Package leaflet: Information for the patient

Tafinlar® 50 mg hard capsules
Tafinlar® 75 mg hard capsules
dabrafenib

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

1. What Tafinlar is and what it is used for

Tafinlar is a medicine that contains the active substance dabrafenib. It is used either on its own or in combination with another medicine containing trametinib in adults to treat a type of skin cancer called melanoma that has spread to other parts of the body, or cannot be removed by surgery.

Tafinlar in combination with trametinib is also used to prevent melanoma from coming back after it has been removed by surgery.

Tafinlar in combination with trametinib is also used to treat a type of lung cancer called non-small cell lung cancer (NSCLC).

Both cancers have a particular change (mutation) in a gene called BRAF at the V600 position. This mutation in the gene may have caused the cancer to develop. Your medicine targets proteins made from this mutated gene and slows down or stops the development of your cancer.

2. What you need to know before you take Tafinlar

Tafinlar should only be used to treat melanomas and NSCLC with the BRAF mutation. Therefore before starting treatment your doctor will test for this mutation.

If your doctor decides that you will receive treatment with the combination of Tafinlar and trametinib, **read the trametinib leaflet carefully as well as this leaflet.**

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

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

Check with your doctor if you think this applies to you.

Warnings and precautions
Talk to your doctor before taking Tafinlar. Your doctor needs to know if you:
- have any **liver problems.**
- have or have ever had any **kidney problems**.
  Your doctor may take blood samples to monitor your liver and kidney function while you are taking Tafinlar.
- **have had a different type of cancer other than melanoma or NSCLC**, as you may be at greater risk of developing other skin and non-skin cancers when taking Tafinlar.

Before you take Tafinlar in combination with trametinib your doctor also needs to know if you:
- have heart problems such as heart failure or problems with the way your heart beats.
- have eye problems including blockage of the vein draining the eye (retinal vein occlusion) or swelling in the eye which may be caused by fluid leakage (chorioretinopathy).
- have any lung or breathing problems, including difficulty in breathing often accompanied by a dry cough, shortness of breath and fatigue.
- have or have had any gastrointestinal problems such as diverticulitis (inflamed pouches in the colon) or metastases to the gastrointestinal tract.

Check with your doctor if you think any of these may apply to you.

Conditions you may need to look out for
Some people taking Tafinlar develop other conditions, which can be serious. You need to know about important signs and symptoms to look out for while you're taking this medicine. Some of these symptoms (bleeding, fever, changes to your skin and eye problems) are briefly mentioned in this section, but more detailed information is found in section 4, "Possible side effects".

Bleeding
Taking Tafinlar in combination with trametinib can cause serious bleeding including in your brain, the digestive system (such as stomach, rectum or intestine), lungs, and other organs, and can lead to death. Symptoms may include:
- headaches, dizziness, or feeling weak
- passing blood in the stools or passing black stools
- passing blood in the urine
- stomach pain
- coughing / vomiting up blood

Tell your doctor as soon as possible if you get any of these symptoms.

Fever
Taking Tafinlar or the combination of Tafinlar and trametinib may cause fever, although it is more likely if you are taking the combination treatment (see also section 4). In some cases, people with fever may develop low blood pressure, dizziness or other symptoms.

Tell your doctor immediately if you get a temperature above 38ºC or if you feel a fever coming on while you are taking this medicine.

Heart disorder
Tafinlar can cause heart problems, or make existing heart problems worse (see also "Heart conditions" in section 4), in people taking Tafinlar in combination with trametinib.

Tell your doctor if you have a heart disorder. Your doctor will run tests to check that your heart is working properly before and during your treatment with Tafinlar in combination with trametinib. Tell your doctor immediately if it feels like your heart is pounding, racing, or beating irregularly, or if you experience dizziness, tiredness, light-headedness, shortness of breath or swelling in the legs. If necessary, your doctor may decide to interrupt your treatment or to stop it altogether.

Changes in your skin which may indicate new skin cancer
Your doctor will check your skin before you start taking this medicine and regularly while you are taking it. **Tell your doctor immediately** if you notice any changes to your skin while taking this medicine or after treatment (see also section 4).

