

## Drug Information Sheet (“Kusuri-no-Shiori”) For Injectables

Submitted : 03/2005

Information is based on approvals granted in Japan. In some cases, the approved details may vary in countries other than Japan.

<b>DESCRIPTION</b>	<b>Brand Name:</b> PEGINTRON for Subcutaneous Injection 150 µg/0.5 mL <b>Generic Name:</b> Peginterferon alfa-2b	<b>Application:</b> Identification Code : 620002420	<b>Photo</b>
<b>THIS INJECTION WORKS FOR</b>	• Used in combination with Rebetol. It works by decreasing the amount of hepatitis C virus (HCV) in the body. It helps eliminating virus from your body; that supports the liver functions recovery.		
<b>BEFORE RECEIVING INJECTION</b>	<ul style="list-style-type: none"> <li>• <b>Tell your Health Care Provider :</b> <ul style="list-style-type: none"> <li>- If you ever had any unusual or allergic reaction to any medicines/injections.</li> <li>- If you take Shosaikoto (Sho-saiko-to, herbal preparation)</li> <li>- Patient with: autoimmune hepatitis, allergic disposition, badly deteriorated liver/kidney function, hypertension, diabetes, autoimmune diseases, convulsions.</li> <li>- If you ever had: heart disease, mental illness, abnormality in thyroid function.</li> </ul> </li> <li>• <b>Dosage schedule :</b> 48 weeks</li> <li>• <b>Administration :</b> Normally, subcutaneous injection. Once a week.</li> <li>• <b>Others:</b> Make sure your doctor knows if you or your partner is possibly/already pregnant or breastfeeding during the dosage and within 6 month afterward.</li> </ul>		
<b>SIDE EFFECT(s)</b>	<ul style="list-style-type: none"> <li>• <b>An injection may cause some unwanted effects.</b></li> <li>◎ <b>Check with your doctor, pharmacist or other healthcare professional immediately if any of the following side effects occur:</b></li> <li><u>&lt;Interstitial pneumonia&gt; Fever, dry cough, breathing difficulty, headache, generalized fatigability.</u></li> <li><u>&lt;Suicide attempts&gt; Thinking about hurting or killing yourself.</u></li> <li><u>&lt;Pulmonary fibrosis&gt; Breathing difficulty upon exertion, dry cough, fever, headache, generalized fatigability.</u></li> <li><u>&lt;Pulmonary edema&gt; Palpitation upon exertion, breathing difficulty (relieved when sitting upright), nausea, vomiting, frequent pulse, pink, foamy phlegm,</u></li> <li><u>&lt;Depression&gt; Depressed and listless situation (depressed, having no energy, generalized fatigability, loss of appetite, loss of sleep).</u></li> <li><u>&lt;Anemia&gt; Palpitation when going upstairs or uphill, shortness of breath, headache, dull headache, dizziness, ear ringing, or generalized fatigability.</u></li> </ul>		

**<Agranulocytosis, Leukocytopenia, Granulocytopenia>** Sore throat, headache, muscle pain, feeling of serious illness, high fever with chills. Likely to cause pneumonia or sepsis.

**<Thrombocytopenia>** Bleeding from the nose, gums, increased menstrual bleeding, bleeding under skin seen in limbs (mixture of bleeding point under 1mm  $\phi$  and bleeding spot between 3-5mm  $\phi$ ).

**<Aplastic anemia>** Symptoms of anemia, bleeding tendency (bleeding from nose/gum, purpura), fever.

**<Pancytopenia>** Generalized fatigability, dull headache, headache, dizziness, ear ringing, palpitation when going upstairs or uphill, palpitation, bleeding from nose/gum, subcutaneous bleeding.

**<Impaired consciousness>** Faint consciousness, impaired mind, judgment failure.

**<Convulsion>** Muscle's spasmodically contracting, **<Disorientation>** Unable to

recognize time, place or name, **<Delirium>** Conscious disorder along with

hallucination or illusion, **<Confusion>** Disoriented, unable to recognize time or

place, delusions, **<Hallucination>** To see or hear something that is not really there,

**<Delusion>** Groundless belief in something untrue, **<Stupor>** Almost no reaction,

and only reacts when talked loudly, shaken by the shoulder repeatedly, stung by a needle or pinched.

