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

The medicine is dispensed with a doctor's prescription only

Alecensa® 150 mg Capsules

Composition:
Each capsule contains:
alectinib 150 mg
For information on the inactive ingredients, see section 6 - "Further information".

Read this leaflet carefully in its entirety before using the medicine as it contains important information for you.
- Keep this leaflet. You may need to read it again.
- 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?

Alecensa is intended to treat a type of lung cancer called 'non-small cell lung cancer' ('NSCLC') that is ALK-positive - this means your cancer cells have a fault in a gene called ALK ('anaplastic lymphoma kinase').

Alecensa can be prescribed to you in these cases:
- after removal of the tumor as a postsurgical (adjuvant) treatment, or
- as the first treatment for advanced cancer, or
- as treatment for localized advanced cancer or cancer that has spread to another part of your body (metastatic) after treatment with a medicine called crizotinib, or intolerance to crizontinib.

How **Alecensa** works

Alecensa blocks the action of an enzyme called 'ALK-type tyrosine kinase'. An abnormal form of this enzyme (due to a fault in the gene) encourages cancer cell growth. **Alecensa** can slow down or stop the growth of your cancer and may prevent the tumor from coming back after removal by surgery. It can also help to shrink your cancer.

Therapeutic group: Tyrosine kinase inhibitor

2) Before using the medicine

Do not use the medicine if:
- you are sensitive (allergic) to the active ingredient (alectinib) or any of the additional ingredients contained in the medicine (detailed in section 6 – "Further information").

! Special warnings regarding use of the medicine

Before treatment with Alecensa, consult the doctor or pharmacist if:
- You have suffered in the past from problems in the stomach or intestine, such as holes (perforation), or if you have had conditions that caused an inflammation in the abdomen (diverticulitis), or if the cancer spread inside the abdomen (metastasis). It is possible that **Alecensa** may increase the risk of developing holes in the intestinal wall.
- You have an inherited problem of galactose intolerance, congenital lactase deficiency, or glucose-galactose malabsorption.

After taking **Alecensa**, tell the doctor **immediately**:
- If you experience severe pain in the abdomen or stomach, fever, chills, nausea, vomiting, or abdominal rigidity or bloating, since these can be symptoms of a hole in the intestinal wall.

If the following side effects develop during the course of treatment with **Alecensa**, contact your doctor **immediately**:
- Liver injury - your doctor will perform blood tests before commencing treatment, then every 2 weeks for the first 3 months of treatment and afterwards less often. This is to check that you do not have any liver problems while taking **Alecensa**. Tell your doctor **immediately** if you experience any of the following signs:
  Yellowing of the skin or the whites of the eyes, pain on the right side of the stomach area, dark urine, itchy skin, decreased appetite, nausea or vomiting, feeling tired, bleeding or bruising occur more easily than previously.
- Slow heart beat (bradycardia).
- Lung inflammation (pneumonitis) - **Alecensa** may cause severe or life-threatening swelling of the lungs (inflammation) during treatment. The signs can be similar to signs of your lung cancer. Tell your doctor **immediately** if you have any new or worsening signs including difficulty in breathing, shortness of breath, or cough with or without mucous or fever.
- Severe muscle pain, muscle tenderness and weakness. Your doctor will perform blood tests at least every 2 weeks for the first month and when needed during treatment with **Alecensa**. Tell your doctor **immediately** if you have new or worsening signs of muscle problems, including unexplained muscle pain or muscle pain that does not go away, muscle tenderness or weakness.
- Abnormal breakdown of red blood cells (haemolytic anaemia). Tell your doctor immediately if you feel tired, weak or short of breath.

You should pay attention to these side effects while you are using **Alecensa**. For more information, see 'Side effects' in section 4.

Sensitivity to sunlight
- Do not expose yourself to the sun for a long period of time while taking **Alecensa** and for 7 days after stopping treatment.
  You need to apply sunscreen and lip balm with a Sun Protection Factor (SPF) of 50 or higher to prevent sunburns.

Children and adolescents
Alecensa has not been studied in children or adolescents. Do not give this medicine to children or adolescents under the age of 18.

Tests and follow-up
When you take **Alecensa** your doctor will perform blood tests before commencing treatment, then every 2 weeks for the first 3 months of treatment and afterwards less often. This is to check that you do not have any liver or muscle problems while taking **Alecensa**.