Eye problems
You should have your eyes examined by your doctor while you are taking this medicine.
Tell your doctor immediately if you get eye redness and irritation, blurred vision, eye pain or other vision changes during your treatment (see also section 4).
Tafinlar when given in combination with trametinib can cause eye problems including blindness. Trametinib is not recommended if you have ever had blockage of the vein draining the eye (retinal vein occlusion). Tell your doctor immediately if you get the following symptoms of eye problems: blurred vision, loss of vision or other vision changes, coloured dots in your vision or halos (seeing blurred outline around objects) during your treatment. If necessary, your doctor may decide to interrupt your treatment or to stop it altogether.

➔ **Read the information about fever, changes in your skin and eye problems in section 4 of this leaflet. Tell your doctor, pharmacist or nurse if you get any of the signs and symptoms listed.**

Liver problems
Tafinlar in combination with trametinib can cause problems with your liver which may develop into serious conditions such as hepatitis and liver failure, which may be fatal. Your doctor will monitor you periodically. Signs that your liver may not be working properly may include:
- loss of appetite
- feeling sick (nausea)
- being sick (vomiting)
- pain in your stomach (abdomen)
- yellowing of your skin or the whites of your eyes (jaundice)
- dark-coloured urine
- itching of your skin

Tell your doctor as soon as possible if you get any of these symptoms

Muscle pain
Tafinlar in combination with trametinib can result in the breakdown of muscle (rhabdomyolysis). **Tell your doctor** as soon as possible if you get any of these symptoms.
- muscle pain
- dark urine due to kidney damage

If necessary, your doctor may decide to interrupt your treatment or to stop it altogether.

Hole in the stomach or intestine (perforation)
Taking the combination of Tafinlar and trametinib may increase the risk of developing holes in the gut wall. **Tell your doctor** as soon as possible if you have severe abdominal pain.

Serious skin reactions
Serious skin reactions have been reported in people taking Tafinlar in combination with trametinib. Tell your doctor immediately if you notice any changes to your skin (see section 4 for symptoms to be aware of).

Inflammatory disease mainly affecting the skin, lung, eyes and lymph nodes
An inflammatory disease mainly affecting the skin, lung, eyes and lymph nodes (sarcoidosis). Common symptoms of sarcoidosis may include coughing, shortness of breath, swollen lymph nodes, visual disturbances, fever, fatigue, pain and swelling in the joints and tender bumps on your skin. Tell your doctor if you get any of these symptoms.

Immune system disorders
Tafinlar in combination with trametinib may in rare instances cause a condition (haemophagocytic lymphohistiocytosis or HLH) in which the immune system makes too many infection-fighting cells, called histiocytes and lymphocytes. Symptoms may include enlarged liver and/or spleen, skin rash, lymph node enlargement, breathing problems, easy bruising, kidney abnormalities, and heart problems. Tell your doctor immediately if you experience multiple symptoms such as fever, swollen lymph glands, bruising or skin rash, at the same time.

Tumour lysis syndrome
If you experience the following symptoms, tell your doctor immediately as this can be a life-threatening condition: nausea, shortness of breath, irregular heartbeat, muscular cramps, seizures, clouding of urine, decrease in urine output and tiredness. These may be caused by a group of metabolic complications that can occur during treatment of cancer that are caused by the breakdown products of dying cancer cells (tumour lysis syndrome or TLS) and can lead to changes in kidney function (see also section 4).

Children and adolescents
Tafinlar is not recommended for children and adolescents. The effects of Tafinlar in people younger than 18 years old are not known.

Other medicines and Tafinlar
Before starting treatment, tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription.

