Package leaflet: Information for the patient

FENESA 200 mg filmomhulde tabletten
sorafenib

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 FENESA is and what it is used for

FENESA is used to treat liver cancer *(hepatocellular carcinoma).*
FENESA is also used to treat kidney cancer *(advanced renal cell carcinoma)* at an advanced stage when standard therapy has not helped to stop your disease or is considered unsuitable.

FENESA is a so-called *multikinase inhibitor*. It works by slowing down the rate of growth of cancer cells and cutting off the blood supply that keeps cancer cells growing.

2. What you need to know before you take FENESA

Do not take FENESA
- **If you are allergic** to sorafenib or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking FENESA

Take special care with FENESA

- **If you experience the following symptoms, contact your doctor immediately as this can be a life-threatening condition: nausea, shortness of breath, irregular heartbeat, muscular cramps, seizure, clouding of urine and tiredness.** These may be caused by a group of metabolic complications that can occur during treatment of cancer that are caused by the break-down products of dying cancer cells (Tumour lysis syndrome (TLS)) and can lead to changes in kidney function and acute renal failure (see also section 4: Possible side effects).
- **If you experience skin problems.** FENESA can cause rashes and skin reactions, especially on the hands and feet. These can usually be treated by your doctor. If not, your doctor may interrupt treatment or stop it altogether.
- **If you have high blood pressure.** FENESA can raise blood pressure, and your doctor will usually monitor your blood pressure and may give you a medicine to treat your high blood pressure.
- **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 diabetes.** Blood sugar levels in diabetic patients should be checked regularly in order to assess if anti-diabetic medicine's dosage needs to be adjusted to minimize the risk of low blood sugar.
- **If you get any bleeding problems, or are taking warfarin or phenprocoumon.** Treatment with FENESA may lead to a higher risk of bleeding. If you are taking warfarin or phenprocoumon, medicines which thin the blood to prevent blood clots, there may be a greater risk of bleeding.
- **If you get chest pain or heart problems.** Your doctor may decide to interrupt treatment or stop it altogether.
- **If you have a heart disorder**, such as an abnormal electrical signal called "prolongation of the QT interval".
- **If you are going to have surgery, or if you had an operation recently.** FENESA might affect the way your wounds heal. You will usually be taken off FENESA if you are having an operation.

Your doctor will decide when to start with FENESA again.

- **If you are taking irinotecan or are given docetaxel**, which are also medicines for cancer.

FENESA may increase the effects and, in particular, the side effects of these medicines.

- **If you are taking Neomycin or other antibiotics**. The effect of FENESA may be decreased.
- **If you have severe liver impairment**. You may experience more severe side effects when taking this medicine.
- **If you have poor kidney function.** Your doctor will monitor your fluid and electrolyte balance.
- **Fertility**. FENESA may reduce fertility in both men and women. If you are concerned, talk to a doctor.

- **Holes in the gut wall** (*gastrointestinal perforation*) may occur during treatment (see section 4: Possible Side Effects). In this case your doctor will interrupt the treatment.

Tell your doctor if any of these affect you. You may need treatment for them, or your doctor may decide to change your dose of FENESA, or stop treatment altogether (see also section 4: Possible side effects).

Children and adolescents

Children and adolescents have not yet been tested with FENESA.

Other medicines and FENESA

Some medicines may affect FENESA, or be affected by it. Tell your doctor or pharmacist if you are taking, have recently taken or might take anything in this list or any other medicines, including medicines obtained without a prescription:

- Rifampicin, Neomycin or other medicines used to treat infections **(antibiotics)**.
- St John's wort, a herbal treatment for **depression**.
- Phenytoin, carbamazepine or phenobarbital, treatments for **epilepsy** and other conditions.
- Dexamethasone, a **corticosteroid** used for various conditions.
- Warfarin or phenprocoumon, anticoagulants used to **prevent blood clots**.
- Doxorubicin, capecitabine, docetaxel, paclitaxel and irinotecan, which are **cancer treatments**.
- Digoxin, a treatment for mild to moderate **heart failure**.

Pregnancy and breast-feeding

Avoid becoming pregnant while being treated with FENESA. If you could become pregnant use adequate contraception during treatment. If you become pregnant while being treated with FENESA, immediately tell your doctor who will decide if the treatment should be continued.

