Your PEGASYS RBV treatment is usually taken for between 24 and 72 weeks. However, your doctor may ask you to take PEGASYS RBV for a different period of time. Your doctor will determine when your treatment should be stopped.

If you forget to use your PEGASYS RBV

If it is almost time for your next COPEGUS dose, skip the tablets you missed and take your next dose when you are meant to. Do not double the dose.

Otherwise, take your COPEGUS tablets as soon as you remember and then go back to taking it as you would normally.

If you realise you missed your PEGASYS injection within two days after the scheduled dose, you should inject your recommended dose as soon as you remember. Take your next injection on the following regularly scheduled day.

If you realise you missed your injection by more than 2 days contact your doctor, nurse or pharmacist for advice.

Do not take a double dose to make up for the PEGASYS injection or COPEGUS tablet that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you use too much PEGASYS RBV (overdose)

Immediately telephone your doctor or National Poisons Information Centre (telephone 0800 POISON or 0800 764 766) for advice, or go to your nearest Accident and Emergency Centre, if

you think you or anyone else may have taken too much PEGASYS or COPEGUS. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep telephone numbers for these places handy.

If you are not sure what to do, contact your doctor or pharmacist.

While you are using PEGASYS RBV

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are using PEGASYS RBV.

Tell your doctor if you become pregnant while using PEGASYS RBV or within 6 months of stopping treatment.

Extreme care must be taken to avoid pregnancy during treatment and for 6 months after treatment.

Female patients and female partners of male patients taking PEGASYS RBV must have a pregnancy test each month during treatment and for 6 months after treatment with PEGASYS RBV has stopped to show that they are not pregnant.

Female patients taking PEGASYS RBV should use two forms of effective contraception at the same time.

Male patients taking PEGASYS RBV should use condoms and their female partners should also use an effective contraceptive.

Tell your doctor that you are taking PEGASYS RBV if you are going to have any laboratory tests.

Tell your doctor if, for any reason, you have not used PEGASYS RBV exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you feel that PEGASYS RBV is not working for you.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Your doctor will keep track of your response to PEGASYS RBV by asking questions and performing occasional laboratory tests.

Things you must not do

Do not stop using PEGASYS RBV or change any dose without first checking with your doctor.

Do not let yourself run out of medicine over the weekend or on holidays.

Do not give PEGASYS RBV to anyone else even if they have the same condition as you.

Do not use PEGASYS RBV to treat other complaints unless your doctor says to.

Do not switch to any other brand of interferon without consulting your doctor first.

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

PEGASYS RBV may cause dizziness, drowsiness or light-headedness in some people, or cause them to become confused. Be careful driving or operating machinery until you know how PEGASYS RBV affects you. If you drink alcohol, dizziness, drowsiness or light-headedness may be worse.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using PEGASYS RBV.

PEGASYS RBV helps most people with chronic hepatitis C but it may have 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.

Tell your doctor if you notice any of the following and they worry you:

- loss of appetite or weight loss
- nausea, vomiting, diarrhoea or stomach pain
- hair loss
- itching, rash or dry skin
- tingling or numbness of the hands or feet
- increased or decreased feeling or sensitivity, especially in the skin
- reaction at injection site
- flu-like symptoms such as fever, tiredness/fatigue, chills, muscle or joint pain or headache
- cough or sore throat
- flushing
- increased sweating, night sweats
- dry mouth, thirst
- blocked, runny or bleeding nose
- trouble concentrating or sleeping (insomnia)
- sleepiness, drowsiness
- feeling anxious, nervousness
- irritability (getting easily upset)
- depression (feeling low, feeling bad about yourself or feeling hopeless)
- aggressive behaviour
- impotence or decreased sexual drive

These are the more common side effects of PEGASYS RBV.

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

- severe chest pain or difficulty breathing
- fast or irregular heart beats
- severe changes in emotions or mood
- seeing, feeling or hearing things that are not there
- mental illness with strange or disturbing thoughts or moods
- feeling very depressed or having suicidal thoughts or attempt
- thoughts of causing serious harm to others
- signs of anaemia (e.g. tiredness, headaches, being short of breath when exercising, dizziness and looking pale)

- a red or purple rash that spreads; blisters on the skin, mouth or nose; red swollen, sore tongue; unexplained skin pain
- difficulty swallowing
- problems with your eyesight such as blurred or loss of vision, eye inflammation, dryness, or pain
- bleeding or bruising more easily than normal
- ringing or other persistent noise in the ears

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

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

After using PEGASYS RBV

Storage of PEGASYS RBV

The PEGASYS RBV pack should be stored in the refrigerator prior to use.

