PACKAGE LEAFLET

Package leaflet: Information for the patient

Axitinib Teva 1 mg, filmomhulde tabletten
Axitinib Teva 3 mg, filmomhulde tabletten
Axitinib Teva 5 mg, filmomhulde tabletten
Axitinib Teva 7 mg, filmomhulde tabletten
axitinib

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, pharmacist, or nurse.
- 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, pharmacist or nurse. 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

<PRODUCT NAME> is a medicine containing the active substance axitinib. Axitinib reduces the blood supply to the tumour and slows down the growth of cancer.

<PRODUCT NAME> is indicated for the treatment of advanced kidney cancer (advanced renal cell carcinoma) in adults, when another medicine (called sunitinib or a cytokine) is no longer stopping disease from progressing.

If you have any questions about how this medicine 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 axitinib or any of the other ingredients of this medicine (listed in section 6).
If you think you may be allergic, ask your doctor for advice.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking <PRODUCT NAME>.

- **If you have high blood pressure.**
  <PRODUCT NAME> can raise your blood pressure. It is important to check your blood pressure before you take this medicine, and regularly while you are taking it. If you have high blood pressure (hypertension) you may be treated with medicines to reduce the blood pressure. Your doctor should make sure that your blood pressure is under control before starting <PRODUCT NAME> treatment, and while on treatment with this medicine.

- **If you have thyroid gland 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 this medicine. 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 before, or while on treatment with this medicine, you should be treated with thyroid hormone replacement.

- **If you have had a recent problem with blood clots in your veins and arteries (types of blood vessels), including stroke, heart attack, embolism, or thrombosis.**
  Get emergency help right away and call your doctor 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 one side of your body; trouble talking; headache; vision changes; or dizziness while on treatment with this medicine.

- **If you suffer from bleeding problems.**
  <PRODUCT NAME> may increase your chance of bleeding. Tell your doctor if you have any bleeding, coughing up of blood or bloody sputum while on treatment with this medicine.

- **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 during treatment with this medicine you get severe stomach (abdominal) pain or stomach pain that does not go away.**
  <PRODUCT NAME> may increase the risk of developing a hole in the stomach or intestine or formation of fistula (abnormal tube-like passage from one normal body cavity to another body cavity or the skin).
  Tell your doctor if you have severe abdominal pain while on treatment with this medicine.

- **If you are going to have an operation or if you have an unhealed wound.**
  Your doctor should stop <PRODUCT NAME> at least 24 hours before your operation as it may affect wound healing. Your treatment with this medicine should be restarted when the wound has adequately healed.

- **If during treatment with this medicine, you get symptoms such as headache, confusion, seizures (fits), or changes in vision with or without high blood pressure.**
  Get emergency help right away and call your doctor. This could be a rare neurological side effect named posterior reversible encephalopathy syndrome.

- **If you have liver problems.**
  Your doctor should do blood tests to check your liver function before and during treatment with <PRODUCT NAME>.

- **If during treatment with this medicine, you get symptoms such as excessive tiredness, swelling of the abdomen, legs or ankles, shortness of breath, or protruding neck veins.**
  <PRODUCT NAME> may increase the risk of developing heart failure events. Your doctor should monitor for signs or symptoms of heart failure events periodically throughout treatment with axitinib.

Use in children and adolescents

<PRODUCT NAME> is not recommended for people aged under 18. This medicine has not been studied in children and adolescents.

Other medicines and <PRODUCT NAME>

Some medicines may affect <PRODUCT NAME>, or be affected by it. Please tell your doctor, pharmacist or nurse about all the medicines you have recently taken, are currently taking, or plan to take, including medicines obtained without a prescription, vitamins, and herbal medicines. The medicines listed in this leaflet may not be the only ones that could interact with <PRODUCT NAME>.

