PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

TASIGNA® 150 mg Capsules

Each capsule contains:
Nilotinib as hydrochloride monohydrate 150 mg

TASIGNA® 200 mg Capsules

Each capsule contains:
Nilotinib as hydrochloride monohydrate 200 mg

Inactive and allergenic ingredients in the preparation: See "Important information about some of the ingredients of the medicine" section, listed under section 2, and also section 6 "Further information".

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 the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Tasigna 150 mg and Tasigna 200 mg are used:
For treatment of adult patients with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia - Ph+ CML in the chronic phase.

Tasigna 200 mg **only** is used:
For treatment of patients with Philadelphia chromosome-positive chronic myeloid leukemia - Ph+ CML in the chronic or accelerated phase, who are resistant to or who experienced significant toxicity during treatment with imatinib.

Therapeutic group: Antineoplastic.

CML is a cancer of the blood which causes the body to produce too many abnormal white blood cells.
In CML patients, a change in the genetic material (DNA) triggers a signal which causes the body to produce abnormal white blood cells. Tasigna blocks this signal and stops the production of these cells.
If you have any question about how Tasigna works or why this medicine has been prescribed for you, refer to your doctor.

2. BEFORE USING THE MEDICINE:

Do not use the medicine if:
- you are allergic to nilotinib or to any of the additional ingredients contained in the medicine, as listed in section 6 "Further information".

If you think you may be allergic, inform the doctor **before taking** Tasigna.

Special warnings regarding use of the medicine:
Before treatment with Tasigna, tell the doctor if:
- You have had prior cardiovascular events such as a heart attack, chest pain (angina), problems with the blood supply to your brain (stroke), or problems with the blood flow to your leg (claudication), or if you have risk factors for cardiovascular disease such as high blood pressure (hypertension), diabetes, or problems with the level of fats in your blood (lipid disorders).
- You have **a heart disorder** such as an abnormal electrical signal called "prolongation of the QT interval".
- You are **being treated with medicines** that lower your blood cholesterol (statins), or affect the heart rate (anti-arrhythmics) or the liver (see below "**Drug interactions**").
- You suffer from potassium or magnesium deficiency.
- You have a liver or pancreatic disorder.
- You have symptoms such as bruising easily, feeling tired or shortness of breath, or recurrent infections.
- You underwent surgery for removal of your entire stomach (gastrectomy).
- You have ever had or you may have a hepatitis B viral infection. Tasigna could cause hepatitis B to become active again, which can be fatal in some cases. Patients will be carefully checked by their doctor for signs of this infection before treatment is started.

During treatment with Tasigna
- **Refer to your doctor immediately** if you faint (lose consciousness), or have irregular heartbeats during treatment with this medicine, as these may indicate a serious heart problem. Prolongation of the QT interval or irregular heartbeats may lead to sudden death.
  Uncommon cases of sudden death have been reported in patients treated with Tasigna.
- **Refer to your doctor immediately** if you have sudden heart palpitations, severe muscle weakness or paralysis, seizures or sudden changes in your thinking or level of alertness, since this may be a sign of the rapid breakdown of cancer cells called "tumor lysis syndrome". Rare cases of tumor lysis syndrome have been reported in patients taking Tasigna.
- **Refer to your doctor immediately** in the event that you develop chest pain or discomfort, numbness or weakness, problems with walking or speech, pain, discoloration or a cold sensation in one of the limbs, since this may be a sign of a cardiovascular event. Severe cardiovascular events, including problems with blood flow to the leg (peripheral arterial occlusive disease), ischemic heart disease and problems with blood supply to the brain (ischemic cerebrovascular disease) have been reported in patients taking Tasigna. Your doctor should monitor the level of fats (lipids) and sugar in your blood before initiating treatment with Tasigna and during the treatment.
- If you develop swelling of the feet or hands, generalized swelling or rapid weight gain, tell your doctor since these may be signs of severe fluid retention. Uncommon cases of severe fluid retention have been reported in patients taking Tasigna.

Children and adolescents:
Tasigna is not intended to be used in children.

