Package leaflet: Information for the user

Sunitinib Mylan 12,5 mg, harde capsules
Sunitinib Mylan 25 mg, harde capsules
Sunitinib Mylan 37,5 mg, harde capsules
Sunitinib Mylan 50 mg, harde capsules
sunitinib

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What <Product name> is and what it is used for
2. What you need to know before you take <Product name>
3. How to take <Product name>
4. Possible side effects
5. How to store <Product name>
6. Contents of the pack and other information

1. What <Product name> is and what it is used for

<Product name> contains the active substance sunitinib, which is a protein kinase inhibitor. It is used to treat cancer by preventing the activity of a special group of proteins which are known to be involved in the growth and spread of cancer cells.

<Product name> is used to treat adults with the following types of cancer:

- Gastrointestinal stromal tumour (GIST), a type of cancer of the stomach and bowel, where imatinib (another anticancer medicine) no longer works or you cannot take imatinib.
- Metastatic renal cell carcinoma (MRCC), a type of kidney cancer that has spread to other parts of the body.
- Pancreatic neuroendocrine tumours (pNET) (tumours of the hormone-producing cells in the pancreas) that have progressed or cannot be removed with surgery.

If you have any questions about how <Product name> works or why this medicine has been prescribed for you, ask your doctor.

2. What you need to know before you take <Product name>

Do not take <Product name>:
- if you are allergic to sunitinib or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking <Product name>:

- **If you have high blood pressure.** <Product name> can raise blood pressure. Your doctor may check your blood pressure during treatment with <Product name>, and you may be treated with medicines to reduce the blood pressure, if needed.

- **If you have or have had blood disease, bleeding problems, or bruising**. Treatment with <Product name> may lead to a higher risk of bleeding or lead to changes in the number of certain cells in the blood which may lead to anaemia or affect the ability of your blood to clot. If you are taking warfarin or acenocoumarole, medicines which thin the blood to prevent blood clots, there may be a greater risk of bleeding. Tell your doctor if you have any bleeding while on treatment with <Product name>.

- **If you have heart problems.** <Product name> can cause heart problems. Tell your doctor if you feel very tired, are short of breath, or have swollen feet and ankles.

- **If you have abnormal heart rhythm changes.** <Product name> can cause abnormality of your heart rhythm. Your doctor may obtain electrocardiograms to evaluate for these problems during your treatment with <Product name>. Tell your doctor if you feel dizzy, faint, or have abnormal heartbeats while taking <Product name>.

- **If you have had a recent problem with blood clots in your veins and/or arteries (types of blood vessels), including stroke, heart attack, embolism, or thrombosis.** Call your doctor immediately if you get symptoms such as chest pain or pressure, pain in your arms, back, neck or jaw, shortness of breath, numbness or weakness on 1 side of your body, trouble talking, headache, or dizziness while on treatment with <Product name>.

- **If you have or have had an aneurysm (enlargement and weakening of a blood vessel wall) or a tear in a blood vessel wall.**

- **If you have or have had damage to the smallest blood vessels known as thrombotic microangiopathy (TMA).** Tell your doctor if you develop fever, fatigue, tiredness, bruising, bleeding, swelling, confusion, vision loss and seizures.

- **If you have thyroid glands problems.** <Product name> can cause thyroid gland problems. Tell your doctor if you get tired more easily, generally feel colder than other people or your voice deepens whilst taking <Product name>. Your thyroid function should be checked before you take <Product name> and regularly while you are taking it. If your thyroid gland is not producing enough thyroid hormone, you may be treated with thyroid hormone replacement.

- **If you have or have had pancreatic or gallbladder disorders.** Tell your doctor if you develop any of the following signs and symptoms: pain in the area of the stomach (upper abdomen), nausea, vomiting, and fever. These may be caused by inflammation of the pancreas or gallbladder.

- **If you have or have had liver problems.** Tell your doctor if you develop any of the following signs and symptoms of liver problems during <Product name> treatment: itching, yellow eyes or skin, dark urine, and pain or discomfort in the right upper stomach area. Your doctor should do blood tests to check your liver function before and during treatment with <Product name>, and as clinically indicated.