The following medicines may increase the risk of side effects with <PRODUCT NAME>:
- ketoconazole or itraconazole, used to treat fungal infections;
- clarithromycin, erythromycin or telithromycin, antibiotics used to treat bacterial infections;
- atazanavir, indinavir, nelfinavir, ritonavir or saquinavir, used to treat HIV infections/AIDS;
- nefazodone, used to treat depression.

The following medicines may reduce the effectiveness of <PRODUCT NAME>:
- rifampicin, rifabutin or rifapentin, used to treat tuberculosis (TB);
- dexamethasone, a steroid medicine prescribed for many different conditions, including serious illnesses;
- phenytoin, carbamazepine or phenobarbital, anti-epileptics used to stop seizures or fits;
- St. John's wort (*Hypericum perforatum*), a herbal product used to treat depression.

You **should not** take these medicines during your treatment with <PRODUCT NAME>. If you are taking any of them, tell your doctor, pharmacist or nurse. Your doctor may change the dose of these medicines, change the dose of <PRODUCT NAME>, or switch you to a different medicine.

<PRODUCT NAME> may increase side effects associated with theophylline, used to treat asthma or other lung diseases.

<PRODUCT NAME> with food and drink

Do not take this medicine with grapefruit or grapefruit juice, as it may increase the chance of side effects.

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, pharmacist or nurse for advice before taking this medicine.

- <PRODUCT NAME> could harm an unborn baby or breast-fed baby.

- Do not take this medicine during pregnancy. Talk to your doctor before taking it if you are pregnant or might become pregnant.

- Use a reliable method of contraception while you are taking <PRODUCT NAME> and up to 1 week after the last dose of this medicine, to prevent pregnancy.

- Do not breast-feed during treatment with <PRODUCT NAME>. If you are breast-feeding, your doctor should discuss with you whether to discontinue breast-feeding or discontinue <PRODUCT NAME> treatment.

Driving and using machines

If you experience dizziness and/or feel tired while on treatment with <PRODUCT NAME>, take special care when driving or using machines.

<PRODUCT NAME> contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

<PRODUCT NAME> contains sodium

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

3. How to take <PRODUCT NAME>

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

The recommended dose is 5 mg twice a day. Your doctor may subsequently increase or decrease your dose depending on how you tolerate treatment with <PRODUCT NAME>.

Swallow the tablets whole with water, with or without food. Take the <PRODUCT NAME> doses approximately 12 hours apart.

Use in children and adolescents

<PRODUCT NAME> is not recommended for people aged under 18. This medicine has not been studied in children and adolescents

If you take more <PRODUCT NAME> than you should
If you accidentally take too many tablets or a higher dose than you need, contact a doctor for advice right away. If possible, show the doctor the pack, or this leaflet. You may require medical attention.

If you forget to take <PRODUCT NAME>
Take your next dose at your regular time. Do not take a double dose to make up for the forgotten tablets.

If you vomit while taking <PRODUCT NAME>
If you vomit, an additional dose should not be taken. The next prescribed dose should be taken at the usual time.

If you stop taking <PRODUCT NAME>
If you are not able to take this medicine as your doctor prescribed or you feel you do not need it anymore, contact your doctor right away.

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

4. Possible side effects

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

Some side effects could be serious. You must immediately contact your doctor if you experience any of those following serious side effects (see also section 2 "What you need to know before you take <PRODUCT NAME>"):

- **Heart failure events.** Tell your doctor if you experience excessive tiredness, swelling of the abdomen, legs, or ankles, shortness of breath, or protruding neck veins.

- **Blood clots in your veins and arteries (types of blood vessels), including stroke, heart attack, embolism, or thrombosis.** Get emergency help right away and call your doctor 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 one side of your body; trouble talking; headache; vision changes: or dizziness.

- **Bleeding.** Tell your doctor right away if you have any of these symptoms or a serious bleeding problem during treatment with <PRODUCT NAME>: black tarry stools, coughing up of blood or bloody sputum, or change in your mental status.

- **Hole in the stomach or intestine or formation of fistula (abnormal tube-like passage from one normal body cavity to another body cavity or the skin).** Tell your doctor if you have severe abdominal pain.

