

Combination pack containing:

PEGASYS; pronounced *peg-ah-sis*, contains the active ingredient *peginterferon alfa-2a* and

COPEGUS; pronounced *co-peg-us*, contains the active ingredient *ribavirin*

Consumer Medicine Information

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 they expect it will have 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 consists of two products, an injection called PEGASYS and tablets called COPEGUS.

PEGASYS belongs to a group of medicines called interferons. PEGASYS is a long-acting interferon.

Interferons are proteins that modify the response of the body's immune system to help fight infections and severe diseases.

COPEGUS belongs to a group of medicines called antivirals.

The combination of PEGASYS and COPEGUS makes the treatment of chronic hepatitis C more effective.

The use of COPEGUS alone is not effective for the treatment of chronic hepatitis C.

Most people who get hepatitis C carry the virus in their blood for the rest of their lives, unless successfully treated. Most of these people will have some liver damage, but not all feel sick from 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.

Cirrhosis can also be caused by 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.

PEGASYS RBV treatment will not prevent a hepatitis C infected person from giving another person hepatitis C.

There are many different types of medicines used to treat chronic hepatitis C.

Your doctor, however, may have prescribed PEGASYS RBV for another purpose.

Ask your doctor if you have any questions 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 it

Do not use PEGASYS if:

- 1. you have had an allergic reaction to alfa interferons, ribavirin, *E. coli*-derived products, polyethylene glycol or any of the ingredients listed at the end of this leaflet**

Some symptoms of an allergic reaction include:

- hives or skin rash
- swelling of the face, lips or tongue
- wheezing or trouble breathing,
- faintness

- 2. you have autoimmune hepatitis**
- 3. you have decompensated cirrhosis (severe liver disease)**
- 4. you have severe heart problems or any previous heart conditions**
- 5. you are breast-feeding or plan to breast-feed**

It is not known whether PEGASYS or COPEGUS passes into the breast milk. Your doctor will discuss the risks and benefits of using PEGASYS RBV if you are breast-feeding

- 6. you are HIV co-infected with cirrhosis (Child-Pugh score ≥ 6)**

7. the package is torn or shows signs of tampering

8. the expiry date (EXP) printed on the pack has passed

If you use this medicine after the expiry date has passed it may not work as well.

Do not take COPEGUS if:

1. you are pregnant or your female partner is pregnant (if you are male).

COPEGUS may cause birth defects and/or death of an unborn baby. Extreme care must be taken to avoid pregnancy during treatment and for 6 months after completion of treatment. Effective contraception must be used during this time.

2. you have had an allergic reaction to ribavirin or any ingredients listed at the end of this leaflet.

Some symptoms of an allergic reaction include:

- hives or skin rash
- swelling of the face, lips or tongue
- wheezing or trouble breathing,
- faintness.

3. you have blood disorders including anaemia (low number of red blood cells), thalassaemia (mediterranean anaemia)

Before starting PEGASYS RBV, you should talk to your doctor about the possible benefits and possible side effects of treatment, to decide if PEGASYS RBV is right for you. While taking PEGASYS RBV you will need to see your doctor regularly for medical examinations and blood tests to make sure your treatment is working and to check for side effects.

Use in children

Do not give PEGASYS RBV to children under 18 years of age.

Safety and effectiveness in children have not been established.

PEGASYS injection solution contains benzyl alcohol and should not be given to babies from birth up to the age of 3 years.

Before you start to use it

Your doctor must know all about the following before you start to use PEGASYS RBV.

Tell your doctor if:

1. you or your female partner plan to become pregnant

Extreme care must be taken to avoid pregnancy. Your doctor will discuss the risks of PEGASYS RBV to the unborn baby.

2. you have ever had any of the following medical conditions, tell your doctor before you start taking PEGASYS RBV:

- current, or a history of depression (feeling low)
- history of injecting drug use or excessive alcohol use
- history of heart disease or previous heart attack
- autoimmune disease (where the body's immune system attacks the body's own cells), such as psoriasis (a skin disease)
- liver problems, other than hepatitis C
- kidney disorders
- blood disorders
- problems with the thyroid gland
- diabetes (high blood sugar levels)
- vision problems

3. you have HIV infection and are being treated with anti-HIV medicines

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 from a pharmacy, supermarket or healthfood shop.

