

# PEGASYS<sup>®</sup> Pre-Filled Pen

Consumer Medication Information Leaflet (RiMUP)

Peginterferon alfa-2a (135mcg/0.5ml and 180mcg/0.5ml)

## What is in this leaflet

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## 1. What PEGASYS Pre-Filled Pen is used for

Chronic Hepatitis B and/or Chronic Hepatitis C.

## 2. How PEGASYS Pre-Filled Pen works

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.

## 3. Before you use PEGASYS Pre-Filled Pen

### *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 passes into the breast milk. Your doctor will discuss the risks and benefits of

using PEGASYS if you are breast-feeding

**6. You are HIV co-infected with cirrhosis (Child-Pugh score of 6 or more)**

**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.

### *Use in children*

The safety and effectiveness in children under 18 years of age 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 take PEGASYS*

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

#### **Tell your doctor if:**

**1. You or your partner plan to become pregnant**

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

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

- current, or a history of depression (feeling nervous), mental disorder
- 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 (anaemia)
- 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.**

### *Taking other medicines*

**Tell your doctor if you are taking any other medicines including any that you have bought from a pharmacy.**

You must tell your doctor if you are taking:

- theophylline, a medicine used to treat asthma, bronchitis and emphysema
- methadone, used to treat opioid dependence
- 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 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.

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

## 4. How to use PEGASYS Pre-Filled Pen

**Follow all directions given to you by your doctor carefully.**

They may differ from the information contained in this leaflet.

### *How to take PEGASYS*

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

PEGASYS is usually administered as a 180 mcg per 0.5 mL injection once a week for 16 to 48 weeks depending on the type of virus you are infected with and any previous treatment you have had. It may also be used together with ribavirin between 800 – 1200mg depending on the type of virus you are infected with.

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*

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

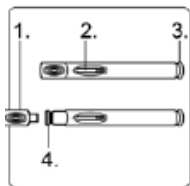
The PEGASYS Pre-Filled Pen is for single use only and is then to be discarded.

### Do not:

- attempt to open or dismantle the pre-filled pen.
- expose to excessive forces or shock
- use through clothing covering the skin
- use if pre-filled pen appears to be damaged
- use if medicine is cloudy, hazy, discoloured or has particles in it
- shake
- remove the cap until you are ready to inject
- try to re-use the pre-filled pen
- manipulate the needle-shield before, during or after use, as this is a safety device.

## PEGASYS Pre-Filled Pen components:

1. cap
2. viewing window
3. activation button
4. needle-shield



### What you will need:

- Gather all the medical supplies you will need:
  - one PEGASYS Pre-Filled Pen
  - two alcohol pads
  - a sharps disposal bin
- Find a clean, comfortable area.

### How to proceed:

1. visually check the pre-filled pen
2. allow the pre-filled pen to adjust to room temperature
3. clean your hands

4. choose and prepare an injection site
5. remove cap
6. place pre-filled pen on injection site
7. give injection
8. dispose of pre-filled pen

### 1. Visually check the pre-filled pen

Take the PEGASYS Pre-Filled Pen from the fridge. Visually examine the pre-filled pen, as well as the medicine through the viewing window. Do not shake. If there is foam on the medicine, put the pre-filled pen back in the refrigerator for use another time, and take a new pre-filled pen from the fridge. Dispose of the pre-filled pen (see point 8 below) and use another if:

- the medicine is cloudy
- the medicine contains particles
- the medicine is any colour beside colourless to light yellow
- any part of the pre-filled pen appears to be damaged
- the expiry date has passed. You will find the expiry date on the box as well as on the label of the pre-filled pen itself

Keep the protective cap on the pre-filled pen until step 5.

### 2. Allow the pre-filled pen to adjust to room temperature

Leave the pre-filled pen out of the fridge for 30 minutes before use. Be careful not to shake the medication.

### 3. Clean your hands

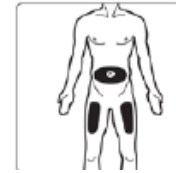
Wash your hands well using soap and water.



Remember that cleanliness is vital.

### 4. Choose and prepare an injection site

Pick a place on your stomach or thigh (see the picture). Avoid your navel and waistline. You should use a different place each time you give yourself an injection. Never inject PEGASYS into a red or swollen area. Never inject it into a vein or muscle. To minimize discomfort from the injection, you may want to gently tap the area where you plan to give yourself an injection.



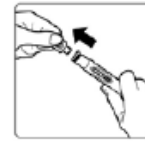
Clean the area using an alcohol pad. Let the skin dry for 10 seconds. Be sure not to touch the cleaned area prior to injection.



### 5. Remove the cap

Hold the pre-filled pen firmly with one hand and pull off the protective cap with the other hand.

NOTE: The cap contains a loose-fitting metal tube. Once the cap is removed, the pre-filled pen should be used immediately. If it is not used within 5 minutes, the pre-filled pen should be disposed of and a new pre-filled pen should be used. Never re-attach the protective cap after removal.