Tests and follow-up:
During the course of treatment with this medicine, tests should be performed regularly, including blood tests. These tests will monitor:
- The amount of blood cells (white blood cells, red blood cells and platelets) in the body to see how Tasigna is being tolerated.
- Pancreatic and liver function in the body to see how Tasigna is being tolerated.
- Electrolytes in the body (potassium, magnesium). These are important in the functioning of the heart.
- The level of sugar and fats in the blood.

The heart rate will also be checked using a machine that measures the electrical activity of the heart (a test called "ECG").
Your doctor will regularly monitor your treatment and decide whether you should continue taking Tasigna.
If you are told to stop taking this medicine, your doctor will carefully continue to monitor your CML and may instruct you to resume taking Tasigna if necessary, depending on your condition.

Drug interactions:
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:
- Anti-arrhythmics - used to treat irregular heart rhythm;
- Chloroquine, halofantrine, clarithromycin, haloperidol, methadone, moxifloxacin - medicines that may have an unwanted effect on the electrical activity of the heart;
- Ketoconazole, itraconazole, voriconazole, clarithromycin, telithromycin – used to treat infections;
- Ritonavir – a medicine for the treatment of AIDS (HIV) from the "antiprotease" group;
- Carbamazepine, phenobarbital, phenytoin - used to treat epilepsy;
- Rifampicin - used to treat tuberculosis;
- St. John's wort – a herbal product used to treat depression and other conditions (also known as *Hypericum perforatum*);
- Midazolam – used to relieve states of anxiety before surgery;
- Alfentanil and fentanyl - used to treat pain and as a sedative before or during surgery or medical procedures;
- Cyclosporine, sirolimus and tacrolimus - preparations that suppress the "self-defense" capability of the body and ability to fight infections and are usually used to prevent the rejection of transplanted organs such as liver, heart and kidney;
- Dihydroergotamine and ergotamine - used to treat dementia;
- Lovastatin, simvastatin - used to treat high levels of fats in blood;
- Warfarin - used to treat blood coagulation disorders (such as blood clots and thrombosis);
- Astemizole, terfenadine, cisapride, pimozide, quinidine, bepridil or ergot alkaloids (ergotamine, dihydroergotamine).

During treatment with Tasigna, avoid taking these medicines. If you are taking one or more of these medicines, the doctor may prescribe alternative medicines for you.

If you are taking statins (a type of medicine that lowers cholesterol levels in your blood), refer to your doctor or pharmacist. If used with certain kinds of statins, Tasigna may increase the risk of statin-related muscle problems, which on rare occasions can lead to serious muscle breakdown (rhabdomyolysis) resulting in kidney damage.

In addition, inform the doctor or pharmacist before taking Tasigna, if you are taking antacids (medicines for treatment of heartburn). Take these medicines separately from Tasigna:
- Antacids called H2 blockers, which decrease the production of acidity in the stomach - should be taken approximately 10 hours before, and approximately 2 hours after, you take Tasigna.
- Antacids such as those containing aluminum hydroxide, magnesium hydroxide and simethicone, which neutralize high acidity of the stomach - should be taken approximately 2 hours before or 2 hours after taking Tasigna.

If you are already taking Tasigna, notify your doctor if you are prescribed a new medicine you have not previously taken during Tasigna treatment.

Use of the medicine and food:
Do not take Tasigna with food. Food may enhance the absorption of Tasigna and thereby increase its amount in the blood, possibly to a harmful level.
Do not drink grapefruit juice or eat grapefruit. It may increase the amount of Tasigna in the blood, possibly to a harmful level.

Pregnancy, breast-feeding and fertility:
It is not recommended to use Tasigna during pregnancy unless clearly necessary. If you are pregnant or think that you may be pregnant, inform the doctor who will discuss with you whether you can use this medicine during pregnancy.
Women of child-bearing age must use highly effective contraception while using Tasigna and for 2 weeks after treatment ends.
Breast-feeding is not recommended during treatment with Tasigna and for two weeks after taking the last dose. Inform your doctor if you are breast-feeding.

If you are pregnant or breast-feeding, think you are pregnant or are planning to become pregnant, consult with the doctor or pharmacist before taking this medicine.