Some medicines may affect how Tafinlar works, or make it more likely that you will have side effects. Tafinlar can also affect how some other medicines work. These include:
- **birth control medicines** (*contraceptives)* containing hormones, such as pills, injections, or patches
- warfarin and acenocoumarol, medicines used to **thin the blood**
- digoxin, used to treat **heart conditions**
- medicines to treat **fungal infections**, such as ketoconazole, itraconazole, voriconazole and posaconazole
- some calcium channel blockers, used to treat **high blood pressure**, such as diltiazem, felodipine, nicardipine, nifedipine or verapamil
- medicines to treat **cancer,** such as cabazitaxel
- some medicines to **lower fat (lipids)** in the blood stream, such as gemfibrozil
- some medicines used to treat certain **psychiatric conditions**, such as haloperidol
- some **antibiotics**, such as clarithromycin, doxycyline and telithromycin
- some medicines **for tuberculosis** (TB), such as rifampicin
- some medicines that reduce **cholesterol** levels, such as atorvastatin and simvastatin
- some **immunosuppressants**, such as cyclosporin, tacrolimus and sirolimus
- some **anti-inflammatory** medicines, such as dexamethasone and methylprednisolone
- some medicines to treat **HIV**, such as ritonavir, amprenavir, indinavir, darunavir, delavirdine, efavirenz, fosamprenavir, lopinavir, nelfinavir, tipranavir, saquinavir and atazanavir
- some medicines used for **pain relief**, such as fentanyl and methadone
- medicines to treat seizures (**epilepsy**), such as phenytoin, phenobarbital, primidone, valproic acid or carbamazepine
- **antidepressant** medicines such as nefazodone and the herbal medicine St John's wort (*Hypericum perforatum)*

➔ **Tell your doctor, pharmacist or nurse** if you are taking any of these (or if you are not sure). Your doctor may decide to adjust your dose.

Keep a list of the medicines you take, so you can show it to your doctor, pharmacist or nurse.

Pregnancy, breast-feeding and fertility
Tafinlar is not recommended during pregnancy.

- If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before taking this medicine. Tafinlar is not recommended during pregnancy, since it may potentially harm an unborn baby.
- If you are a woman who could become pregnant you must use a reliable birth control method while you are taking Tafinlar and for at least 2 weeks after you stop taking it and for at least 16 weeks following the last dose of trametinib when given in combination with Tafinlar.
- Birth control medicines containing hormones (such as pills, injections or patches) may not work as well while you are taking Tafinlar or combination treatment (Tafinlar as well as trametinib). You need to use another effective method of birth control so you do not become pregnant while you are taking this medicine. Ask your doctor, pharmacist or nurse for advice.
- If you do become pregnant while you are taking this medicine, tell your doctor immediately.

Tafinlar is not recommended while breast-feeding.
It is not known whether the ingredients of this medicine can pass into breast milk.
If you are breast-feeding, or planning to breast-feed, you must tell your doctor. You and your doctor will decide if you will take this medicine or breast-feed.

Fertility – both men and women
Animal studies have shown that the active substance dabrafenib may permanently reduce male fertility. In addition, men who are taking Tafinlar may have a reduced sperm count and their sperm count may not return to normal levels after they stop taking this medicine.

Prior to starting treatment with Tafinlar, talk to your doctor about options to improve your chances to have children in the future.

Taking Tafinlar with trametinib: trametinib may impair fertility in both men and women.

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

Driving and using machines
Tafinlar can have side effects that may affect your ability to drive or use machines.
Avoid driving or using machines if you have problems with your vision or if you feel tired or weak, or if your energy levels are low.
Descriptions of these effects can be found in sections 2 and 4.
Discuss with your doctor, pharmacist or nurse if you are unsure about anything. Even your disease, symptoms and treatment situation may affect your ability to drive or use machines.

3. How to take Tafinlar

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

How much to take
The usual dose of Tafinlar either used alone or in combination with trametinib is two 75 mg capsules twice a day (corresponding to a daily dose of 300 mg). The recommended dose of trametinib, when used in combination with Tafinlar, is 2 mg once a day.

Your doctor may decide that you should take a lower dose if you get side effects.

Tafinlar are also available as 50 mg capsules if a dose reduction is recommended.

Don’t take more Tafinlar than your doctor has recommended, since this may increase the risk of side effects.

