UNOVARTIS

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE

PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986 The medicine is dispensed with a doctor's prescription only

TAFINLAR[®] 50 ma Each hard capsule contains: Dabrafenib (as mesilate) 50 mg

TAFINLAR[®] 75 mg

Each hard capsule contains: Dabrafenib (as mesilate) 75 mg

The list of additional ingredients is detailed in section 6.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is simila

1. WHAT IS THE MEDICINE INTENDED 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, to treat adults with a type of skin cancer called melanoma that has spread to other parts of the body or cannot be surgically resected.

Tafinlar in combination with trametinib is also used to prevent recurrence of stage 3 melanoma in adults after the lesion has been fully removed by surgery.

who have advanced-stage lung cancer called non-small cell lung cancer (NSCLC).

afinlar in combination with trametinib is indicated to treat a type of thyroid cancer called anaplastic thyroid cancer (ATC) that has a mutation in the BRAF gene (BRAF V600E mutation), and which has spread to other parts of the body or locally advanced and with no satisfactory results from local treatment.

Therapeutic group: protein kinase inhibitor.

In the three types of cancer there is a particular change (mutation) in the gene called BRAF at the V600 position

The mutation in this gene may have caused the cancer to develop Your medicine targets proteins made from this modified gene and slows down or stops the development of your cancer.

2. BEFORE USING THE MEDICINE

Tafinlar should only be used to treat melanomas, non-small cell lung cancer (NSCLC) and anaplastic thyroid cancer (ATC) 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, refer to the doctor or pharmacist.

Do not use the medicine if:

you are sensitive (allergic) to dabrafenib, or any of the other ngredients of the medicine (listed in section 6). Check with your doctor if you think this applies to you.

Special warnings regarding use of the medicine

Before the treatment with Tafinlar, tell the doctor 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, non-small cell lung cancer (NSCLC) or anaplastic thyroid cancer (ATC) 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 needs to know if: vou have heart problems such as heart failure or problems with the
- way your heart beats. you 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). you have any lung or breathing problems, including difficulty in
- breathing occasionally accompanied by a dry cough, shortness of breath and fatique.
- you have or have had problems in the digestive system such as diverticulitis (inflamed pouches in the large intestine) or metastases in the digestive system.

Check with your doctor if you think any of these apply to you. Conditions you 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 are taking this medicine. Some of these symptoms (bleeding, fever, changes in your skin and eye problems) are briefly mentioned in this section, but more detailed information is found in section 4. "Side effects"

Bleedina

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

- blood in the stools or black stools
- blood in the urine stomach pain
- coughing/vomiting up blood

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

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 vou**

while you are taking this medicine Heart problems

 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 problem. 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 as if your heart is pounding, racing, or beating irregularly, or if you experience dizziness, tiredness, lightheadedness, shortness of breath or swelling of the legs. If necessary, your doctor may decide to interrupt your treatment temporarily 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 in your skin while taking this medicine or after treatment (see also section 4).

Eve problems You should undergo an eye examination by your doctor while you are taking this medicine.

Tell your doctor immediately if you get eve redness and irritation. red 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, colored dots in your vision or halos (seeing blurred outlines around objects) during your treatment. If necessary, your Tafinlar in combination with trametinib is also used to treat adults doctor may decide to interrupt your treatment temporarily 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

or pharmacist if you get any of the signs and symptoms listed. Liver problems

Tafinlar in combination with trametinib, can cause problems with you 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 Nausea
- Vomiting
- Stomach pain
- Yellowing of the skin or the whites of your eyes (jaundice) Dark-colored urine
- Itching of your skin

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

Muscle pain

Tafinlar in combination with trametinib, can result in the breakdown of muscle tissue (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

temporarily or to stop it altogether

Hole in the stomach or intestine (perforation)

Taking a combination of Tafinlar with trametinib may increase the risk of development of perforations in the wall of the intestine. Tell the doctor as soon as possible if you experience severe

abdominal pain.

Serious skin reactions Serious skin reactions have been reported in people taking Tafinlar in combination with trametinib. Tell the doctor immediately if you notice any changes in 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.

Children and adolescents

Tafinlar is not intended for children and adolescents. The effects of Your doctor may decide that you should take a lower dose if you Tafinlar in children and adolescents younger than 18 years old are not known.

Drug interactions

recommended Before starting treatment, tell your doctor or pharmacist Do not exceed the recommended dose, since this may increase if you are taking, have recently taken or might take any other medicines, including non-prescription medicines and the risk of side effects. nutritional supplements. Swallow the capsules whole with water, one after the other.