- **If you have or have had kidney problems.** Your doctor will monitor your kidney function.

- **If you are going to have surgery or if you had an operation recently.** <Product name> may affect the way your wounds heal. You will usually be taken off <Product name> if you are having an operation. Your doctor will decide when to start <Product name> again.

- **You may be advised to have a dental check-up before you start treatment with <Product name>.**
    - If you have or have had pain in the mouth, teeth and/or jaw, swelling or sores inside the mouth, numbness or a feeling of heaviness in the jaw, or loosening of a tooth tell your doctor and dentist immediately.
    - If you need to undergo an invasive dental treatment or dental surgery, tell your dentist that you are being treated with <Product name> in particular when you are also receiving or

have received intravenous bisphosphonates. Bisphosphonates are medicines used to prevent bone complications that may have been given for another medical condition.

- **If you have or have had skin and subcutaneous tissue disorders.** While you are on this medicine "pyoderma gangrenosum" (painful skin ulceration) or “necrotising fasciitis” (rapidly spreading infection of the skin/soft tissue that may be life-threatening) may occur. Contact your doctor immediately if symptoms of infection occur around a skin injury, including fever, pain, redness, swelling, or drainage of pus or blood. This event is generally reversible after sunitinib discontinuation. Severe skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme) have been reported with the use of sunitinib, appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk. The rash may progress to widespread blistering or peeling of the skin and may be life-threatening. If you develop a rash or these skin symptoms, seek immediate advice from a doctor.

- **If you have or have had seizures.** Notify your doctor as soon as possible if you have high blood pressure, headache, or loss of sight.

- **If you have diabetes.** Blood sugar levels in diabetic patients should be checked regularly in order to assess if antidiabetic medicine’s dosage needs to be adjusted to minimise the risk of low blood sugar. Notify your doctor as soon as possible if you experience any signs and symptoms of low blood sugar (fatigue, palpitations, sweating, hunger and loss of consciousness).

Children and adolescents

<Product name> is not recommended for patients aged under 18.

Other medicines and <Product name>

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines can affect the levels of <Product name> in your body. You should inform your doctor if you are taking medicines containing the following active substances:

- ketoconazole, itraconazole – used to treat fungal infections
- erythromycin, clarithromycin, rifampicin – used to treat infections
- ritonavir –used to treat HIV
- dexamethasone – a corticosteroid used for various conditions (such as allergic/breathing disorders or skin diseases)
- phenytoin, carbamazepine, phenobarbital – used to treat epilepsy and other neurological conditions
- herbal preparations containing St. John’s Wort (Hypericum perforatum) – used to treat depression and anxiety

<Product name> with food and drink
You should avoid drinking grapefruit juice while on treatment with <Product name>.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you might get pregnant, you should use a reliable method of contraception during treatment with <Product name>.

If you are breast-feeding, tell your doctor. You should not breast-feed during treatment with <Product name>.

Driving and using machines

If you experience dizziness or you feel unusually tired, take special care when driving or using machines.

<Product name> contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

3. How to take <Product name>

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will prescribe a dose that is right for you, depending on the type of cancer to be treated. If you are being treated for
- GIST or MRCC: the usual dose is 50 mg once daily taken for 28 days (4 weeks), followed by 14 days (2 weeks) of rest (no medicine), in 6-week cycles.
- pNET: the usual dose is 37.5 mg once daily without a rest period.

Your doctor will determine the appropriate dose you need to take, as well as if and when you need to stop treatment with <Product name>.

<Product name> can be taken with or without food.

If you take more <Product name> than you should
If you have accidentally taken too many capsules, talk to your doctor straight away. You may require medical attention.

If you forget to take <Product name>
Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

You must immediately contact your doctor if you experience any of these serious side effects (see also **What you need to know before you take <Product name>**):

Heart problems. Tell your doctor if you feel very tired, are short of breath, or have swollen feet and ankles. These may be symptoms of heart problems that may include heart failure and heart muscle problems (cardiomyopathy).

