

Patient Information Leaflet

Dabrafenib - TAFINLAR®

What is TAFINLAR®

Medicine Name	Description
Dabrafenib	50 or 75 mg gelatin capsule: brown

How should you take your medicine?

Your doctor has determined your medicine dosage.

Swallow whole with a glass of water, without opening or diluting the capsules.

At a set time, with a time interval between taking the medicine and eating (1 hour before a meal or 2 hours after a meal).

If you forgot to take a dose or in case of vomiting, do not take an additional dose but wait for the time to take the next dose.

Dosage - therapy regimen

Twice a day, at a set time, with a time interval between taking a medicine		<1h			(1h	,		(1h) 2h	·
With no gaps	D1	D2	D3	D4	D 5	D 6	D7	•••	D28

How to get the medicine supply?

This medicine is available in local pharmacies.

Getting this medicine might take time. Be careful and order the medicine in advance. Store this product in its original packaging, away from sources of heat and moisture.

What else do you need to know?

Precautions and monitoring

Laboratory tests are necessary while taking your medication (blood test to monitor kidney and liver function), as well as clinical condition monitoring (dermatological examinations, ECG, cardiac scintigraphy).

Using contraceptives

This drug may harm an unborn baby. During the entire treatment, you and your partner need to use effective contraception methods (condoms combined with another method).

Interactions with other medications and/or food

The occurrence of interactions between TAFINLAR® and your other treatments may have harmful consequences (reduced drug efficacy and tolerance). It is important to tell your pharmacist and doctor about all medications and/or other substances (foods, plants, probiotics, essential oils, nutritional supplements, etc.) that you are taking.

Example: While taking TAFINLAR®, it is necessary to avoid using Saint John's wort and grapefruit juice.

What are possible side effects?

Only the most common side effects are listed below. There might be some other side effects. For additional information, refer to your medicine leaflet or seek advice from your doctor or pharmacist.

SIDE EFFECTS			
Most common ones	Skin problems: tumors (benign or malignant), rash, skin induration, dryness, itching, redness, inflammation of palms, soles of the feet, and areas of friction Digestive problems: nausea, diarrhea, constipation, loss of appetite Eye problems: inflammation Cardiac problems Muscle problems: pain Others: headaches, fatigue, fever, flu syndrome, cough		



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Some patients require special attention	Patients with diabetes(hyperglycemia risk)
WHEN TO ALERT THE MEDIC	AL TEAM?
Tell medical personnel if the following conditions are present and in the absence of specific medical advice	Skin problems > Wart generation > Skin tenderness or a reddish bump on the skin that bleeds or does not heal Mole size or color change Significant blisters or severe peeling of the skin Digestive problems > Significant and/or rapid weight loss > Very frequent diarrhea, bowel movement over 4 times a day > Severe abdominal pain > Inability to drink for 24 hours and/or eat for about 48 hours > Bowel movements fewer than 3 times a week Pain that prevents you from doing your normal activities > Headaches > Pain and inflammation in hands and feet > Unusual and inexplicable pain in muscles Eye problems Pain in the eyes, tearing or redness, blurred vision, or light sensitivity Hypertension symptoms > Headaches, buzzing in the ears, and/or dizziness > Blood pressure increase Symptoms suggestive of hemorrhage > Blood in stool or in vomit > Hematomas (bruises), nose bleedings Symptoms of phlebitis > Red, warm, and painful calf Respiratory disorders > Increasing constant cough or problems breathing
HOW TO PREVENT SIDE EFFI	ECTS?
Skin care	On hands and feet: Apply moisturizing cream or milk and/or healing cream on hands and feet (without rubbing hard). Avoid exposing hands and feet to heat (hot water). Avoid activities that cause rubbing or injury. Avoid wearing overly tight clothing, socks, or shoes Body: Opt for soft soap and moisturizer, pat skin dry. Avoid using any irritating products.
Protection from the sun	ESSENTIAL. Apply broad spectrum sunscreen (SPF 50) and avoid sun exposure. Opt for long-sleeve clothing with a collar, long trousers, and hats.
Hair loss	Cut your hair. Find out about wigs and how they are reimbursed. Use a small amount of mild shampoo (for babies). Opt for a soft brush. Avoid washing your hair too often. Avoid heat sources (hairdryer, heated curlers, hot smoothing iron), dyes, highlights, or perm.
Weight	Regularly check your weight in case of digestive problems.
Fatigue	Opt for activities contributing to well-being, in particular adjusted and regular physical activities: walking, work in the garden, swimming, biking, sports Alternate periods of activity and rest.
Bleedings	Avoid taking anti-inflammatory drugs (ibuprofen, aspirin) Notify your doctor: > if you take blood thinners or thrombocytic antiaggregants: careful monitoring is needed > about surgical or dental intervention.
Infection	Avoid visiting high risk areas (crowds, contact with sick people,). A flu and pneumococcal infection vaccine might be recommended for you: it will protect you.
Constipation	To stimulate intestinal transit, engage in adjusted and regular physical activities: walking, work in the garden, swimming, biking, sports
Blood pressure control	Elevated blood pressure needs to be corrected. Taking arterial pressure regularly is recommended. Pharmacists can help you take your blood pressure. You can also ask to do it by yourself using an automatic blood pressure monitor.
HOW TO ADAPT YOUR DIET?	
Diarrhea	Opt for a low fiber diet. It is preferable to consume starchy products, carrots, and bananas. Avoid using raw fruit and vegetables, dairy products, coffee, or alcohol. Drink more water.
Nausea	Opt for split nutrition consisting of several light meals, liquid and cold dishes. Limit consumption of fatty, fried, and spicy foods.
Weight loss	Opt for a higher calorie diet and "pleasure diet".



Constipation

Opt for a high fiber diet. Drink more water.