Some medicines may affect how Tafinlar works, or increase the risk of side effects. Tafinlar can also affect how 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 problems

 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 bloodstream, such as aemfibrozil

• some medicines used to treat certain **psychiatric problems**, such If you forget to take the medicine as haloperidol

 some antibiotics, such as clarithromycin, doxycycline and telithromycin

• some medicines for treating tuberculosis (TB), such as rifampicin • some medicines that reduce **cholesterol** levels, such as atorvastatin at the regular times, as usual. and simvastatin

doctor immediately if you get a temperature above 38.5°C • some immunosuppressants, such as cyclosporin, tacrolimus and If you stop taking the medicine sirolimus

• some anti-inflammatory medicines, such as dexamethasone and methylprednisolone

 some medicines to treat HIV such as ritonavir amprenavir. ndinavir, darunavir, delavirdine, efavirenz, fosamprenavir, lopinavir, them 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

•anti-depressant medicines such as nefazodone and the herbal medicine St. John's wort (Hypericum) some anti-anxiety (hypnotic) medicines such as diazepam, midazolam zolnid

Tell your doctor or pharmacist if you are taking any of these edicines (or if you are not sure). Your doctor may decide to adjust vour dosage.

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

Use of the medicine and food

doctor or pharmacist for advice

vour doctor immediately.

this medicine or breast-feed.

both men and women.

or use machines.

only.

a day

capsules.

emember

time

develop side effects

Method of administration

dose. Take your next dose at the usual time.

If you accidentally took a higher dosage

Driving and using machines

Fertility - both men and women

sperm count, ask your doctor or pharmacist.

may affect your ability to drive or use machines.

3. HOW SHOULD YOU USE THE MEDICINE?

treatment regimen of the preparation

with Tafinlar.

into breast milk

Take Tafinlar 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 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 or pharmacist for advice before taking his 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

following the last dose of trametinib, when given in combination

or patches) may not work as effectively 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

If you do become pregnant while you are taking this medicine, tell

It is not known whether the ingredients of this medicine can pass

If you are breast-feeding or planning to breast-feed you must tell

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

Taking Tafinlar with trametinib: trametinib may impair fertility in

If you have any further questions on the effect of this medicine on

Tafinlar can have side effects that may affect your ability to drive

Avoid driving or using machines if you have problems with your vision

Discuss with your doctor or pharmacist if you are unsure about

anything. Even your disease, symptoms and treatment situation

Always use Tafinlar according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and

The dosage and treatment regimen will be determined by the doctor

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

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

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

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

Don't take the morning and evening doses of Tafinlar at the same

In case of vomiting after taking the medicine, do not take another

If you took an overdose or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital

emergency room, and bring the package of the medicine with you.

If the missed dose is less than 6 hours late, take it as soon as you

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

Don't take a double dose to make up for a missed dose

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.

options to improve your chances to have children in the future.

your doctor. You and your doctor will decide whether you will take

Tafinlar is not recommended while breast-feeding

Birth control medicines containing hormones (such as pills, injections from any of them.

glass of water

Fever

nediately

your treatment.

new wart

Eve problems

blurred vision

eve pain

Adhere to the treatment regimen as recommended by the doctor. Don't stop unless your doctor or pharmacist advises you to.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need

If you have further questions regarding use of the medicine. consult a doctor or pharmacist.

- How should you take Tafinlar in combination with trametinib Take Tafinlar in combination with trametinib exactly as your doctor tells you. Do not change your dose and don't stop taking Tafinlar or trametinib unless your doctor tells you.
- Take Tafinlar twice daily and take trametinib once daily. It may be better for you to adopt the habit of taking both medicines at the same time each day. The Tafinlar doses should be about 12 hours apart. Trametinib, when given in combination with Tafinlar, should preferably 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 them whole with a full
- 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 there are less than 6 hours until your next scheduled dose of Tafinlar, which is taken twice daily
- if there are less than 12 hours until your next scheduled dose of trametinib, which is taken once daily.
- If you get side effects, your doctor may decide that you should take a lower dosage of Tafinlar and/or trametinib. Take the doses of Tafinlar and trametinib exactly as your doctor tells you.
- If you have further questions regarding use of the medicine, 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 **4. SIDE EFFECTS**
 - As with any medicine use of Tafinlar may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer

Possible side effects in patients taking Tafinlar alone Possible serious side effects

Taking Tafinlar may cause fever in more than one in 10 users. **Tell** your doctor immediately if you develop a fever (temperature of 38.5°C or above) while you are taking this medicine. The tor will perform tests to find out if there are other causes for the fever and will 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 while treating the fever with other medicines. Once the fever is controlled, your doctor may recommend that you start taking Tafinlar again. Changes in your skin

Serious skin reactions have been reported in people taking Tafinlar in combination with trametinib (frequency unknown). If you notice any of the following:

- Reddish patches on the skin that are circular or target-shaped, with central blisters. Skin peeling. Ulcer in the 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 (DRESSsyndrome or drug hypersensitivity syndrome

Stop using the medicine and seek medical attention

- Patients taking Tafinlar may commonly (1-10 in 100 users) develop a different type of skin cancer called cutaneous squamous cel 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, and will 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 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
- Check your skin regularly whilst taking Tafinlar If you notice any of the following:
- skin sore or reddish bump that bleeds or does not heal change of a mole in size or color
- Tell your doctor 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 notice a skin rash while taking Tafinlar in combination with trametinib.
- Patients taking Tafinlar alone can uncommonly (1-10 in 1.000 users) develop an eye problem called uveitis, which could damage your vision if it is not treated. This condition may occur commonly (1-10 in 100 users) in patients taking Tafinlar in combination with trametinib. Uveitis may develop rapidly and the symptoms include: eve redness and irritation

increased sensitivity to light

- floating spots before the eves
- Contact your doctor immediately if you develop these symptoms. Tafinlar can cause eve problems when taken in combination with trametinib. Trametinib is not recommended if you have ever had a doctor may advise an eye examination before you take Tafinlar in combination with trametinib and while you are taking them. Your •Tiredness, lack of energy, weakness doctor may ask you to stop taking trametinib or refer you to a • Chills

specialist, if you develop signs and symptoms in your vision that include

- loss of vision • eye redness or itching
- colored dots in your vision
- halo (seeing blurred outlines around objects) blurred vision

Contact your doctor or pharmacist immediately if you get these symptoms.

It is very important to tell your doctor immediately if you develop these symptoms, especially if you have a painful, red eye that does not clear up quickly. He may refer you to a specialist eve doctor for a complete eve examination

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

- Very common side effects (may occur in more than one in 10 users): Papilloma (a type of skin tumor which is usually not harmful)
- Decreased appetite Headache
- Cough
- Nausea, vomiting
- Diarrhea
- 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)
- loint pain, muscle pain, or pain in the hands or feet
- Fever (see "Fever" earlier in section 4)
- Sense of fatigue, lack of energy Chills

Feeling weak

- Common side effects (may occur in 1-10 in 100 users):
- 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 the skin, patches of thick, scaly, or crusty skin (actinic keratosis), skin lesions, skin redness, increased sensitivity of the skin to sun Constination
- A flu-like illness
- Common side effects that may show up in your blood tests
- · Low levels of phosphate (hypophosphatemia) in the blood Increase in blood sugar level (hyperglycemia)
- Uncommon side effects (may occur in 1-10 in 1.000 users): 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

Possible side effects when Tafinlar and trametinib are taken togethe

When you take Tafinlar and trametinib together, you may get any of the side effects given in the lists above, although their 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.

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 immediately and get medical help right away if you have any unusual signs of bleeding, including:

- headache, dizziness, or weakness
- coughing up blood or blood clots

vomit containing blood or that looks like "coffee grounds" red or black stools that look like tar

Heart conditions

Tafinlar can affect the way 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 of the leas

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

The other side effects that you may see when you take Tafinlar in combination with trametinib are as follows: Very common side effects (may occur in more than one in 10 users):

- 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 (hemorrhage) Cough
- Stomach ache
- Constipation
- Diarrhea
- Nausea, vomiting
- Rash, dry skin, itching, skin reddening
- blockage of the vein draining the eye (retinal vein occlusion). Your Joint pain, muscle pain, or pain in the hands or feet Muscle spasms

- Swelling of the hands or feet (peripheral edema)
- Fever • A flu-like illness
- Very common side effects that may show up in your blood tests:

• 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 wit

nus-filled blisters, cutaneous squamous cell carcinoma (a type o

skin cancer), papilloma (a type of skin tumor which is usually no

harmful), wart-like growths, increased sensitivity of the skin to sur

• Blurred vision, eyesight problems, inflammation of the eye (uveitis)