You must not breast-feed your baby during FENESA treatment, as this medicine may interfere with the growth and development of your baby.

Driving and using machines

There is no evidence that FENESA will affect the ability to drive or to operate machines.

FENESA contains sodium.

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to take FENESA

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

The recommended dose of FENESA in adults is 2×200 mg tablets, twice daily.
This is equivalent to a daily dose of 800 mg or four tablets a day.

Swallow FENESA tablets with a glass of water, either without food or with a low-fat or moderate fat meal. Do not take this medicine with high fat meals, as this may make FENESA less effective. If you intend to have a high fat meal, take the tablets at least 1 hour before or 2 hours after the meal.
Always take this medicine exactly as your doctor has told you to. Check with your doctor or pharmacist if you are not sure.

It is important to take this medicine at about the same times each day, so that there is a steady amount in the bloodstream.

You will usually carry on taking this medicine as long as you are getting clinical benefits, and not suffering unacceptable side effects.

If you take more FENESA than you should
Tell your doctor straight away if you (or anyone else) have taken more than your prescribed dose. Taking too much FENESA makes side effects more likely or more severe, especially diarrhoea and skin reactions. Your doctor may tell you to stop taking this medicine.

If you forget to take FENESA
If you have missed a dose, take it as soon as you remember. If it is nearly time for the next dose, forget about the missed one and carry on as normal. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. This medicine may also affect the results of some blood tests.

Very common:
may affect more than 1 in 10 people
- Diarrhoea.
- Feeling sick *(nausea)*.
- Feeling weak or tired *(fatigue)*.
- Pain (including mouth pain, abdominal pain, headache, bone pain, tumour pain).
- Hair loss *(alopecia)*.

- Flushed or painful palms or soles *(hand foot skin reaction).*
- Itching or rash.
- Throwing up *(vomiting).*
- Bleeding (including bleeding in the brain, gut wall and respiratory tract; *haemorrhage*).
- High blood pressure, or increases in blood pressure *(hypertension).*
- Infections.
- Loss of appetite *(anorexia).*
- Constipation.
- Joint pain *(arthralgia).*
- Fever.
- Weight loss.
- Dry skin.

Common:
may affect up to 1 in 10 people

- Flu-like illness.
- Indigestion *(dyspepsia).*
- Difficulty swallowing *(dysphagia).*
- Inflamed or dry mouth, tongue pain *(stomatitis and mucosal inflammation).*
- Low calcium levels in the blood *(hypocalcaemia).*
- Low potassium levels in the blood *(hypokalaemia).*
- Low blood sugar level *(hypoglycaemia).*
- Muscle pain *(myalgia).*
- Disturbed sensations in fingers and toes, including tingling or numbness *(peripheral sensory neuropathy).*
- Depression.
- Erection problems *(impotence).*
- Altered voice *(dysphonia).*
- Acne.
- Inflamed, dry or scaly skin that sheds *(dermatitis, skin desquamation).*
- Heart failure.
- Heart attack *(myocardial infarction)* or chest pain.
- Tinnitus *(ringing sound in the ear).*
- Kidney failure.
- Abnormally high levels of protein in the urine *(proteinuria).*
- General weakness or loss of strength *(asthenia).*
- Decrease in the number of white blood cells *(leucopenia and neutropenia).*
- Decrease in the number of red blood cells *(anaemia).*
- Low number of platelets in the blood *(thrombocytopenia).*
- Inflammation of hair follicles *(folliculitis).*
- Underactive thyroid gland *(hypothyroidism).*

- Low sodium levels in the blood *(hyponatraemia)*.
- Distortion of the sense of taste *(dysgeusia)*.
- Red in the face and often other areas of the skin *(flushing)*.
- Runny nose *(rhinorrhoea)*.
- Heartburn *(gastro oesophageal reflux disease)*.
- Skin cancer *(keratoacanthomas/squamous cell cancer of the skin)*.
- A thickening of the outer layer of the skin *(hyperkeratosis)*.
- A sudden, involuntary contraction of a muscle *(muscle spasms)*.