You must tell your doctor if you are taking:

- theophylline, a medicine used to treat asthma, bronchitis and emphysema
- Sho-saiko-to, a Chinese herbal medicine also known as Xiao-Chai-Hu-Tang
- methadone, used to treat opioid dependence
- antacids, used to treat heartburn and indigestion
- stavudine, zidovudine or didanosine, medicines used to treat HIV/AIDS
- telbivudine, a medicine used to treat hepatitis B infection
- azathioprine, a medicine used to suppress the immune system.

Some medicines may interfere with PEGASYS RBV or may affect how well it works. You may need to use different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

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 carefully.

They may differ from the information contained in this leaflet.

PEGASYS

How much to inject

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

PEGASYS is usually administered as a 180 µg per 0.5 mL injection once a week for 24 to 72 weeks depending on the type of virus you are infected with and any previous treatment you have had.

If necessary, your dose may be changed by your doctor during therapy according to your response.

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

Do not exceed or change the dose recommended by your doctor.

How to inject it

PEGASYS is administered by subcutaneous injection. This means that 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 your doctor has directed you to use PEGASYS by subcutaneous injection at home, please follow the instructions below. Your doctor or nurse will also show you how to inject PEGASYS.

Directions for self-injection

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 or nurse if you require further instructions.

Remember that cleanliness is vital.

1. Preparing to self-inject

Before you begin:

- Wash your hands thoroughly
- Find a clean, comfortable area
- Gather all the medicinal supplies you will need:
 - An alcohol swab
 - One PEGASYS pre-filled syringe and unused injection needle
 - Some cotton wool
 - A sharps disposal bin
- Check the expiry date. Do not use PEGASYS after the expiry date shown on the pre-filled syringe label
- Check the liquid has no discolouration, cloudiness or particles. The liquid should look clear and colourless to slightly yellow
- Remove the PEGASYS pre-filled syringe from the fridge. Leave the syringe out of the fridge for 30 minutes before use; or gently warm the syringe in the palms of your hands for about 1 minute. Be careful not to shake the medication.

2. Preparing the syringe and needle

- Remove the protective cap from the end of the needle
- Remove the rubber cap from the end of the syringe
- Place the needle firmly on the end of the syringe

- If you notice any air bubbles in the syringe, hold the syringe with the needle facing upwards, lightly tap the syringe to bring the air bubbles to the top. You may need to gently push the plunger in slightly to push air out of the syringe
- Check the dose of medication your doctor has prescribed. You may need to gently push the plunger to push out some medication to get to the dose your doctor has prescribed
- If you need to put the syringe (with the needle attached) down, make sure the plastic guard covers the needle and place on a clean flat surface
- The syringe is now ready for use.

3. Choosing the injection site

- Choose an injection site in your stomach area or the top of your thigh
- Avoid your navel and waistline
- Change injection sites each time to prevent soreness in one spot
- Never inject into a red or swollen area
- Never inject PEGASYS into a vein or muscle.

4. Preparing the injection site

- Clean the injection site with an alcohol swab and let the skin dry (10 seconds)
- Remove the protective needle guard from the end of the syringe and hold the syringe with the needle facing upwards
- Grab your skin at the injection site firmly between your thumb and forefinger to elevate your skin.

5. Injecting the medication

- Hold the syringe at a 45° angle to your skin
- Insert the needle in one quick motion with the bevel (flat edge) facing upwards
- Slowly push the plunger all the way down
- Once all the liquid has left the syringe, pull out the needle at the same angle at which you put it in
- Do not recap the needle
- If you notice slight bleeding gently press over the injection site with some cotton wool.

6. Cleaning up after your injection

- Place the syringe and needle (as one) into the sharps container immediately after injection
- When the sharps container is full, take it to your clinic for correct disposal
- **Never** throw used needles and syringes in with your household rubbish
- Never re-use the syringe or needle. The needle and syringe are to be used **once** only.

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.

Please note that the needle supplied with the PEGASYS pre-filled syringe is for subcutaneous injection only and is **not** suitable for any other type of injection (e.g. 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 cause unusual tiredness or flu-like symptoms.

If you are working, you should inject PEGASYS at the beginning of the weekend. This will help to reduce the impact of side effects of PEGASYS on your ability to work.

COPEGUS

How much 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 of COPEGUS depends on your weight and genotype. This can range from 800 mg to 1200 mg once daily, to be taken in two divided doses (morning and evening).

COPEGUS is usually taken between 24 and 48 weeks, however your doctor may ask you to take COPEGUS for a different period of time.

How to take it

Swallow tablets whole with a glass of water. Do not chew the tablets

COPEGUS has a special coating to stop them dissolving until they have gone past the stomach.

Take COPEGUS at the same time every day.

