

Consumer Medicine Information

PEGASYS[®]

Peginterferon alfa-2a

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

What is in this leaflet

This leaflet answers some common questions about PEGASYS solution for injection.

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 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 is used for

PEGASYS contains the active ingredient peginterferon alfa-2a.

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.

PEGASYS is used to treat chronic hepatitis B and chronic hepatitis C, which are viral infections of the liver.

If these viral infections are 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 can prevent liver failure or liver cancer that is caused by hepatitis infection.

People who get hepatitis B or 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. In some people, the liver becomes badly damaged and scarred. This is called cirrhosis. Cirrhosis can cause the liver to stop working properly.

Chronic Hepatitis B: PEGASYS is usually used alone.

Chronic Hepatitis C: PEGASYS is best used for this treatment in combination with ribavirin (COPEGUS[®]) tablets.

If you receive the combination therapy, you should also read the COPEGUS Consumer Medicine Information leaflet before use.

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

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

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

PEGASYS is not addictive.

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

Before you use PEGASYS

When you must not use PEGASYS

Do not use PEGASYS if:

1. **you have had an allergic reaction to alpha interferons, 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**
2. **you have autoimmune hepatitis**
3. **you have decompensated cirrhosis (severe liver disease)**
4. **the intended patient is a child less than three years old**
PEGASYS contains benzyl alcohol which has been linked with a serious condition in infants up to three years old.
5. **the package is torn or shows signs of tampering**
6. **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.

PEGASYS, when used in combination with COPEGUS, must not be used by pregnant women.

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

Use in children

PEGASYS is not recommended for use in children and adolescents under the age of 18.

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

Before you start to use PEGASYS

Tell your doctor if:

1. **you or your female partner are pregnant or plan to become pregnant**
COPEGUS tablets, which may be used in combination with PEGASYS, 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.

Two forms of effective contraception used at the same time are recommended for both males and females while they are taking PEGASYS in combination with COPEGUS, and for 6 months after treatment has been completed.

It is not known whether PEGASYS is harmful to an unborn baby, when used by a pregnant woman. PEGASYS is not recommended for pregnant women.

Effective contraception is recommended for females while they are taking PEGASYS.

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

It is not known whether PEGASYS or COPEGUS passes into the breast milk. PEGASYS, alone or in combination with COPEGUS, is not recommended for breast-feeding women. If you are breast-feeding, your doctor will discuss with you the risks and benefits of discontinuing breast-feeding or delaying PEGASYS treatment.

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.

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.

You must tell your doctor if you are taking:

- theophylline (Nuelin[®]), a medicine used to treat asthma, bronchitis and emphysema, as your dose may need to be changed
- telbivudine (Sebivo[®]), a medicine used to treat chronic hepatitis B
- methadone, a medicine used to treat opioid dependence

If you are using PEGASYS in combination with COPEGUS, you must tell your doctor if you are taking:

- didanosine (Videx[®]), zidovudine (Retrovir[®], Combivir[®]), stavudine (Zerit[®]), medicines used to treat HIV (Human Immunodeficiency Virus), the virus which causes AIDS
- azathioprine (Azamun[®], Imuran[®]), a medicine used to suppress the immune system

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

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

How to use PEGASYS

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 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.

When given in combination with COPEGUS tablets, for hepatitis C, PEGASYS is usually administered as a 180 mcg injection once a week for between 24 and 72 weeks.

When PEGASYS is used on its own, for hepatitis B or hepatitis C, the usual dose of PEGASYS is a 180 mcg injection once a week for 48 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.

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.

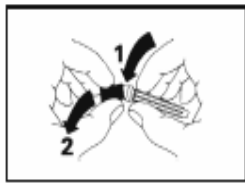
Remember that cleanliness is vital.

I. Before subcutaneous injection

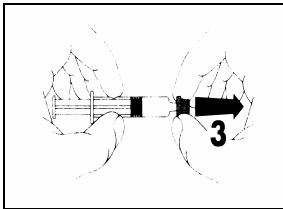
- Check the expiry date. Do not use PEGASYS after the expiry date shown on the prefilled syringe label.
- Check the dose that you have been prescribed.
- Check the liquid has no discolouration, cloudiness or particles. The liquid should look clear and colourless to slightly yellow.
- To allow the solution 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

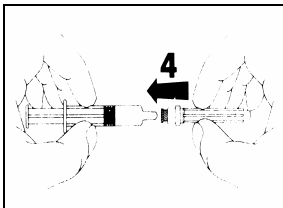
- A. Take the sealed needle in both hands and snap the cap backwards. Remove the cap. *Do not* remove the plastic needle shield.