Elderly (patients from 65 years and over):
Tasigna can be used in people aged 65 and over in the same dosages as other adults.

Driving and operating machinery:
If you experience side effects (such as dizziness or visual disorders) that can affect the ability to drive safely or operate tools or machinery after taking this medicine, refrain from these activities until the effect has passed.

Important information about some of the ingredients of the medicine:
The preparation contains lactose (milk sugar). If you know that you have an intolerance to certain sugars, inform the doctor before taking Tasigna.
Each 150 mg Tasigna capsule contains approximately 117 mg lactose monohydrate.
Each 200 mg Tasigna capsule contains approximately 156 mg lactose monohydrate.

3. HOW SHOULD YOU USE THE MEDICINE?

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

The dosage and the treatment regimen will be determined by the doctor only. The usual dosage is generally:
Adult patients with newly diagnosed Ph+ CML: 2 capsules of 150 mg, twice daily (300 mg, twice daily).
For patients with Ph+ CML in the chronic or accelerated phase who are resistant to or who experienced significant toxicity during treatment with imatinib: 2 capsules of 200 mg, twice daily (400 mg, twice daily).
Your doctor may prescribe a lower dosage depending on your response to treatment.

Do not exceed the recommended dose.

When to take Tasigna:
Take the capsules:
- twice a day (approximately every 12 hours);
- at least 2 hours after eating any food;
- then wait at least 1 hour before eating again.

If you have questions about when to take the medicine, refer to your doctor or pharmacist.
Taking the medicine at the same time each day will help you remember to take your capsules.

How to take:
Swallow the capsules whole with water.
Do not consume any food together with the capsules.
Do not open the capsules unless you are unable to swallow the capsules whole.
In this case, you may mix the contents of each capsule in **one** teaspoon of applesauce (pureed apple) and take it immediately. Do not use more than one teaspoon of applesauce for each capsule and do not use any food other than applesauce.

Duration of treatment:
Continue taking the medicine every day for as long as your doctor instructs you to; this is a long-term treatment. Your doctor will regularly monitor your condition to check that the treatment is having the desired effect.
The doctor will consider stopping the treatment with Tasigna according to specific criteria.
If you have questions regarding how long to take Tasigna, consult the doctor or pharmacist.

If you accidentally took a higher dosage, 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. Medical treatment may be necessary.

If you forgot to take the medicine at the designated time, do not take a double dose. Take the next dose at the regular time and consult the doctor.

Adhere to the treatment regimen as recommended by the doctor.

Even if there is an improvement in your health condition, do not stop treatment with the medicine without consulting the doctor.
Stopping treatment with this medicine without a doctor's recommendation places you at risk for worsening of your illness, which may come with life-threatening consequences. Make sure that you talk with your doctor, nurse and/or pharmacist if you are considering discontinuing treatment with Tasigna.

If your doctor recommended discontinuation of Tasigna treatment
Your doctor will regularly monitor your treatment by a certain diagnostic test and will decide if you should continue taking this medicine.
If you have been told to stop taking Tasigna, your doctor will continue to carefully monitor your CML, before, during and after stopping treatment and may instruct you to resume taking Tasigna if necessary, depending on your condition.

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

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

4. SIDE EFFECTS:

As with any medicine, use of Tasigna may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them. Most of the side effects are mild to moderate, and generally disappear after a few days to a few weeks after starting treatment.