How to take it
Swallow the capsules whole with water, one after the other.

Don’t chew or crush the capsules, since they will otherwise lose their effect.

Take Tafinlar twice a day, on an empty stomach. This means that
- after taking Tafinlar, you must wait **at least 1 hour** before eating.
- after eating, you must wait **at least 2 hours** before taking Tafinlar.

Take Tafinlar in the morning and evening, about 12 hours apart. Take your morning and evening doses of Tafinlar at the same times every day. This will increase the chance of remembering to take the capsules.

Don’t take the morning and evening doses of Tafinlar at the same time.

If you take more Tafinlar than you should
If you take too many capsules of Tafinlar, **contact your doctor, pharmacist or nurse for advice.** If possible, show them the Tafinlar pack with this leaflet.

If you forget to take Tafinlar
If the missed dose is less than 6 hours late, take it as soon as you remember.
If the missed dose is more than 6 hours late, skip that dose and take your next dose at the usual time. Then carry on taking your capsules at regular times as usual.
Do not take a double dose to make up for a forgotten dose.

If you stop taking Tafinlar
Take Tafinlar for as long as your doctor recommends. Do not stop unless your doctor, pharmacist or nurse advises you to.

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

How should you take Tafinlar in combination with trametinib
- Take Tafinlar in combination with trametinib exactly as your doctor, pharmacist or nurse tells you. Do not change your dose or stop Tafinlar or trametinib unless your doctor, pharmacist or nurse tells you to.
- Take **Tafinlar twice daily** and take **trametinib once daily**. It may be good for you to get into the habit of taking both medicines at the same times each day. The Tafinlar doses should be about 12 hours apart. Trametinib when given in combination with Tafinlar should be taken with **either** the morning dose of Tafinlar **or** the evening dose of Tafinlar.
- Take Tafinlar and trametinib on an empty stomach, at least one hour before or two hours after a meal. Take whole with a full glass of water.
- If you miss a dose of Tafinlar or trametinib, take it as soon as you remember. Do not make up for missed doses and just take your next dose at your regular time:
    - If it is less than 6 hours to your next scheduled dose of Tafinlar, which is taken twice daily.
    - If it is less than 12 hours to your next scheduled dose of trametinib, which is taken once daily.
- If you take too much Tafinlar or trametinib, immediately contact your doctor, pharmacist or nurse. Take Tafinlar capsules and trametinib tablets with you when possible. If possible, show them the Tafinlar and trametinib pack with each leaflet.
- If you get side effects your doctor may decide that you should take lower doses of Tafinlar and / or trametinib. Take the doses of Tafinlar and trametinib exactly as your doctor, pharmacist or nurse tells you.

4. Possible side effects

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

Possible serious side effects
Bleeding problems
Tafinlar can cause serious bleeding problems, especially in your brain when taken in combination with trametinib. Call your doctor or nurse and get medical help right away if you have any unusual signs of bleeding, including:
- headaches, dizziness, or weakness
- coughing up of blood or blood clots
- vomit containing blood or that looks like "coffee grounds"
- red or black stools that look like tar

Fever
Taking Tafinlar may cause fever in more than 1 in 10 people. **Tell your doctor, pharmacist or nurse immediately if you get a fever (temperature 38ºC or above) or if you feel a fever coming on while you are taking this medicine**. They will carry out tests to find out if there are other causes for the fever and treat the problem.

In some cases, people with fever may develop low blood pressure and dizziness. If the fever is severe, your doctor may recommend that you stop taking Tafinlar, or Tafinlar and trametinib, while they treat the fever with other medicines. Once the fever is controlled, your doctor may recommend that you start taking Tafinlar again.

Heart conditions
Tafinlar can affect how well your heart pumps blood when taken in combination with trametinib. It is more likely to affect people who have an existing heart problem. You will be checked for any heart problems while you are taking Tafinlar in combination with trametinib. Signs and symptoms of heart problems include:
- feeling like your heart is pounding, racing, or beating irregularly
- dizziness
- tiredness
- feeling lightheaded
- shortness of breath
- swelling in the legs

Tell your doctor as soon as possible if you get any of these symptoms, either for the first time or if they get worse.