- **Severe increase in blood pressure (hypertensive crisis).** Tell your doctor if you have a very high blood pressure, severe headache, or severe chest pain.

- **Reversible swelling of the brain (posterior reversible encephalopathy syndrome).** Get emergency help right away and call your doctor if you get symptoms such as headache, confusion, seizures (fits), or changes in vision with or without high blood pressure.

Other side effects with <PRODUCT NAME> may include:

Very common: may affect more than 1 in 10 people
- High blood pressure, or increases in blood pressure
- Diarrhoea, feeling or being sick (nausea or vomiting), stomach ache, indigestion, soreness of the mouth, tongue or throat, constipation
- Shortness of breath, cough, hoarseness
- Lack of energy, feeling weak or tired
- Under-active thyroid gland (may show in your blood tests)
- Redness and swelling of the palms of the hands or soles of the feet (hand-foot syndrome), skin rash, dryness of the skin
- Joint pain, pain in hands or feet
- Loss of appetite
- Protein in the urine (may show in your urine tests)
- Weight loss
- Headache, taste disturbance or loss of taste

Common: may affect up to 1 in 10 people
- Dehydration (loss of body fluids)
- Kidney failure
- Flatulence (wind), haemorrhoids, bleeding from gums, bleeding from the rectum, a burning or stinging sensation in the mouth
- Hyper-active thyroid gland (may show in your blood tests)
- Sore throat or nose and throat irritation
- Muscle pain
- Nose bleeding
- Skin itching, redness of the skin, hair loss
- Ringing/sound in the ears (tinnitus)
- Reduction in the number of red blood cells (may show in your blood tests)
- Reduction in the number of blood platelets (cells that help blood to clot) (may show in your blood tests)
- Presence of red blood cells in the urine (may show in your urine tests)

- Changes in the levels of different chemicals/enzymes in the blood (may show in your blood tests)
- Increase in the number of red blood cells (may show in your blood tests)
- Swelling of the abdomen, legs, or ankles, protruding neck veins, excessive tiredness, shortness of breath (signs of heart failure events)
- Fistula (abnormal tube like passage from one normal body cavity to another body cavity or the skin)
- Dizziness
- Inflammation of the gall bladder

Uncommon: may affect up to 1 in 100 people
- Reduction in the number of white blood cells (may show in your blood tests)

Not known: frequency cannot be estimated from the available data
- An enlargement and weakening of a blood vessel wall or a tear in a blood vessel wall (aneurysms and artery dissections).

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. 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 and blister foil after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from moisture. This medicine does not require any special temperature storage conditions.

Do not use any pack that 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 axitinib.
  <PRODUCT NAME> 1 mg: each tablet contains 1 mg axitinib
  <PRODUCT NAME> 3 mg: each tablet contains 3 mg axitinib
  <PRODUCT NAME> 5 mg: each tablet contains 5 mg axitinib
  <PRODUCT NAME> 7 mg: each tablet contains 7 mg axitinib

- The other ingredients are microcrystalline cellulose, lactose monohydrate (see section 2 <PRODUCT NAME> contains lactose), croscarmellose sodium (see section 2 "<Product name> contains sodium"), magnesium stearate, hypromellose, titanium dioxide (E171), triacetin (E1518), iron oxide red (E172).

What <PRODUCT NAME> looks like and contents of the pack

<PRODUCT NAME> 1 mg film-coated tablets are red colour, round biconvex coated tablet, approximately 6 mm diameter and debossed with “A7TI” on one side and “1” on the other.

<PRODUCT NAME> 3 mg film-coated tablets are red colour, oval biconvex coated tablet, approximately 12 mm long by 7 mm wide and debossed with “A7TI” on one side and “3” on the other.

<PRODUCT NAME> 5 mg film-coated tablets are red colour, oval biconvex coated tablet, approximately 15 mm long by 8 mm wide and debossed with “A7TI” on one side and “5” on the other.