Some side effects can be serious.
These side effects are very common (effects that occur in more than one user in ten), common (effects that occur in 1-10 in 100 users), uncommon (effects that occur in 1-10 in 1,000 users), rare (effects that occur in 1-10 in 10,000 users) or were reported at unknown frequencies (effects whose frequency has not yet been determined).
- Signs of musculoskeletal pain: pain in joints and muscles;
- Signs of heart disorders: chest pain or discomfort, high or low blood pressure, irregular heart rhythm (fast or slow), palpitations (sensation of rapid heartbeat), fainting, blue discoloration of the lips, tongue or skin;
- Pain, discomfort, weakness or cramping in the leg muscles, which may be due to decreased blood flow, ulcers on the legs or arms that heal slowly or not at all and noticeable changes in color (blueness or paleness) or temperature (coolness) of the legs and hands, as these symptoms could be signs of artery blockage in the affected limb (leg or hand) and digits (toes or fingers);
- Signs of underactive thyroid gland: weight gain, tiredness, hair loss, muscle weakness, feeling cold;
- Signs of overactive thyroid gland: fast heartbeat, bulging eyes, weight loss, swelling at the front of the neck;
- Signs of kidney or urinary tract disorders: thirst, dry skin, irritability, dark urine, decreased urine output, difficulty and pain when urinating, exaggerated sense of needing to urinate, blood in urine, abnormal urine color;
- Signs of high blood level of sugar: excessive thirst, high urine output, increased appetite with weight loss, tiredness;
- Signs of vertigo: dizziness or spinning sensation;
- Signs of pancreatitis: severe upper (middle or left) abdominal pain;
- Signs of skin disorders: painful red lumps, skin pain, skin reddening, peeling or blisters;
- Signs of water retention: rapid weight gain, swelling of hands, ankles, feet or face;
- Signs of migraine: severe headache often accompanied by nausea, vomiting and sensitivity to light;
- Signs of blood disorders: fever, easy bruising or unexplained bleeding, severe or frequent infections, unexplained weakness;
- Signs of clotting within a vein: swelling and pain in one part of the body;
- Signs of nervous system disorders: weakness or paralysis of the limbs or face, difficulty speaking, severe headache, seeing, hearing or feeling things that are not there, changes in eyesight, loss of consciousness, confusion, disorientation, trembling, sensation of tingling, pain or numbness in fingers and toes;
- Signs of lung disorders: difficulty or painful breathing, cough, wheezing with or without fever, swelling of legs and feet;
- Signs of gastrointestinal disorders: abdominal pain, nausea, vomiting of blood, black or bloody stools, constipation, heartburn, stomach acid reflux, swollen abdomen;
- Signs of liver disorders: yellow skin and eyes, nausea, loss of appetite, dark-colored urine;
- Recurrence (reactivation) of hepatitis B infection when you have had hepatitis B in the past;
- Signs of eye disorders: vision disturbances, including blurred vision, double vision or seeing flashes of light, decreased visual acuity or loss of vision, blood in the eye, increased sensitivity of the eyes to light, eye pain, redness, itching or irritation, dry eye, swelling or itching of the eyelids;
- Nausea, shortness of breath, irregular heartbeat, clouding of urine, tiredness and/or joint discomfort accompanied by abnormal blood test results (such as an increase in potassium, uric acid and phosphorous levels and decrease in calcium levels in the blood);

If you experience any of these side effects, **tell your doctor immediately**.

Additional side effects:

Very common side effects (effects that occur in more than 1 in 10 users): fever; diarrhea; headache; lack of energy; muscle pain; itching, rash; nausea; upper abdominal pain; constipation; vomiting; hair loss; pain in extremities, pain in joints, bone pain, and back pain with discontinuation of Tasigna treatment, upper respiratory tract infections (including sore throat and runny nose and sneezing); low level of blood cells (red cells, platelets) or hemoglobin; high level of lipase (pancreas function); high level of bilirubin (liver function); high blood level of alanine aminotransferases (liver enzymes).