Lung or breathing problems. Tell your doctor if you develop cough, chest pain, sudden onset of shortness of breath, or coughing up blood. These may be symptoms of a condition called pulmonary embolism that occurs when blood clots travel to your lungs.

Kidney disorders. Tell your doctor if you experience altered frequency or absence of urination which may be symptoms of kidney failure.

Bleeding. Tell your doctor if you have any of these symptoms or a serious bleeding problem during treatment with <Product name>: painful, swollen stomach (abdomen); vomiting blood; black, sticky stools; bloody urine; headache or change in your mental status; coughing up of blood or bloody sputum from the lungs or airway.

Tumour destruction leading to hole in the intestine. Tell your doctor if you have severe abdominal pain, fever, nausea, vomiting, blood in your stool, or changes in bowel habits.

Other side effects with <Product name> may include:

Very common: may affect more than 1 in 10 people
- Reduction in the number of platelets, red blood cells and/or white blood cells (e.g. neutrophils).
- Shortness of breath.
- High blood pressure.
- Extreme tiredness, loss of strength.
- Swelling caused by fluid under the skin and around the eye, deep allergic rash.
- Mouth pain/irritation, mouth sores/inflammation/dryness, taste disturbances, upset stomach, nausea, vomiting, diarrhoea, constipation, abdominal pain/swelling, loss/decrease of appetite.
- Decreased activity of thyroid gland (hypothyroidism).
- Dizziness.
- Headache.
- Nose bleeding.
- Back pain, joint pain.
- Pain in arms and legs.
- Yellow skin/skin discoloration, excess pigmentation of the skin, hair colour change, rash on the palms of the hands and soles of the feet, rash, dryness of the skin.
- Cough.
- Fever.
- Difficulty in falling asleep.

Common: may affect up to 1 in 10 people
- Blood clots in the blood vessels.
- Deficiency of blood supply to the heart muscle, due to obstruction or constriction of the coronary arteries.
- Chest pain.
- Decreased in the amount of blood pumped by the heart.
- Fluid retention including around the lungs.
- Infections.
- Complication of severe infection (infection is present in the bloodstream) that can lead to tissue damage, organ failure, and death.
- Decreased blood sugar level (see section 2).
- Loss of protein in the urine sometime resulting in swelling.
- Influenza-like syndrome.
- Abnormal blood tests including pancreatic and liver enzymes.
- High level of uric acid in the blood.
- Haemorrhoids, pain in the rectum, gingival bleeding, difficulty in swallowing or inability to swallow.
- Burning or painful sensation in the tongue, inflammation of the digestive tract lining, excessive gas in the stomach or intestine.
- Weight loss.
- Musculoskeletal pain (pain in muscles and bones), muscular weakness, muscular fatigue, muscle pain, muscle spasms.
- Nasal dryness, congested nose.
- Excessive tear flow.
- Abnormal sensation of the skin, itching, flaking and inflammation of the skin, blisters, acne, nail discolouration, hair loss.
- Abnormal sensations in extremities.
- Abnormally decreased/increased sensitivity, particularly to touch.
- Acid heartburn.

- Dehydration.
- Hot flushes.
- Abnormally coloured urine.
- Depression.
- Chills.