<PRODUCT NAME> 7 mg film-coated tablets are red colour, oval biconvex coated tablet, approximately 17 mm long by 9 mm wide and debossed with “A7TI” on one side and “7” on the other.

OPA/Al/PVC/Al (Al/Al) blisters and perforated unit-dose blisters packed into carton boxes.
Pack sizes of 56, 60, 56 x 1 or 120 x 1 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Houder van de vergunning voor het in de handel brengen
Teva GmbH
Graf-Arco-Straße 3
89079 Ulm
Duitsland

Fabrikant
Synthon Hispania, S.L.
c/ Castelló, 1
Sant Boi de Llobregat
08830 Barcelona
Spanje

Synthon B.V.
Microweg 22
6545 CM Nijmegen
Nederland

Balkanpharma-Dupnitsa AD
3 Samokovsko Shosse Str.
2600 Dupnitsa
Bulgarije

In het register ingeschreven onder
RVG 131632, Axitinib Teva 1 mg, filmomhulde tabletten
RVG 131633, Axitinib Teva 3 mg, filmomhulde tabletten
RVG 131635, Axitinib Teva 5 mg, filmomhulde tabletten
RVG 131636, Axitinib Teva 7 mg, filmomhulde tabletten

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

Oostenrijk	Axitinib-ratiopharm 1 mg Filmtabletten Axitinib-ratiopharm 3 mg Filmtabletten Axitinib-ratiopharm 5 mg Filmtabletten Axitinib-ratiopharm 7 mg Filmtabletten

Belgie	Axitinib Teva 1 mg filmomhulde tabletten/comprimés pelliculés/Filmtabletten Axitinib Teva 3 mg filmomhulde tabletten/comprimés pelliculés/Filmtabletten Axitinib Teva 5 mg filmomhulde tabletten/comprimés pelliculés/Filmtabletten Axitinib Teva 7 mg filmomhulde tabletten/comprimés pelliculés/Filmtabletten
Bulgarije	Акситиниб Тева 1 mg филмирани таблетки Axitinib Teva 1 mg film-coated tablets Акситиниб Тева 5 mg филмирани таблетки Axitinib Teva 5 mg film-coated tablets
Duitsland	Axitinib-ratiopharm 1 mg Filmtabletten Axitinib-ratiopharm 3 mg Filmtabletten Axitinib-ratiopharm 5 mg Filmtabletten Axitinib-ratiopharm 7 mg Filmtabletten
Denemarken	Axitinib Teva
Griekenland	Axitinib/Teva
Spanje	Axitinib Teva 1 mg comprimidos recubiertos con película EFG Axitinib Teva 5 mg comprimidos recubiertos con película EFG
Frankrijk	Axitinib Teva 1 mg, Comprimé Pelliculé Axitinib Teva 3 mg, Comprimé Pelliculé Axitinib Teva 5 mg, Comprimé Pelliculé Axitinib Teva 7 mg, Comprimé Pelliculé
Kroatie	Aksitinib Teva 1 mg filmom obložene tablete Aksitinib Teva 5 mg filmom obložene tablete
Italie	Axitinib Teva
Luxemburg	Axitinib Teva 1 mg comprimés pelliculés Axitinib Teva 3 mg comprimés pelliculés Axitinib Teva 5 mg comprimés pelliculés Axitinib Teva 7 mg comprimés pelliculés
Nederland	Axitinib Teva 1 mg, filmomhulde tabletten Axitinib Teva 3 mg, filmomhulde tabletten Axitinib Teva 5 mg, filmomhulde tabletten Axitinib Teva 7 mg, filmomhulde tabletten
Noorwegen	Axitinib Teva
Portugal	Axitinib Teva
Zweden	Axitinib Teva
Slovenie	Aksitinib Teva 1 mg filmsko obložene tablete Aksitinib Teva 5 mg filmsko obložene tablete

Deze bijsluiter is voor het laatst goedgekeurd in mei 2024.