When to take it

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

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

If you forget to take it

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

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

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

PEGASYS

If you realise you missed your injection within 2 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 3 to 5 days after your scheduled dose, you should inject your recommended dose as soon as you remember. Take your next doses at 5 day intervals until you return to your regularly scheduled day of the week.

If you realise you missed your injection 6 days after the scheduled dose, you should wait and inject your dose on the next day.

COPEGUS

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

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

How long to use PEGASYS RBV

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

If you become pregnant while taking PEGASYS RBV, you should immediately stop using it and tell your doctor.

If you use too much PEGASYS RBV (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at your

nearest hospital if you think that you or anyone else may have used too much PEGASYS RBV, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep telephone numbers for these places handy.

While you are using PEGASYS RBV

Things you must do

Use PEGASYS RBV exactly as your doctor has prescribed.

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.

Extreme care must be taken to avoid pregnancy during treatment and for 6 months after completion of treatment. The COPEGUS component may cause birth defects and/or death of an unborn baby. Female patients taking COPEGUS should use an effective contraceptive. Male patients taking COPEGUS and their female partners should each use an effective contraceptive.

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.

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

Things you must not do

Do not stop using PEGASYS RBV or change the 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 because a change in dose may be required.

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

Things to be careful of

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

PEGASYS RBV may cause dizziness, drowsiness or light-headedness in some people. 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.

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:

- flu-like symptoms such as fever, tiredness/fatigue, chills, muscle or joint pain and headache (these symptoms can usually be relieved by paracetamol)
- injection site reaction
- nausea (feeling sick)
- insomnia (difficulty sleeping)
- loss of appetite
- temporary hair loss (reversible after finishing treatment)
- diarrhoea
- itchiness or rash
- depression (feeling low, feeling bad about yourself or feeling hopeless)
- anxiety
- irritability (getting easily upset)
- aggressive behaviour
- weight loss

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

- signs of anaemia, such as tiredness, shortness of breath when exercising, headaches, dizziness and looking pale
- severe chest pain
- feeling very depressed or suicidal
- thoughts of causing serious harm to others
- persistent cough
- trouble breathing
- irregular heartbeat
- problems with your eyesight, such as blurred or loss of vision
- severe stomach pain
- unusual bleeding or bruising
- swelling of the face or tongue, hives, skin pain
- a red or purple skin rash that spreads
- blisters, particularly on your mouth, nose, or eyes

- fever or chills beginning a few weeks after treatment has started

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

Always keep this medicine in the carton until it is time to take it.

Store PEGASYS in the fridge at 2 to 8 °C. Do not freeze. You may store COPEGUS in a cool dry place where the temperature stays below 30 °C.

Do not shake PEGASYS.

Shaking can destroy PEGASYS so that it will not work.

Protect PEGASYS from light.

Do not leave PEGASYS RBV in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep PEGASYS RBV where young children cannot reach it.

The top shelf of the refrigerator is a good place to store this medicine.

PEGASYS pre-filled syringes are for single use only.

The pre-filled 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 product has passed its expiry date, ask your pharmacist what to do with any pre-filled syringes or tablets that are left over.

If you use PEGASYS RBV at home, you must throw away the syringes and needles in a sharps container.

This will help protect you and other people from accidental needle sticks. Being struck by a needle can pass diseases onto other people. Sharps containers are available from your pharmacist.

Product description

Availability

- A pack of four PEGASYS 135 µg per 0.5 mL prefilled syringes with COPEGUS 200 mg tablets (pack of 168).
- A pack of four PEGASYS 180 µg per 0.5 mL prefilled syringes with COPEGUS 200 mg tablets (pack of 112, 140 or 168).

What PEGASYS pre-filled syringes look like

PEGASYS injection solution 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 pre-filled 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 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 maize starch
- sodium starch glycolate
- starch soluble maize
- cellulose microcrystalline
- magnesium stearate

The film coating contains

- hydroxypropylcellulose
- purified talc
- titanium dioxide (E171)
- iron oxide yellow (E172)
- iron oxide red (E172)
- ethylcellulose
- glycerol triacetate

COPEGUS tablets are gluten free and lactose free.

Distributor

PEGASYS RBV is distributed by:

Roche Products Pty Limited
ABN 70 000 132 865



4-10 Inman Road
Dee Why NSW 2099

Customer enquires: 1 800 233 950

Please check with your pharmacist for
the latest Consumer Medicine
Information

Australian Registration Numbers:

180 µg/0.5mL plus 200 mg.
(AUST R 91843)

135 µg/0.5mL plus 200 mg
(AUST R 91842)

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