SCHEDULING STATUS

S4

Alecensa® 150 mg (Hard capsule)

Alectinib

Contains sugar, lactose monohydrate 33,67 mg.

Read all of this leaflet carefully before you start using this Alecensa

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- Alecensa 150 mg has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What Alecensa is and what it is used for

Alecensa is a cancer medicine that contains the active ingredient alectinib.

Alecensa blocks the action of an enzyme called ‘ALK tyrosine kinase’. Abnormal forms of this enzyme (due to fault in the gene that makes it) help encourage cancer cell growth. Alecensa may slow down or stop the growth of your cancer. It may also help to shrink your cancer.

Alecensa is used to treat adults with a type of lung cancer called 'non-small cell lung cancer' ('NSCLC'). It is used if your lung cancer:

- is 'ALK-positive' - this means your cancer cells have a fault in a gene that makes an enzyme called ALK ('anaplastic lymphoma kinase'), see 'How Alecensa works', below
- and is advanced.

Alecensa can be prescribed to you as first treatment of your lung cancer, or if you have been previously treated with a medicine containing 'crizotinib'.

2. What you need to know before you take Alecensa

Do not use Alecensa:

- If you are allergic to alectinib or to any of the other ingredients of this medicine, listed in "What ALECENSA contains". If you are not sure, talk to your doctor or nurse before taking Alecensa.
- If you are pregnant or are breastfeeding your baby.

Warnings and precautions

Talk to your doctor or healthcare professional before you take Alecensa:

- if you have an inherited problem called 'galactose intolerance', 'congenital lactase deficiency' or 'glucose-galactose malabsorption'.

Alecensa can cause side effects that you need to tell your doctor about straight away. These include:

- liver injury (hepatotoxicity). Your doctor will take blood tests before you start treatment, then every 2 weeks for the first 3 months of your treatment and then less often. This is to check you do not have any liver problems while taking Alecensa. Tell your doctor straight away if you get any of the following signs: yellowing of your skin or the whites of your eyes, pain on the right

side of your stomach area, dark urine, itchy skin, feeling less hungry than usual, nausea or vomiting, feeling tired, bleeding or bruising more easily than normal.

- slow heart beat (bradycardia).
- lung inflammation (pneumonitis). Alecensa may cause severe or life-threatening swelling (inflammation) of the lungs during treatment. The signs may be similar to those from your lung cancer. Tell your doctor straight away 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, tenderness, and weakness (myalgia). Your doctor will do blood tests at least every 2 weeks for the first month and as needed during treatment with Alecensa. Tell your doctor straight away if you get new or worsening signs of muscle problems, including unexplained muscle pain or muscle pain that does not go away, tenderness, or weakness.

Look out for these while you are taking Alecensa. See ‘Side effects’ for more information.

Sensitivity to sunlight

Do not expose yourself to the sun for any long period of time while you are taking Alecensa and for 7 days after you stop. You need to apply sunscreen and lip balm with a Sun Protection Factor of 50 or higher to help prevent sunburn.

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 years.

Tests and checks

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

Other medicines and Alecensa

Taking other medicines with Alecensa:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Alecensa can affect the way some other medicines work. Also, some other medicines can affect the way Alecensa works.

Talk to your doctor before taking Alecensa if you are taking:

- digoxin, a medicine used to treat heart problems
- dabigatran etexilate, a medicine used to treat blood clots
- methotrexate, a medicine used to treat certain types of cancer or to treat autoimmune diseases (e.g. rheumatoid arthritis)
- nilotinib, a medicine used to treat certain types of cancer
- lapatinib, a medicine used to treat certain types of breast cancer
- mitoxantrone, a medicine used to treat certain types of cancer or autoimmune diseases (e.g. multiple sclerosis)
- everolimus, a medicine used to treat certain types of cancer or used to prevent the body's immune system from rejecting a transplanted kidney, heart or liver
- sirolimus, a medicine used to prevent the body's immune system from rejecting a transplanted kidney, heart or liver
- topotecan, a medicine used to treat certain types of cancer
- medicines used to treat AIDS/HIV (e.g. ritonavir, saquinavir)
- medicines used to treat infections. These include medicines that treat fungal infections (antifungals such as ketoconazole, itraconazole, voriconazole, posaconazole) and medicines that treat certain types of bacterial infection (antibiotics such as telithromycin)

- St. John's Wort, a herbal medicine used to treat depression
- medicines used to stop seizures or fits (anti-epileptics such as phenytoin, carbamazepine, or phenobarbitone)
- medicines used to treat tuberculosis (e.g. rifampicin, rifabutin)
- nefazodone, a medicine used to treat depression

Oral contraceptives

If you take Alecensa whilst using oral contraceptives, the oral contraceptives may be less effective.

Taking Alecensa with food and drink

You should use caution when drinking grapefruit juice or eating grapefruit or Seville oranges while on treatment with Alecensa as they may change the amount of Alecensa in your body. See also section 3 "How to take Alecensa".

Pregnancy and breastfeeding

Alecensa is not for use in women who are pregnant, may become pregnant or plan to breastfeed their babies.

If you are pregnant or breastfeeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Contraception

- You should not become pregnant while taking 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 whilst using oral contraceptives, the oral contraceptives may be less effective.