### 6. Place the pre-filled pen on the injection site

Hold the pre-filled pen comfortably in your hand. Pinch and hold a fold of skin at the injection site with your free hand, such that the needle-shield can rest on the skin-fold firmly and safely.



Hold the pre-filled pen straight up and place down at a right angle (90°) on the injection site.

NOTE: Do not yet attempt to press the activation button.

Press the pre-filled pen firmly against the skin until the needle-shield is completely pushed in.

The pre-filled pen is now unlocked and ready for injection.



### 7. Give injection

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While holding the pre-filled pen firmly in place, press the activation button with your thumb and immediately release the button.

- A "click" sound will indicate the start of the injection.
- The red indicator will move down in the viewing window as the injection is ongoing.



Keep the pre-filled pen pressed on the skin for 10 seconds for injection to complete.

- You should hear a second click as the activation button pops back up.
- The viewing window will now be completely red.



Make sure you take your thumb off the activation button. Lift the pre-filled pen straight up (90° angle).

- The needle-shield will automatically move out and lock to prevent needle injuries.



## CAUTION:

If the viewing window is not completely filled by the red indicator:

- the needle-shield may not have locked.

Do not touch the tip of the pre-filled pen, since needlestick injuries may occur.

- you may not have received an entire dose.

Do not try to use the pre-filled pen again. Do not repeat the injection.

Contact your healthcare provider.

After the injection:

Wipe the injection site with another alcohol pad. If you notice slight bleeding gently press over the injection site with some cotton wool.



## 8. Dispose of pre-filled pen

Recapping is not required.

Place used pre-filled pen and cap in a puncture-proof disposable container that is available through your pharmacy or healthcare provider (sharps container). Store the sharps container out of reach of children at all times.

Dispose of the full container as instructed by your healthcare provider or pharmacist.

Never throw the used pre-filled pen in with your household rubbish.



Please note that the PEGASYS Pre-Filled Pen is for subcutaneous injection only and is not suitable for any other type of injection (e.g. intramuscular injection).

## When to take PEGASYS

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.

## How long to take PEGASYS

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

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

## If you forget to take PEGASYS

**If you realise you missed your injection please contact your doctor.**

## If you take too much (overdose)

**If you think that you may have used too much PEGASYS, immediately telephone your doctor for advice or go to Accident and Emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.**

## 5. While you are using PEGASYS Pre-Filled Pen

### Things you must do

**Use PEGASYS exactly as your doctor has prescribed. 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.**

Extreme care must be taken to avoid pregnancy in female patients or in partners of male patients during treatment. Women of childbearing potential and their partners must use 2 forms of effective contraception simultaneously, during treatment and for 6 months after completion of treatment.

**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.**

### 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 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 while driving or operating machinery until you know how PEGASYS affects you.**

PEGASYS may cause dizziness, drowsiness or light-headedness in some people. If you drink alcohol, dizziness, drowsiness or light-headedness may be worse.

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## 6. Side effects

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

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 sad/down, feeling bad about yourself or feeling hopeless)
  - anxiety
  - irritability (getting easily upset)
  - aggressive behaviour
  - weight loss
  - 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.**

You may report any side effects or adverse drug reactions to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers → Reporting).

## 7. Storage and Disposal of PEGASYS Pre-Filled Pen

### 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.**

**Do not shake PEGASYS.**

Shaking can destroy PEGASYS and it will not work.

**Protect PEGASYS from light.**

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

Heat and dampness can destroy some medicines.

### Disposal

**Throw away the pre-filled pens in a sharps container.**

Sharps containers are available from your doctor or pharmacist.

## 8. Product Description

### *What PEGASYS Pre-Filled Pen looks like*

PEGASYS solution for subcutaneous injection is contained in a disposable pre-filled pen. The solution is clear and colourless to light yellow.

### *Ingredients*

**Active ingredient** – pegylated interferon alfa-2a

### **Inactive ingredients -**

Each pre-filled pen also contains:

- sodium chloride
- benzyl alcohol
- sodium acetate
- acetic acid
- polysorbate 80
- water for injections

MAL number

PEGASYS Pre-Filled Pen 135µg/0.5ml:  
MALXXXXXXXXAR

PEGASYS Pre-Filled Pen 180µg/0.5ml:  
MALXXXXXXXXAR

## 9. Manufacturer and Product Registration Holder

**Made for Hoffman-La Roche Ltd., Basel, Switzerland by Catalent Belgium SA, Brussels, Belgium.**

### **Product Registration Holder**

Roche (M) Sdn. Bhd.  
Level 21, The Pinnacle,  
Persiaran Lagoon, Bandar Sunway,  
47500 Subang Jaya,  
Selangor, Malaysia.

### **Date of Revision**

17/07/14  
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13.0)

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