Drug interactions
If you are taking, have recently taken, or might take other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist, since **Alecensa** can affect the way some medicines work, and some medicines can affect the way **Alecensa** works.
In particular inform the doctor or pharmacist if you are taking any of the following medicines:
- Digoxin, a medicine for treatment of heart problems
- Dabigatran etexilate, a medicine for treatment of blood clots
- Methotrexate, a medicine for treatment of severe joint inflammation, cancer and the skin disease psoriasis
- Nilotinib, a medicine for treatment of certain types of cancer
- Lapatinib, a medicine for treatment of certain types of breast cancer
- Mitoxantrone, a medicine for treatment of certain types of cancer or multiple sclerosis (a disease that affects the central nervous system which damages the coating that protects the nerves)
- Everolimus, a medicine for treatment of certain types of cancer or to prevent the rejection of a transplanted organ by the body's immune system
- Sirolimus, a medicine to prevent the rejection of a transplanted organ by the body's immune system
- Topotecan, a medicine for treatment of certain types of cancer
- Medicines for treatment of acquired immune deficiency syndrome (AIDS)/HIV virus (e.g. ritonavir, saquinavir)
- Medicines for treatment of infections, including fungal infections (ketoconazole, itraconazole, voriconazole, posaconazole) and bacterial infections (antibiotics, such as: telithromycin)
- The herb, St. John's Wort, for treatment of depression
- Medicines to stop seizures (anti-epileptic medicines, such as: phenytoin, carbamazepine, phenobarbital)
- Medicines for treatment of tuberculosis (e.g. rifampicin, rifabutin)
- Nefazodone, a medicine for treatment of depression

Oral contraceptives
If you take **Alecensa** and oral contraceptives, the contraceptives may be less effective.

Alecensa with food and drink
Take the medicine with food.
Tell your doctor or pharmacist if you drink grapefruit juice or eat grapefruits or Seville oranges during treatment with **Alecensa** as they may change the amount of medicine in your body.

Contraception, pregnancy and breast-feeding - information for women
Contraception:
You should not become pregnant while using this medicine. If you are able to become pregnant, you must use highly effective contraception while on treatment and for at least 3 months after stopping treatment. Talk to your doctor about the right methods of contraception for you and your partner.
If you take **Alecensa** and oral contraceptives together, the contraceptives may be less effective.

Pregnancy:
- Do not take **Alecensa** if you are pregnant, as the medicine may harm your baby.
- If you become pregnant during the treatment or during the 3 months after taking the last dose, tell your doctor **immediately**.

Breast-feeding:
Do not breast-feed during use of the medicine. The reason for this is that it is unknown whether **Alecensa** can pass into breast milk, and could therefore harm your baby

Driving and using machinery
While taking **Alecensa**, take care when driving and using machinery. This is because you may develop vision problems, slowing of the heart beat or low blood pressure that can cause fainting or dizziness.

Important information about some of the ingredients in this medicine
- **Alecensa** contains lactose (a type of sugar). If you have been told by your doctor that you have an intolerance or cannot digest certain sugars, consult your doctor before commencing treatment with this medicine.
- The usual daily dose of **Alecensa** (1200 mg) contains 48 mg sodium (the main ingredient in table/cooking salt). This quantity is equivalent to 2.4% of the recommended maximum daily sodium intake for an adult.

3) How should you use the medicine?

Always use the medicine 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.

Usual dosage

The dosage and the treatment regimen will be determined by the doctor only.
- The usual dosage is generally 4 capsules (a total of 600 mg), twice a day. This means you take a total of 8 capsules (1200 mg) every day.
- If you have severe liver problems before starting treatment with **Alecensa**:
  The usual dosage is 3 capsules (450 mg) twice a day. This means you take a total of 6 capsules (900 mg) each day.

Sometimes the doctor may lower your dosage, stop your treatment for a short time or stop your treatment completely, if you feel unwell.
Do not exceed the recommended dose.

How to take the medicine
- **Alecensa** is taken orally. Swallow the capsules whole. Do not open or dissolve capsules.
- Take the medicine with food.

If you vomit after taking a dose of **Alecensa**, do not take an additional dose. Take the next dose at the usual time.

If you accidentally took a higher dosage of **Alecensa** than you should have, or if a child has accidentally swallowed the medicine, talk to the doctor or proceed to a hospital **immediately**. Take the package of the medicine with you.

If you forget to take the medicine Alecensa at the required time, act according to the following instructions:
- If it is more than 6 hours until the time for the next dose, take the forgotten dose as soon as you remember.
- If it is less than 6 hours until the time for the next dose, do not take the forgotten dose. Wait and take the next dose at your usual time.
- Do not take a double dose to make up for a forgotten dose.