Changes in your skin
Serious skin reactions have been reported in people taking Tafinlar in combination with trametinib (frequency not known). If you notice any of the following:
- reddish patches on the trunk that are circular or target-shaped, with central blisters. Skin peeling. Ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome).
- widespread rash, fever, and enlarged lymph nodes (DRESS-syndrome or drug hypersensitivity syndrome).

  ➔ **stop using the medicine and seek medical attention immediately.**

Patients taking Tafinlar may commonly (may affect up to 1 in 10 people) develop a different type of skin cancer called *cutaneous squamous cell carcinoma (cuSCC)*. Others may develop a type of skin cancer called *basal cell carcinoma (BCC)*. Usually, these skin changes remain local and can be removed with surgery and treatment with Tafinlar can be continued without interruption.

Some people taking Tafinlar may also notice that new melanomas have appeared. These melanomas are usually removed by surgery and treatment with Tafinlar can be continued without interruption.

Your doctor will check your skin before you start taking Tafinlar, then check it again every month while you are taking this medicine and for 6 months after you stop taking it. This is to look for any new skin cancers.

Your doctor will also check your head, your neck, your mouth, your lymph glands and you will have scans of your chest and stomach area (called CT scans) regularly. You may also have blood tests. These checks are to detect if any other cancer, including squamous cell carcinoma, develops inside your body. Pelvic examinations (for women) and anal examinations are also recommended before and at the end of your treatment.

Check your skin regularly whilst taking Tafinlar
If you notice any of the following:

- new wart
- skin sore or reddish bump that bleeds or does not heal
- change of a mole in size or colour
  - ➔ **Tell your doctor, pharmacist or nurse as soon as possible** if you get any of these symptoms - either for the first time or if they get worse.

Skin reactions (rash) can happen while taking Tafinlar in combination with trametinib. **Talk to your doctor** if you get a skin rash while taking Tafinlar in combination with trametinib.

Eye problems
Patients taking Tafinlar alone can uncommonly (may affect up to 1 in 100 people) develop an eye problem called uveitis, which could damage your vision if it is not treated. This may occur commonly (may affect up to 1 in 10 people) in patients taking Tafinlar in combination with trametinib.

Uveitis may develop rapidly and the symptoms include:

- eye redness and irritation
- blurred vision
- eye pain
- increased sensitivity to light
- floating spots before the eyes
  - ➔ **Contact your doctor, pharmacist or nurse immediately** if you get these symptoms.

Tafinlar can cause eye problems when taken in combination with trametinib. Trametinib is not recommended if you have ever had a blockage of the vein draining the eye (retinal vein occlusion). Your doctor may advise an eye examination before you take Tafinlar in combination with trametinib and while you are taking it. Your doctor may ask you to stop taking trametinib or refer you to a specialist, if you develop signs and symptoms in your vision that include:

- loss of vision
- eye redness and irritation
- coloured dots in your vision
- halo (seeing a blurred outline around objects)
- blurred vision
  - ➔ **Contact your doctor, pharmacist or nurse immediately if you get these symptoms.**

It is very important to tell your doctor, pharmacist or nurse immediately if you develop these symptoms, especially if you have a painful, red eye that does not clear up quickly. They may arrange for you to see a specialist eye doctor for a complete eye examination.

Immune system disorders
If you experience multiple symptoms such as fever, swollen lymph glands, bruising or skin rash, at the same time, tell your doctor immediately. These may be signs of a condition where the immune system

makes too many infection-fighting cells called histiocytes and lymphocytes that may cause various symptoms (haemophagocytic lymphohistiocytosis), see section 2 (frequency rare).

Tumour lysis syndrome
Tell your doctor immediately if you experience the following symptoms: nausea, shortness of breath, irregular heartbeat, muscular cramps, seizures, clouding of urine, decrease in urine output and tiredness. These may be signs of a condition resulting from a rapid breakdown of cancer cells which in some people may be fatal (tumour lysis syndrome or TLS), see section 2 (frequency not known).