Uncommon: may affect up to 1 in 100 people
- Life-threatening infection of the soft tissue including the ano-genital region (see section 2).
- Stroke.
- Heart attack caused by an interrupted or decreased blood supply to the heart.
- Changes in the electrical activity or abnormal rhythm of the heart.
- Fluid around the heart (pericardial effusion).
- Liver failure.
- Pain in the stomach (abdomen) caused by inflammation of the pancreas.
- Tumour destruction leading to hole in the intestine (perforation).
- Inflammation (swelling and redness) of the gallbladder with or without associated gallstones.
- Abnormal tube like passage from one normal body cavity to another body cavity or the skin.
- Pain in the mouth, teeth and/or jaw, swelling or sores inside the mouth, numbness or a feeling of heaviness in the jaw, or loosening of a tooth. These could be signs and symptoms of bone damage in the jaw (osteonecrosis), see section 2.
- Overproduction of thyroid hormones which increases the amount of energy the body uses at rest.
- Problems with wound healing after surgery.
- Increased blood level of enzyme (creatine phosphokinase) from muscle.
- Excessive reaction to an allergen including hay fever, skin rash, itchy skin, hives, swelling of body parts, and trouble breathing.
- Inflammation of the colon (colitis, colitis ischaemic).

Rare: may affect up to 1 in 1,000 people
- Severe reaction of the skin and/or mucous membranes (Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme).
- Tumour lysis syndrome (TLS) – TLS consists of a group of metabolic complications that can occur during treatment of cancer. These complications are caused by the break-down products of dying cancer cells and may include the following: nausea, shortness of breath, irregular heartbeat, muscular cramps, seizure, clouding of urine and tiredness associated with abnormal laboratory test results (high potassium, uric acid and phosphorous levels and low calcium levels in the blood) that can lead to changes in kidney function and acute renal failure.
- Abnormal muscle breakdown which can lead to kidney problems (rhabdomyolysis).
- Abnormal changes in the brain that can cause a collection of symptoms including headache, confusion, seizures, and vision loss (reversible posterior leukoencephalopathy syndrome).
- Painful skin ulceration (pyoderma gangrenosum).
- Inflammation of the liver (hepatitis).
- Inflammation of the thyroid gland.
- Damage to the smallest blood vessels known as thrombotic microangiopathy (TMA).

Not known (frequency cannot be estimated from available data):
- An enlargement and weakening of a blood vessel wall or a tear in a blood vessel wall (aneurysms and artery dissections).
- Lack of energy, confusion, sleepiness, unconsciousness/coma – these symptoms may be signs of brain toxicity caused by high blood levels of ammonia (hyperammonaemic encephalopathy).

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <Product name>

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton, bottle and blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not use this medicine if you notice that the pack is damaged or shows signs of tampering.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What <Product name> contains

- The active substance is sunitinib.

<Product name> 12.5 mg hard capsules
Each capsule contains 12.5 mg of sunitinib.
<Product name> 25 mg hard capsules
Each capsule contains 25 mg of sunitinib.
Product name> 37.5 mg hard capsules
Each capsule contains 37.5 mg of sunitinib.
Product name> 50 mg hard capsules
Each capsule contains 50 mg of sunitinib.

- The other ingredients are:

Capsule content: cellulose, microcrystalline (E460), mannitol (E421), croscarmellose sodium (see section 2 <Product name> contains sodium), povidone (E1201), magnesium stearate (E470b).

<Product name> 12.5 mg hard capsules
Capsule shell: red iron oxide (E172), titanium dioxide (E171), gelatin.
Printing ink, white: shellac, titanium dioxide (E171), propylene glycol (E1520).
<Product name> 25 mg hard capsules
Capsule shell: black iron oxide (E172), red iron oxide (E172), yellow iron oxide (E172), titanium dioxide (E171), gelatin.
Printing ink, white: shellac, titanium dioxide (E171), propylene glycol (E1520).
<Product name> 37.5 mg hard capsules
Capsule shell: yellow iron oxide (E172), titanium dioxide (E171), gelatin.
Printing ink, black: shellac, black iron oxide (E172), propylene glycol (E1520), ammonium hydroxide (E527).
<Product name> 50 mg hard capsules
Capsule shell: black iron oxide (E172), red iron oxide (E172), yellow iron oxide (E172), titanium dioxide (E171), gelatin.
Printing ink, white: shellac, titanium dioxide (E171), propylene glycol (E1520).

What <Product name> looks like and contents of the pack

<Product name> 12.5 mg hard capsules (capsules)
Gelatin capsules of size 4 with orange cap and orange body, printed with white ink “12.5 mg” on the body and containing yellow to orange granules.