Uncommon:

may affect up to 1 in 100 people

- Inflamed stomach lining *(gastritis)*.
- Pain in the tummy *(abdomen)* caused by pancreatitis, inflammation of the gall bladder and/or bile ducts.
- Yellow skin or eyes *(jaundice)* caused by high levels of bile pigments *(hyperbilirubinaemia)*.
- Allergic like reactions (including skin reactions and hives).
- Dehydration.
- Enlarged breasts *(gynaecomastia)*.
- Breathing difficulty *(lung disease)*.
- Eczema.
- Overactive thyroid gland *(hyperthyroidism)*.
- Multiple skin eruptions *(erythema multiforme)*.
- Abnormally high blood pressure.
- Holes in the gut wall *(gastrointestinal perforation)*.
- Reversible swelling in the rear part of the brain that can be associated with headache, altered consciousness, fits and visual symptoms including visual loss *(reversible posterior leukoencephalopathy)*.
- A sudden, severe allergic reaction *(anaphylactic reaction)*.

Rare:

may affect up to 1 in 1,000 people

- Allergic reaction with swelling of the skin (e. g. face, tongue) that may cause difficulty in breathing or swallowing *(angioedema)*.
- Abnormal heart rhythm *(QT prolongation)*.
- Inflammation of the liver, which may lead to nausea, vomiting, abdominal pain, and jaundice *(drug induced hepatitis)*.
- A sunburn-like rash that may occur on skin that has previously been exposed to radiotherapy and can be severe *(radiation recall dermatitis)*.
- Serious reactions of the skin and/or mucous membranes which may include painful blisters and fever, including extensive detachment of the skin *(Stevens-Johnson syndrome and toxic epidermal necrolysis)*.
- Abnormal muscle breakdown which can lead to kidney problems *(rhabdomyolysis)*.

- Damage of the kidney causing them to leak large amounts of protein *(nephrotic syndrome)*.
- Inflammation of the vessels in the skin which may result in rash *(leucocytoclastic vasculitis)*.

Not known:
frequency cannot be estimated from the available data
- Impaired brain function that can be associated with e.g. drowsiness, behavioural changes, or confusion *(encephalopathy)*.
- An enlargement and weakening of a blood vessel wall or a tear in a blood vessel wall *(aneurysms and artery dissections)*.
- Nausea, shortness of breath, irregular heartbeat, muscular cramps, seizure, clouding of urine and tiredness (Tumour lysis syndrome (TLS)) (see section 2).

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 below.
Nederlands Bijwerkingen Centrum Lareb
Website: www.lareb.nl
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store FENESA

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 and blister after EXP. The expiry date refers to the last day of that month.

For Aluminium-OPA/Alu/PVC blisters:
This medicinal product does not require any special storage conditions.

For Aluminium-PVC/PE/PVDC blisters:
Do not store above 30°C

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 FENESA contains

- The active substance is sorafenib. Each film-coated tablet contains 200 mg sorafenib (as tosylate).
- The other ingredients are:

  Tablet core: hypromellose 2910 (E464), croscarmellose sodium (E468), cellulose, microcrystalline (E460), magnesium stearate (E470b), sodium laurilsulfate (E514).

  Tablet coating: hypromellose 2910 (E464), titanium dioxide (E171), macrogol (E1521), red iron oxide (E172).

What FENESA looks like and contents of the pack

FENESA 200 mg film-coated tablets are red-brown, round, biconvex film-coated tablets debossed with "200" on one side and plain on the other side with a diameter of tablet 12.0 mm ± 5%.

They come in packs of 56, 112 film-coated tablets in Aluminium-PVC/PE/PVDC blisters.

They come in packs of 56×1, 112×1 film-coated tablets in Aluminium-PVC/PE/PVDC perforated unit dose blisters.

They come in packs of 60 film-coated tablets in Aluminium-OPA/Alu/PVC blisters.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen

Zentiva k.s., U kabelovny 130, 10237 Praha 10 – Dolní Měcholupy, Czech republic

Fabrikant

Remedica Ltd
Aharnon Street, Limassol Industrial Estate
3056 Limassol
Cyprus

Or

PharOS MT Ltd.,
HF62X, Hal Far Industrial Estate,
Birzebbugia BBG3000,
Malta

In het register ingeschreven onder:

RVG 124967

Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:

Nederland:	FENESA 200 mg, filmomhulde tabletten
Kroatië	FENESA 200 mg filmom obložene tablete
Hongarije	FENESA 200 mg filmtabletta
IJsland	FENESA 200 mg filmuhúðaðar töflur

Deze bijsluiter is voor het laatst goedgekeurd in april 2022.