Common side effects (effects that occur in 1-10 in 100 users): pneumonia; abdominal pain, feeling of stomach discomfort after meals, flatulence, swelling or bloating of the abdomen; signs of inflammation of the stomach lining: abdominal pain, nausea, vomiting, diarrhea, bloating of the abdomen; bone pain, muscle spasms; pain including neck pain; dry skin, acne, decreased skin sensitivity, hives (urticaria); weight gain or loss; insomnia, depression, anxiety; night sweats, increased sweating; general unwell feeling; nosebleed; chest pain (including noncardiac pain); chills; painful and swollen joints (gout); inability to achieve or maintain an erection; flu-like symptoms; sore throat; bronchitis; ear pain, noises (ringing) in the ears that have no external source (tinnitus); hemorrhoids; heavy periods; itching of the hair follicles; oral or vaginal thrush; discharge from the eyes with swelling, redness or itching of the eyelids (signs of conjunctivitis); eye irritation, red eyes; high blood pressure, headaches, dizziness (signs of hypertension); flushing; pain, discomfort, weakness or cramping in the leg muscles, which may be due to decreased blood flow, ulcers on the legs or arms that heal slowly or not at all and noticeable changes in color (blueness or paleness) or temperature (coolness) of the legs or arms, as these symptoms could be signs of a blocked artery in the affected limb (leg or hand) and digits (toes or fingers) (signs of peripheral arterial occlusive disease); shortness of breath; mouth sores with gum inflammation (stomatitis); high blood level of amylase (pancreas function); high blood level of creatinine (kidney function); high blood level of enzymes (alkaline phosphatase, creatine phosphokinase); high blood level of aspartate aminotransferases, gamma glutamyltransferases (liver enzymes); signs of leukopenia or neutropenia (low level of white blood cells); increase in the number of platelets or white cells in the blood; low blood level of magnesium, potassium, sodium, calcium or phosphorus; increased blood level of potassium, calcium or phosphorus; high blood level of fats (including cholesterol); high blood level of uric acid.

Uncommon side effects (effects that occur in 1-10 in 1,000 users): allergy (hypersensitivity to Tasigna); dry mouth, breast pain; pain or discomfort on the side of the body; increased appetite; breast enlargement in men; herpes virus; joint and muscle stiffness; swollen joints; feeling a change in body temperature (including feeling hot, feeling cold); disturbed sense of taste; frequent urine output; memory loss; skin cyst, thinning or thickening of the skin, thickening of the outermost layer of the skin, skin discoloration; thickened patches of red/silver skin (signs of psoriasis); increased sensitivity of the skin to light; difficulty hearing; joint inflammation; urinary incontinence; enterocolitis (inflammation of the intestine); anal abscess; nipple swelling; signs of restless legs syndrome (an irresistable urge to move a part of the body, usually the leg, accompanied by uncomfortable sensations); signs of sepsis: fever, chest pain, increased heart rate, shortness of breath or rapid breathing; skin infection (subcutaneous abscess); skin warts; increase in specific types of white blood cells (eosinophils); signs of lymphopenia: low level of white blood cells; high blood level of parathyroid hormone (a hormone regulating calcium and phosphorus levels); high blood level of lactate dehydrogenase (an enzyme); signs of low or high blood level of sugar: nausea, sweating, weakness, dizziness, trembling, headache; dehydration; abnormal blood level of fat; involuntary shaking; difficulty concentrating; unpleasant and abnormal feeling when touched (dysesthesia); tiredness; sensation of numbness or tingling in the fingers and toes (peripheral neuropathy); paralysis of muscles of the face; red patch in the white of the eye caused by broken blood vessels (conjunctival hemorrhage); blood in eyes (eye hemorrhage); eye irritation; signs of heart attack: sudden and crushing chest pain, tiredness, irregular heartbeat; signs of heart murmur: tiredness, chest discomfort, light-headedness, chest pain, palpitations; signs of heart failure: breathlessness, difficulty breathing when lying down, swelling of the feet and legs; fungal infection of the feet; pain behind the breast bone (pericarditis); signs of hypertensive crisis: severe headache, dizziness, nausea; leg pain and weakness brought on by walking; high blood pressure, painful cramping in one or both hips, thighs or calf muscles after certain activities such as walking or climbing stairs, leg numbness or weakness (signs of narrowing of the arteries of the limbs); bruising (when you have not hurt yourself); fatty deposits in the arteries that may cause blockage (arteriosclerosis); signs of low blood pressure: light-headedness, dizziness or fainting; signs of pulmonary edema: breathlessness; signs of pleural effusion: fluid collection between the layers of tissue that line the lungs and chest cavity (which may decrease the heart's ability to pump blood), chest pain, cough, hiccups, rapid breathing; signs of lung disease: cough, difficulty breathing, painful breathing; chest pain (pleuritic pain); cough, painful breathing (pleurisy); hoarse voice; high blood pressure in the arteries of the lungs (signs of pulmonary hypertension); wheezing; sensitive teeth; gum bleeding, tender or enlarged gums (signs of gum inflammation); high blood level of urea (kidney function); change in blood protein levels (low level of globulins or presence of paraprotein); high blood level of unconjugated bilirubin; high blood level of troponins.