Once the PEGASYS RBV pack has been started, the COPEGUS film coated tablet pack may be removed and stored separately at below 30°C. COPEGUS film coated tablets do not need to be kept in the refrigerator.

Keep PEGASYS prefilled syringes in the fridge at 2 – 8°C. Do not freeze.

Keep PEGASYS RBV where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store COPEGUS tablets.

The top shelf of the refrigerator is a good place to store PEGASYS prefilled syringes.

Do not shake PEGASYS prefilled syringes.

Protect PEGASYS prefilled syringes from light.

Always keep PEGASYS in its carton and COPEGUS tablets in their bottle until it is time to take your medicine. If you take the tablets out of the bottle they may not keep well.

Do not store COPEGUS, or any other medicine, in a bathroom or near a sink.

Do not leave PEGASYS RBV in the car or on window sills. Heat and dampness can destroy some medicines.

PEGASYS prefilled syringes are for single use only. The prefilled syringe should be used once only and any remaining contents should be discarded with the needle.

Disposal

If your doctor tells you to stop using PEGASYS RBV, or the injection or tablets have passed their expiry dates, ask your pharmacist what to do with any injection or tablets that are left over.

If you use the PEGASYS injection at home, you must put the used syringes and needles in a container that will not let the needles stick through it. The full container should be disposed of following the directions given by your doctor or pharmacist. This will help protect you and other people from being accidentally pricked by a used needle. Being pricked by a used needle can pass diseases onto other people.

Product description

Availability

PEGASYS RBV combination comes in a pack containing a box of PEGASYS and a bottle of COPEGUS. PEGASYS RBV is available in the following pack sizes and strengths:

PEGASYS RBV Combination Therapy 4 x 135 mcg PFS/112 tablets

Each pack contains:

- 1 box of four PEGASYS 135 mcg prefilled syringes
- 1 bottle of 112 COPEGUS 200 mg film-coated tablets

PEGASYS RBV Combination Therapy 4 x 180mcg PFS/112 tablets

Each pack contains:

- 1 box of four PEGASYS 180 mcg prefilled syringe
- 1 bottle of 112 COPEGUS 200 mg film-coated tablets

PEGASYS RBV Combination Therapy 4 x 135mcg PFS/168 tablets

Each pack contains:

- 1 box of four PEGASYS 135 mcg prefilled syringes
- 1 bottle of 168 COPEGUS 200 mg film-coated tablets

PEGASYS RBV Combination Therapy 4 x 180mcg PFS/168 tablets

Each pack contains:

- 1 box of four PEGASYS 180 mcg prefilled syringes
- 1 bottle of 168 COPEGUS 200 mg film-coated tablets

What PEGASYS prefilled syringes look like

PEGASYS solution for injection is contained in a disposable glass syringe. The solution is clear and colourless to light yellow. A stainless steel needle is also supplied with the syringe to allow for subcutaneous injection.

Ingredients

Active ingredient - peginterferon alfa-2a

Inactive ingredients - each prefilled syringe also contains: sodium chloride, benzyl alcohol, sodium acetate, acetic acid, polysorbate 80, water for injections

What COPEGUS looks like

COPEGUS tablets are light pink to pink, flat, oval shaped, film-coated tablets with RIB and 200 engraved on one side and ROCHE in the other side.

Ingredients



Active ingredient - ribavirin 200 mg

Inactive ingredients - pregelatinised starch, sodium starch glycolate, microcrystalline cellulose, maize starch, magnesium stearate

The film coating contains - ethyl cellulose, hydroxypropyl methylcellulose, titanium dioxide, talc, iron oxide yellow, iron oxide red, triacetin

Distributor

PEGASYS RBV combination packs are distributed by:

Roche Products (New Zealand) Limited
PO Box 12492 Penrose
Auckland 1642
NEW ZEALAND

Telephone: (09) 635 1500

Toll Free: 0800 656 464

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