**<Aggressive behavior>** Aggressive, sometimes attackable attitude or speech against people or patient itself, **<Schizophrenic symptoms>**

**<Dementia-like symptoms (typical in aged patients)>** A condition which interfere

with normal daily life activities where the patient shows memory loss, impaired

abstraction and planning, language and comprehension disturbances, poor

judgment, **<Excitability>** Concentration loss, uneasiness, shaky limbs, loss of

sleep, **<Syncope>** Fainting, **<Manic state>** Elation, excitable, hyperactivities,

**<Deafness>** Unable to hear voices or sounds,

**< Autoimmune disorder>**

[Thyroid function abnormalities] It has hyperthyroidism and hypothyroidism.

- In Hyperthyroidism: Sweat, weight loss, frequent pulse, tremor, loss of sleep, swollen thyroid, bulging eyes.

- In Hypothyroidism: Dull, enervation, slow in conversation or in motion, intolerance to cold, swollen face.

[Hepatitis] Loss of appetite, generalized fatigability, nausea, vomiting, jaundice.

[Hemolytic anemia] Anemia symptoms (tiredness, generalized fatigability,

palpitation, shortness of breath, headache, dull headache, pale face, ear ringing,

dizziness, loss of appetite), jaundice, fever, reddened urine, [Idiopathic

thrombocytopenic purpura]

[Ulcerative colitis] Fever, stomachache, diarrhea, mucous bloody stool,

[Rheumatoid arthritis] Weight loss, fatigability, fever, swelling, various types of

symmetrical and multiple rheumatoid causing movement disorder, morning hour

hand stiffness.

[Psoriasis] Dry/flaky/peeling skin, itch.

[Recurrence/occurrence of diabetes mellitus] Dry mouth, excess intake of fluid, increase of urine output, fatigue, weight loss.

< **Diabetes mellitus** > Dry mouth, excess intake of fluid, increase of urine output, fatigue, weight loss.

<**Serious hepatic disorder**> Generalized fatigability, loss of appetite, nausea, vomiting, jaundice.

<**Serious renal impairment (e.g. acute renal failure)**> Acute renal failure: decrease of urine output, swelling, headache, loss of appetite, thirst. Chronic renal failure: generalized fatigability, dry skin, loss of appetite, swelling, high blood pressure, heart failure, anemia, muscle convulsion, taste disorder, thirst.

<**Shock**> Pale face, cold sweat, dizziness on standing up, dizziness, shortness of breath, becoming unconscious.

<**Cardiomyopathy**> Chest pain, palpitation, shortness of breath, <**Cardiac failure**> Decrease of cardiac function. Left ventricular cardiac failure will cause shortness of breath, cough, breathing difficulty, easy breathing in upright position. Right ventricular cardiac failure will cause body swelling, pleural effusion, abdominal dropsy, varicosis, <**Myocardial infarction**> Acutely pressured feeling in the chest, anginal pain, cold sweat, fear of death, < **Angina pectoris**> Chest pain, pressured constricted feelings, cold sweat.

<**Arrhythmia**> Palpitation, discomfort/pressured feeling of the chest, chest pain, dizziness, faint, respiratory distress.

<**Gastrointestinal hemorrhage (melena, blood in stools)**>, <**Peptic/small-intestine ulcer**> Pain in the pit of the stomach, tenderness, heartburn, belching, nausea, vomiting, blood vomiting, blood discharge from the bowels, <**Ischemic colitis**> Rapid stomachache, blood discharge from the bowels, fever, nausea, vomiting.

<**Dyspnea**> Breathing difficulty, <**Increased sputum**>

<**Cerebral hemorrhage**> Headache, nausea, vomiting, conscious disorder, hemiplegia (paralysis on one side of the body).

<**Cerebral infarction**> Numbness or paralysis of the face, arm or leg, usually confined to one side of the body. Headache, speech disorder, failing eyesight, conscious disorder (coma).

<**Sepsis**> Chills, rapidly rising high fever with chills, frequent pulse, breathing difficulty, muscle/joint pain, decline of blood pressure, <**Retinopathy**> Failing eyesight.

<**Oculomucocutaneous syndrome (Stevens-Johnson syndrome)**> Fever, loss of appetite, generalized fatigability, red rash with dropsical swelling in the center, bloodshot eyes, rash in the oral mucous membrane with pain.