<Product name> 25 mg hard capsules (capsules)

Gelatin capsules of size 3 with caramel cap and orange body, printed with white ink “25 mg” on the body and containing yellow to orange granules.

<Product name> 37.5 mg hard capsules (capsules)
Gelatin capsules of size 2 with yellow cap and yellow body, printed with black ink “37.5 mg” on the body and containing yellow to orange granules.

<Product name> 50 mg hard capsules (capsules)
Gelatin capsules of size 1 with caramel cap and caramel body, printed with white ink “50 mg” on the body and containing yellow to orange granules.

<Product name> hard capsules are available in blisters containing 28 hard capsules, in perforated unit-dose blisters of 28 x 1 hard capsules, 30 hard capsules, in perforated unit-dose blisters of 30 x 1 hard capsules and in plastic bottles containing 30 hard capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Registratiehouder:
Mylan Pharmaceuticals Ltd
Damastown Industrial Park
Mulhuddart
Dublin 15
DUBLIN
Ierland

Voor informatie en inlichtingen:
Mylan B.V.
Krijgsman 20
Amstelveen

Fabrikant:
Remedica Ltd
Aharnon Street, Limassol Industrial Estate
Limassol 3056, Cyprus

Pharmacare Premium Ltd
HHF003 Hal Far Industrial Estate
Birzebbugia BBG3000, Malta

In het register ingeschreven onder:

Sunitinib Mylan 12,5 mg, harde capsules:	RVG 123584
Sunitinib Mylan 25 mg, harde capsules:	RVG 123597
Sunitinib Mylan 37,5 mg, harde capsules:	RVG 123598
Sunitinib Mylan 50 mg, harde capsules:	RVG 123599

This medicine is authorised in the Member States of the European Economic Area under the following names:

Nederland:	Sunitinib Mylan, 12,5 mg, 25 mg, 37,5 mg, 50 mg, harde capsules
Bulgarije:	Сунитиниб Mylan (Sunitinib Mylan) 12,5 mg, 25 mg, 50 mg твърди капсули
Kroatië:	Sunitinib Mylan 12,5 mg, 25 mg, 37,5 mg, 50 mg tvrde kapsule
Tsjechië:	Sunitinib Mylan
Denemarken:	Sunitinib Mylan

Estland:	Sunitinib Mylan
Finland:	Sunitinib Mylan 12,5 mg, 25 mg, 37,5 mg, 50 mg kovat kapselit
Frankrijk:	SUNITINIB VIATRIS 12.5 mg, 25 mg, 50 mg, gélule
Hongarije:	Szunitinib Mylan 12,5 mg, 25 mg, 37,5 mg, 50 mg kemény kapszula
IJsland:	Sunitinib Mylan 12,5 mg, 25 mg, 37,5 mg, 50 mg hörð hylki
Italië:	Sunitinib Mylan
Litouwen:	Sunitinib Mylan 12,5 mg, 50 mg kietosios kapsulės
Letland:	Sunitinib Mylan 12,5 mg, 50 mg cietās kapsulas
Malta:	Sunitinib Mylan 12.5 mg, 25 mg, 37.5 mg, 50 mg hard capsules
Noorwegen:	Sunitinib Mylan
Polen:	Sunitynib Mylan
Portugal:	Sunitinib Mylan
Roemenië:	Sunitinib Viatris 12,5 mg, 25 mg, 37,5 mg, 50 mg capsule
Slowakije:	Sunitinib Mylan 12,5 mg, 25 mg, 37,5 mg, 50 mg
Spanje:	Sunitinib Mylan 12,5 mg, 25 mg, 37,5 mg, 50 mg cápsulas duras EFG
Verenigd Koninkrijk:	Sunitinib Mylan 12.5 mg, 25 mg, 37.5 mg, 50 mg hard capsules
Zweden:	Sunitinib Mylan

Deze bijsluiter is voor het laatst goedgekeurd in september 2024.