· Sore mouth or mouth ulcers, inflammation of mucous membranes

• Thickening of the outer layer of the skin (hyperkeratosis), patche

Inflammation of the fatty layer under the skin (panniculitis)

Common side effects that may show up in your blood tests:

• Decrease in number of red blood cells (anemia) blood platelet

(cells that help blood to clot), and in a type of white blood cells

•Low levels of sodium (hyponatremia) or phosphate

• Increase in creatine phosphokinase, an enzyme found mainly i

Eye changes including swelling in the eye caused by fluid leakage (chorioretinopathy), separation of the light-sensitive membrane at

the back of the eve (the retina) from its supporting layers (retinal

Heart rate that is lower than the normal range and/or a decrease

Inflammatory disease mainly affecting the skin, lung, eyes and

Side effects of unknown frequency (effects whose frequency has not

• inflammation of the heart muscle (myocarditis), which may cause

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet,

Side effects can be reported to the Ministry of Health by clicking or the link "Report Side Effects of Drug Treatment" found on the Ministry

of Health homepage (<u>www.health.gov.ii</u>) that directs you to the online form for reporting side effects, or by entering the link:

Avoid poisoning! This medicine, and any other medicine, should be

kept in a safe place out of the reach and sight of children and/o

infants in order to avoid poisoning. Do not induce vomiting unless

• Do not use Tafinlar after the expiry date (exp. date) that appears on

the package. The expiry date refers to the last day of that month

Do not store above 30°C. For use for up to 6 months from opening

In addition to the active ingredient, the medicine also contains

Microcrystalline cellulose, magnesium stearate, colloidal silicone

Furthermore, the capsules are printed with black ink that contains

Shellac (E904), Black iron oxide (E172), Propylene glycol (E1520)

Tafinlar 50 mg capsules are opague, dark red and imprinted with

Tafinlar 75 mg capsules are opague, dark pink and imprinted with

The bottles also include a desiccant in a small cylinder shaped

container. The desiccant must be kept inside the bottle and must

Registration Holder and Importer and its address: Novartis Israe

Registration number of the medicine in the National Drug Registr

TAF APL MAR21 V2

• What the medicine looks like and the contents of the package

dioxide, red iron oxide (E172), titanium dioxide (E171), hypromello

Increase in some substances (enzymes) produced by the live

Uncommon side effects (may occur in 1-10 in 1,000 users).

of thick, scaly or crusty skin (actinic keratosis), chapping or cracking

 Abnormal blood test results related to the liver Common side effects (may occur in 1-10 in 100 users)

(see also "Changes in your skin" earlier in section 4)

Infection of the urinary system

• Dehydration (low levels of water or fluid)

Heart pumping less efficiently

• Localized tissue swelling

Shortness of breath

• Acne-like problems

• Swelling of the face

(leukopenia)

• Skin tags

in heart rate

Kidnev failure

Inflammation of pancreas

Inflammation of the kidneys

lymph nodes (sarcoidosis)

yet been determined).

Reporting side effects

https://sideeffects.health.gov.il

6. FURTHER INFORMATION

'GS TEW' and '50 mg'

GS LHF' and '75 mg'

Ltd., P.O.B 7126, Tel Aviv.

of the Ministry of Health:

Tafinlar 50 mg: 151 42 33976

Tafinlar 75 mg: 151 43 33977

not be swallowed.

(F464)

Dry mouth

of the skin

Low blood pressure (hypotension)

Increased sweating, night sweats

Unusual hair loss or thinning

• Red, painful hands and feet

Inflammation of the mucosa

• Low levels of white blood cells

(hypophosphatemia) in the blood

heart, brain, and skeletal muscle

Allergic reactions (hypersensitivity)

Appearance of new skin cancer (melanoma)

detachment) and swelling around the eyes

Rare side effects (may occur in 1-10 in 10,000 users)

shortness of breath, fever, palpitations and chest pain

• A hole (perforation) in the stomach or intestines

• inflamed, flaky skin (exfoliative dermatitis)

consult with the doctor or pharmacist.

5. HOW SHOULD THE MEDICINE BE STORED?

explicitly instructed to do so by the doctor.

The bottles are white and contain 28 capsules.

Revised in March 2021 according to MOH guidelines

• Inflammation of the lung (pneumonitis)

Inflammation in the intestine (colitis)

Increase in blood sugar level