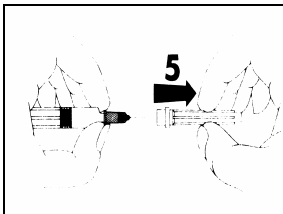
B. Remove the rubber tip from the syringe. Do not touch the tip of the syringe.



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.

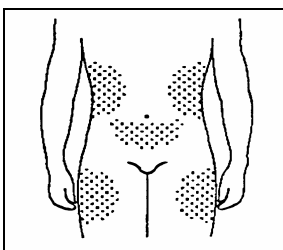


To remove air bubbles from the syringe, hold the syringe with the needle pointing up. Tap the syringe gently to bring the bubbles to the top. Push up the plunger slowly to the correct dose. Replace the needle guard and place the syringe on a clean flat surface.

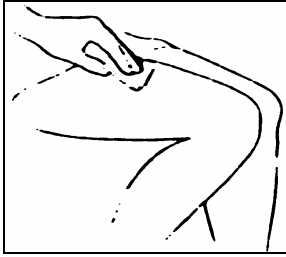
The syringe is now ready for use.

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.

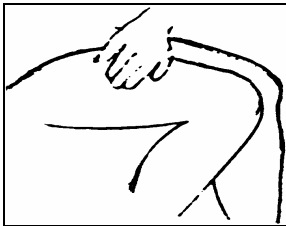


- F. Remove an alcohol swab from one packet and clean and disinfect the site by wiping with the swab.

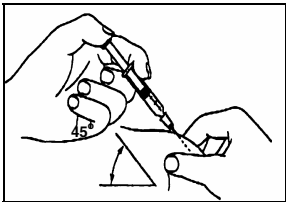


- G. Remove the alcohol swab from the site. Allow the injection site to dry for 10 seconds.

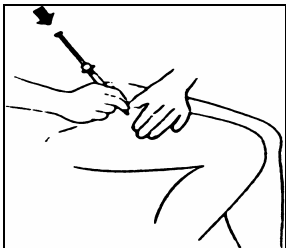
- H. Grasp the skin firmly between the thumb and forefingers (without squeezing) to elevate the subcutaneous tissue.



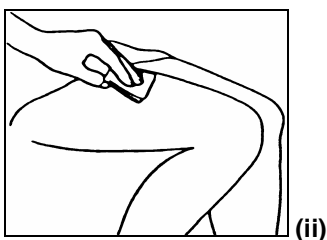
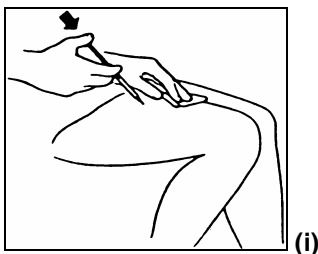
- I. Insert the needle into the grasped skin at an angle of 45° to 90°.



- 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 long to use PEGASYS

Continue using PEGASYS until your doctor tells you to stop.

Your doctor will determine when your treatment should be stopped.

If you forget to use PEGASYS

If you realise you missed your 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 injection 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.

If you use too much PEGASYS (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 that you or anyone else may have used too much PEGASYS, 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

Things you must do

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

Tell your doctor if you become pregnant while using PEGASYS.

If you are taking COPEGUS in combination with PEGASYS extreme care must be taken to avoid pregnancy during treatment and for 6 months after treatment.

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

Female patients taking PEGASYS in combination with COPEGUS, or PEGASYS on its own, should use two forms of effective contraception at the same time.

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

Females taking COPEGUS, and the female partners of males taking COPEGUS, must have a pregnancy test each month during treatment and for 6 months after treatment with COPEGUS has stopped.

Tell your doctor if, for any reason, you have not used PEGASYS 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.

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

Things you must not do

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

Do not use PEGASYS 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 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 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.

PEGASYS helps most people with chronic hepatitis B or 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 alone or when given together with COPEGUS.

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 skin 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

Storage

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

If you take the prefilled syringes out of the pack they may not keep well.

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

Do not shake PEGASYS.

Protect PEGASYS prefilled syringes from light.

Keep PEGASYS where young children cannot reach it.

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

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, or the prefilled syringe has passed its expiry date, ask your pharmacist what to do with any prefilled syringes that are left over.

If you use PEGASYS 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 prefilled syringes are available in packs of four in the following strengths:

- 135 mcg in 0.5 mL solution
- 180 mcg in 0.5 mL solution

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

Distributor

PEGASYS prefilled syringes 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

This leaflet was prepared on 7 August 2009