If you stop taking the medicine Alecensa
Adhere to the treatment regimen as recommended by the doctor.
Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.
It is important to take **Alecensa** twice a day for the period of time determined by your doctor.
Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.
If you have further questions regarding use of this medicine, consult the doctor or pharmacist.

4) Side effects

As with any medicine, use of **Alecensa** 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.
The following side effects may occur during use of this medicine.

Tell the doctor immediately if you notice any of the following side effects. Your doctor may lower your dosage, stop your treatment for a short time or stop your treatment completely:
- New signs or worsening of existing signs including difficulty breathing, shortness of breath, or cough with or without mucous or fever - these signs may be similar to signs caused by lung cancer (potential signs of lung inflammation). **Alecensa** can cause severe or life-threatening inflammation of the lungs during treatment.
- Yellowing of the skin or the whites of the eyes, pain on the right side of the stomach area, dark urine, itchy skin, decreased appetite, nausea or vomiting, tiredness, bleeding or bruising more easily than previously (potential signs of liver problems).
- New signs or worsening of existing signs of muscle problems, including: unexplained muscle pain or muscle pain that does not go away, muscle tenderness or weakness (potential signs of muscle problems).
- Fainting, dizziness and low blood pressure (potential signs of slow heart beat).
- You feel tired, weak or short of breath (potential signs of an abnormal breakdown of red blood cells [haemolytic anaemia]).

Additional side effects:
Refer to your doctor if you notice the following side effects:

Very common side effects (may affect more than one user in ten):
- Abnormal results of blood tests intended to detect whether there are liver problems (high levels of alanine aminotransferase, aspartate aminotransferase and bilirubin)
- Abnormal results of blood tests intended to detect whether there is muscle damage (high levels of creatine phosphokinase)
- Abnormal results of blood tests to check for liver disease or bone problems (high levels of alkaline phosphatase)
- You may feel tired, weak or short of breath due to a reduction in the number of red blood cells - anemia
- Vomiting – if you vomit after taking a dose of **Alecensa**, do not take an additional dose, take your next dose at the usual time
- Constipation
- Diarrhea
- Nausea
- Rash
- Swelling caused by fluid build-up in the body (edema)
- Weight gain

Common side effects (may affect up to one user in ten):
- Abnormal results of blood tests to check kidney function (high level of creatinine)
- Inflammation of the mucous membrane of the mouth
- Sensitivity to sunlight – do not expose yourself to the sun for a long period of time while you are taking **Alecensa** and for 7 days after stopping treatment.
  You need to apply sunscreen and lip balm with a Sun Protection Factor (SPF) of 50 or higher to prevent sunburns.
- Alteration in the sense of taste
- Eye problems including blurred vision, loss of vision, seeing black dots or white spots, seeing double
- Increased levels of uric acid in the blood (hyperuricemia)

Uncommon side effects (may affect up to one user in a hundred)
- Kidney problems including rapid loss of kidney function (acute kidney injury)

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

Reporting side effects
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, should be kept in a closed 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.
- Bottle package: Do not store the medicine above 30°C. Store in the original package in order to protect from light. Keep the bottle closed tightly to protect from moisture.
- Blister package: Do not store the medicine above 30°C. Store in the original package in order to protect from light and moisture.
- Do not discard the medicine into the household waste bin or into the wastewater. Ask the pharmacist how to dispose of the medicine in order to protect the environment.

6) Further information

The active ingredient in the medicine is alectinib. Each capsule contains alectinib hydrochloride, equivalent to 150 mg.
In addition to the active ingredient, the medicine also contains:
Sodium lauryl sulfate, hypromellose, carboxymethylcellulose calcium, lactose monohydrate, hydroxypropylcellulose, titanium dioxide (E171), magnesium stearate, potassium chloride, carrageenan, carnauba wax, corn starch.
Ink: white shellac, FD&C Blue No. 2 aluminium lake (E132), yellow iron oxide (E172), red iron oxide (E172), carnauba wax, and glyceryl monooleate
For further information about some of the ingredients of the medicine (lactose and sodium), refer to section 2.

What does the medicine look like and what are the contents of the package?
Alecensa is provided as a white to yellowish-white capsule comprised of two parts; "ALE" is printed in black on one part, and "150 mg" is printed in black on the other part.
- Bottle package: The package contains a bottle with a child resistant cap, containing 240 capsules.
- Blister package: The package contains 224 capsules (4 packs each containing 56 capsules).

*Not all package types may be marketed.

License holder and address: Roche Pharmaceuticals (Israel) Ltd., P.O.B. 6391, Hod Hasharon 4524079.

Manufacturer name and address: F. Hoffmann-La Roche Ltd., Basel, Switzerland.

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