Possible side effects in patients taking Tafinlar alone

The side effects that you may see when you take Tafinlar alone are as follows:

Very common side effects (may affect more than 1 in 10 people)
- Papilloma (a type of skin tumour which is usually not harmful)
- Decreased appetite
- Headache
- Cough
- Feeling sick (nausea), being sick (vomiting)
- Diarrhoea
- Thickening of the outer layers of the skin
- Unusual hair loss or thinning
- Rash
- Reddening and swelling of the palms, fingers and soles of the feet (see "Changes in your skin" earlier in section 4)
- Joint pain, muscle pain, or pain in the hands or feet
- Fever (see "Fever" earlier in section 4)
- Lack of energy
- Chills
- Feeling weak

Common side effects (may affect up to 1 in 10 people)
- Skin effects including cutaneous squamous cell carcinoma (a type of skin cancer), wart-like growths, skin tags, uncontrolled skin growths or lesions (basal cell carcinoma), dry skin, itching or redness of skin, patches of thick, scaly, or crusty skin (actinic keratosis), skin lesions, skin reddening, increased sensitivity of the skin to sun
- Constipation
- Flu-like illness
- Problem with the nerves that can produce pain, loss of sensation or tingling in hands and feet and/or muscle weakness (peripheral neuropathy)

Common side effects that may show up in your blood tests
- Low levels of phosphate (hypophosphataemia) in the blood
- Increase in blood sugar level (hyperglycaemia)

Uncommon side effects (may affect up to 1 in 100 people)
- New melanoma
- Allergic reaction (hypersensitivity)
- Inflammation of the eye (uveitis, see "Eye problems" earlier in section 4))
- Inflammation of the pancreas (causing strong abdominal pain)
- Inflammation of the fatty layer under the skin (panniculitis)
- Kidney problems, kidney failure
- Inflammation of kidneys
- Raised, painful, red to dark reddish-purple skin patches or sores that appear mainly on the arms, legs, face and neck, with a fever (signs of acute febrile neutrophilic dermatosis)

Possible side effects when Tafinlar and trametinib are taken together

When you take Tafinlar and trametinib together you may get any of the side effects given in the lists above, although the frequency may change (increase or decrease).

You may also get **additional side effects due to taking trametinib** at the same time as Tafinlar.

Tell your doctor as soon as possible if you get any of these symptoms, either for the first time or if they get worse.

Please also read the trametinib package leaflet for details of the side effects you may get with trametinib.

The side effects that you may see when you take Tafinlar in combination with trametinib are as follows:

Very common side effects (may affect more than 1 in 10 people)
- Nasal and throat inflammation
- Decreased appetite
- Headache
- Dizziness
- High blood pressure (hypertension)
- Bleeding, at various sites in the body, which may be mild or serious (haemorrhage)
- Cough
- Stomach ache
- Constipation
- Diarrhoea
- Feeling sick (nausea), being sick (vomiting)
- Rash, dry skin, itching, skin reddening
- Joint pain, muscle pain, or pain in the hands or feet
- Muscle spasms
- Lack of energy, feeling weak
- Chills
- Swelling of the hands or feet (oedema peripheral)
- Fever
- Flu-like illness

Very common side effects that may show up in your blood tests
- Abnormal blood test results related to the liver

Common side effects (may affect up to 1 in 10 people)
- Infection of the urinary system
- Skin effects including infection of the skin (cellulitis), inflammation of hair follicles in the skin, nail disorders such as nail bed changes, nail pain, infection and swelling of the cuticles, skin rash with pus-filled blisters, cutaneous squamous cell carcinoma (a type of skin cancer), papilloma (a type of skin tumour which is usually not harmful), wart-like growths, increased sensitivity of the skin to sun (see also “Changes in your skin” earlier in section 4)
- Dehydration (low levels of water or fluid)
- Blurred vision, eyesight problems, inflammation of the eye (uveitis)
- Heart pumping less efficiently
- Low blood pressure (hypotension)
- Localised tissue swelling
- Shortness of breath
- Dry mouth