<**Toxic epidermal necrolysis (Lyell syndrome)**> Red spots, blisters appearing in vast area, blisters are easily broken (Nicholsky phenomenon), erosion (red skin) with pain. Fever, loss of appetite, generalized fatigability, arthritis, and occasionally conscious disorder.

<**Rhabdomyolysis**> Pain of the limb muscle, stiffness, numbness, lassitude, generalized fatigability, red urine.

<Pancreatitis> Severe pain in the upper abdomen or back pain, fever, nausea, vomiting, loss of appetite.

◆ **Check with your doctor, pharmacist or other healthcare professional early if any of the following side effects occur:**

<Fever>, <Generalized malaise>, <Rigors> Cold chills, <Flu-like symptoms>

<Headache>,<Insomnia>, <Dizziness>, <Irritability>,<Dysphoria>, <Tinnitus>

<Disturbance in attention> Loss of attentiveness/concentration, <Cystitis>, <Pollakiuria>

<Chest pain>, <Hypertension> Headache, dull headache, dizziness, stiff shoulders, palpitation, <Flushing> glow.

<Tachycardia> Rapid pulse (beating 100 times/min. or more), accompanied by pounding heartbeat and discomfort in the chest.

<Edema (limbs/face)> Swelling.

<Anorexia>, <Nausea • vomiting>, <Abdominal pain>, <Stomach discomfort>, <Diarrhea>, <Thirst>

<Stomatitis> Red painful tumor with white center appearing inside the mouth,

<Cheilitis> Lips swelling or turning red. <Dyspepsia>, <Pulpitis>,<Periodontitis • Gingivitis> Swelling or bleeding from gum.

<Toothache>, <Glossitis> Rough tongue, tongue stinging, <Abdominal discomfort>

<Feeling of abdominal bloating> Bloating feeling of the stomach, <Constipation>

<Alopecia>, <Pruritus> Itching, <Rash> Skin pimples, <Tinea> Skin infection due to trichophyton seen mostly in the feet (athlete's foot). Bottom of the feet is thickened and may scale with itch, <Erythema> Red rash on skin.

<Eczema> Map-like borderless-shaped itching rash, <Dermatitis> Inflammation of skin surface (blisters, borderless redness, dropsical swelling, bleeding, itchy, scabbed skin), <Dry skin>

<Arthralgia>, <Myalgia>, <Paraesthesia> Abnormal sensory (tingling/itchy feeling)

<Muscle cramp>, <Pain in limbs>, <Back/Low back pain>

<Upper respiratory tract infection> Red swollen throat, <Coughing>, <Epistaxis>, < Rhinorrhea > Runny nose.

<Retina hemorrhage> Failing eyesight, <Retinal exudates>, <Keratitis> Irritation in the eyes, sensitive to light, teary eyes, <Conjunctivitis> Itchy/painful eyes, eye mucus, sensitive to light, <Eye pain>

<Blurred vision > Vision disturbed, unable to see well or complete loss of vision.

<Asthenopia> Eye tiredness, pain in the eyes, headache, stiff shoulders.

<Injection site reaction (erythema, pruritus, bloating, rash, pain, inflammation, induration, bleeding, dermatitis, feeling hot)>

<Infection>, <Taste alteration> Taste diminished, taste loss, changed taste (Not tasting properly, Tasting differently from the original).

<Weight loss>, <Fatigue>, <Sweating increased> Sweating increase.

◇ **Other side effects not listed above:**

	<ul style="list-style-type: none"> <li>• If you notice any other unusual symptoms, check with your doctor, pharmacist or other healthcare professional.</li> </ul>		
<p><b>PRECAUTIONS AFTER INJECTION</b></p>	<p>Do not rub the injection site.</p> <p>« Patient's family: »</p> <p>Please be attentive to the patient's condition through the daily life. Changes in his/her mood or behavior may be a sign of adverse reaction to the medicine; you should alert the doctor when noticed: declined facial expression, less talkative, depressed.</p> <p>Those changes do not necessarily happen to everyone.</p>		
<p><b>OTHERS</b></p>			
<p><b>INFORMATION GIVEN DATE</b></p>		<p><b>INFORMTION PROVIDED BY</b></p>	

This leaflet contains only basic information.  
For more information, ask your physician and/or Pharmacist.