Rare side effects (effects that occur in 1-10 in 10,000 users):
reddening and/or swelling and possibly peeling on the palms of the hands and soles of the feet (called hand-foot syndrome); warts in the mouth; feeling of hardening or stiffness in the breasts; inflammation of the thyroid gland; disturbed or depressed mood; bone and joint pain, excessive urination, abdominal pain, weakness, tiredness (signs of secondary hyperparathyroidism); loss of vision in part or all of both eyes, double vision, vertigo (spinning sensation), numbness or tingling, loss of coordination, dizziness or confusion (signs of narrowing of the arteries in the brain); swelling of the brain (headache and/or mental status changes); blurred vision, loss of vision (signs of optic neuritis); tiredness, chest discomfort, light-headedness, pain, palpitations (signs of heart dysfunction); low or high blood level of insulin (a hormone regulating blood sugar levels); low blood level of insulin C peptide (pancreas function); sudden death.

The following side effects were reported at unknown frequencies (effects whose frequencies have not yet been determined):
signs of heart dysfunction (ventricular dysfunction): shortness of breath, exertion at rest, irregular heartbeat, chest discomfort, light-headedness, pain, palpitations, excessive urination, swelling in the feet, ankles and abdomen.

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

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il/

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning.
Do not induce vomiting unless explicitly instructed to do so by the doctor.
Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

Storage conditions:
Do not store above 30°C.
Store in the original package in order to protect from moisture.
Do not use a package that is damaged or shows signs of tampering.

6. FURTHER INFORMATION:

In addition to the active ingredient, the medicine also contains:
Lactose monohydrate, Crospovidone, Poloxamer 188, Silica colloidal anhydrous, Magnesium stearate.
Tasigna 150 mg capsule shell: Gelatin, Titanium dioxide (E171), Iron oxide red (E172), Iron oxide yellow (E172) and Printing ink: black.
Qualitative composition of printing ink: Shellac, Iron oxide black, n-butyl alcohol, Purified water, Propylene glycol, Dehydrated ethanol, Isopropyl alcohol, Ammonium hydroxide.
Tasigna 200 mg capsule shell: Gelatin, Titanium dioxide (E171), Iron oxide yellow (E172), Printing ink: red.
Qualitative composition of printing ink a: Shellac, Dehydrated alcohol, Isopropyl alcohol, Butyl alcohol, Propylene glycol, Strong ammonia solution, Iron oxide red (E172), Potassium hydroxide, Purified water.
Qualitative composition of printing ink b: Shellac, Iron oxide red (E172), Iron oxide black (E172), n-butyl alcohol, Purified water, Titanium dioxide (E171), Propylene glycol, Industrial methylated spirit, Isopropyl alcohol.
The printing ink used is 'Printing ink a' or alternatively 'Printing ink b'.

Each 150 mg Tasigna capsule contains approximately 117 mg lactose monohydrate.
Each 200 mg Tasigna capsule contains approximately 156 mg lactose monohydrate.

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

Tasigna 150 mg capsules: White to yellowish powder in red, opaque, size 1 capsules, with black imprint "NVR"/"BCR".

Tasigna 200 mg capsules: White to yellowish powder in light yellow, opaque, size 0 capsules, with red imprint "NVR"/"TKI".

A monthly package of Tasigna 150 mg contains 112 capsules. The monthly package contains 4 weekly packs (28x4 capsules).
A monthly package of Tasigna 200 mg contains 120 capsules. The monthly package contains 3 ten-day packs (40x3 capsules).

Not all package sizes may be marketed.

Registration Holder and Importer and its address:
Novartis Israel Ltd., P.O.B 7126, Tel Aviv.

Revised in September 2022 according to MOH guidelines.

Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:
Tasigna 150 mg: 145 84 33271
Tasigna 200 mg: 138 17 31681