- Sore mouth or mouth ulcers, inflammation of mucous membranes
- Acne-like problems
- Thickening of the outer layer of the skin (hyperkeratosis), patches of thick, scaly, or crusty skin (actinic keratosis), chapping or cracking of the skin
- Increased sweating, night sweats
- Unusual hair loss or thinning
- Red, painful hands and feet
- Inflammation of the fatty layer under the skin (panniculitis)
- Inflammation of the mucosa
- Swelling of the face
- Problem with the nerves that can produce pain, loss of sensation or tingling in hands and feet and/or muscle weakness (peripheral neuropathy)
- Irregular heartbeat (atrioventricular block)

Common side effects that may show up in your blood tests
- Low levels of white blood cells
- Decrease in number of red blood cells (anaemia), blood platelets (cells that help blood to clot), and a type of white blood cells (leukopenia)
- Low levels of sodium (hyponatraemia) or phosphate (hypophosphataemia) in the blood
- Increase in blood sugar level
- Increase in creatine phosphokinase, an enzyme found mainly in heart, brain, and skeletal muscle
- Increase in some substances (enzymes) produced by the liver

Uncommon side effects (may affect up to 1 in 100 people)
- Appearance of new skin cancer (melanoma)
- Skin tags
- Allergic reactions (hypersensitivity)
- Eye changes including swelling in the eye caused by fluid leakage (chorioretinopathy), separation of the light-sensitive membrane in the back of the eye (the retina) from its supporting layers (retinal detachment) and swelling around the eyes
- Heart rate that is lower than the normal range and/or a decrease in heart rate
- Inflammation of the lung (pneumonitis)
- Inflammation of pancreas
- Inflammation of the intestines (colitis)
- Kidney failure
- Inflammation of the kidneys
- Inflammatory disease mainly affecting the skin, lung, eyes and lymph nodes (sarcoidosis)
- Raised, painful, red to dark reddish-purple skin patches or sores that appear mainly on the arms, legs, face and neck, with a fever (signs of acute febrile neutrophilic dermatosis)

Rare side effects (may affect up to 1 in 1 000 people)
- A hole (perforation) in the stomach or intestines

Not known (frequency cannot be estimated from the available data)
- Inflammation of the heart muscle (myocarditis) which can result in breathlessness, fever, palpitations and chest pain
- Inflamed, flaky skin (exfoliative dermatitis)

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tafinlar

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 bottle label and the carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Tafinlar contains
- The active substance is dabrafenib. Each hard capsule contains dabrafenib mesilate equivalent to 50 mg or 75 mg of dabrafenib.
- The other ingredients are: microcrystalline cellulose, magnesium stearate, colloidal silicone dioxide, red iron oxide (E172), titanium dioxide (E171), and hypromellose (E464). Further, the capsules are printed with black ink that contains black iron oxide (E172) shellac and propylene glycol.

What Tafinlar looks like and contents of the pack
Tafinlar 50 mg hard capsules are opaque dark red and imprinted with “GS TEW” and “50 mg”.
Tafinlar 75 mg hard capsules are opaque dark pink and imprinted with “GS LHF” and “75 mg”.

The bottles are opaque white plastic with threaded plastic closures.

The bottles also include a silica gel desiccant in a small cylinder-shaped container. The desiccant must be kept inside the bottle and must not be eaten.

Tafinlar 50 mg and 75 mg hard capsules are available in packs containing 28 or 120 capsules. Not all pack sizes may be marketed in your country.

Marketing Authorisation Holder
Novartis Pharmaceuticals UK Limited,
2nd Floor, The WestWorks Building, White City Place,
195 Wood Lane,
London,
W12 7FQ
United Kingdom

Manufacturers
Novartis Pharmaceuticals UK Limited,
2nd Floor, The WestWorks Building, White City Place,
195 Wood Lane,
London,
W12 7FQ
United Kingdom

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

United Kingdom
Novartis Pharmaceuticals UK Ltd.

Tel: +44 1276 698370

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