- Male patients receiving Alecensa, who have female partners of child-bearing potential. The female partner must use highly effective contraceptive methods during treatment and for at least 3 months following the last dose of Alecensa.

Pregnancy

- Do not take Alecensa if you are pregnant. This is because it may harm your baby.
- If you become pregnant when taking the medicine or during the 3 months after taking your last dose, tell your doctor straight away.

Breastfeeding

- Do not breastfeed while taking this medicine.

If you are pregnant or breastfeeding your baby, please consult your doctor or other healthcare professional for advice before taking this medicine.

Driving and using machines

Take special care when driving and using machines as you may develop problems with vision or slowing of the heartbeat or low blood pressure that can lead to fainting or dizziness while you are taking Alecensa.

Important information about some of the ingredients of Alecensa:

Alecensa contains lactose monohydrate. Patients with the rare hereditary conditions of lactose intolerance eg. galactosaemia, should not take Alecensa.

Alecensa contains sodium. The recommended daily dose of Alecensa (1200 mg) contains 48 mg of sodium. Please take this amount into consideration if you are on a controlled sodium diet.

3. How to take Alecensa

Do not share medicines prescribed for you with any other person.

Always take Alecensa exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

How much to take

- The recommended dose is 4 capsules (600 mg) twice a day.
- This means you take a total of 8 capsules (1200 mg) each day.
- Sometimes your doctor may lower your dose, stop your treatment for a short time or stop your treatment completely if you feel unwell.

How to take

- Alecensa is taken by mouth. Swallow each capsule whole. Do not open or dissolve the capsules.
- You must take Alecensa with food.

Your doctor will tell you how long your treatment with Alecensa will last. Do not stop treatment early if you are sick (vomit) after taking Alecensa. Do not take an extra dose of Alecensa on that day. Continue to take Alecensa as normal, the next day. If you have the impression that the effect of Alecensa is too strong or too weak, tell your doctor or pharmacist.

If you take more Alecensa than you should

If you take more Alecensa than you should, talk to a doctor straight away. Take the medicine package and this leaflet with you.
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take Alecensa

- If it is more than 6 hours before your next dose, take the missed dose as soon as you remember.
- If it is less than 6 hours before your next dose, skip the missed dose. Then take the next dose at the usual time.

- Do not take a double dose to make up for a missed dose.

Effects when treatment with Alecensa is stopped

It is important to keep taking Alecensa twice a day for as long as your doctor prescribes it.

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

4. Possible side effects

Alecensa can have side effects.

Not all side effects reported for Alecensa are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Tell your doctor straight away or go to casualty department or hospital if you notice any of the following side effects:

- Yellowing of your skin or the whites of your eyes, pain on the right side of your stomach area, dark urine, itchy skin, feeling less hungry than usual, nausea or vomiting, feeling tired, bleeding or bruising more easily than normal (potential signs of liver problems)
- New or worsening signs of muscle problems, including unexplained muscle pain or muscle pain that does not go away, tenderness, or weakness (potential signs of muscle problems).
- Fainting, dizziness and low blood pressure (potential signs of slow heart beat)
- New or worsening signs including difficulty in breathing, shortness of breath, or cough with or without mucous, or fever - the signs may be similar to those from your lung cancer (potential signs of lung inflammation – pneumonitis). Alecensa can cause severe or life-threatening inflammation of the lungs during treatment.

These are all serious side effects. You may need urgent medical attention.

Other side effects

Tell your doctor, pharmacist or nurse if you notice any of the following side effects:

Frequent:

- abnormal results of blood tests to check for liver problems (high levels of alanine aminotransferase, aspartate aminotransferase and bilirubin)
- abnormal results of blood tests to check for muscle damage (high level of creatine phosphokinase)
- you may feel tired, weak or short of breath due to a reduction in the number of red blood cells, known as anaemia
- vomiting – if you vomit after taking a dose of Alecensa, do not take an extra dose, just take your next dose at the usual time
- constipation
- diarrhoea
- nausea
- rash
- swelling caused by fluid build-up in the body (oedema)
- weight gain.
- abnormal results of blood tests to check kidney function (high level of creatinine)
- blurred vision, loss of sight, black dots or white spots in your vision, and seeing double (problems with your eyes)
- abnormal results of blood tests to check for liver disease or bone disorders (high level of alkaline phosphatase)
- inflammation of the mucous membrane of the mouth
- sensitivity to sunlight – do not expose yourself to the sun for any long period of time while you are taking Alecensa and for 7 days after you stop. You need to apply sunscreen and lip balm with a Sun Protection Factor of 50 or higher to help prevent sunburn.
- alteration in sense of taste

- rapid loss of kidney function (kidney problems).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of Alecensa.

5. How to store Alecensa

Store all medicines out of reach of children.

Store at or below 30 °C.

Store in the original package.

Keep the container in the outer carton to protect from light and moisture.

Do not use after the expiry date on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Alecensa contains

The active substance is alectinib. Each tablet contains 150 mg alectinib.

The other ingredients are:

- carboxymethycellulose calcium, hydroxypropylcellulose, lactose monohydrate, magnesium stearate, sodium lauryl sulphate.
- The capsule shell contains carnauba wax, carrageenan, corn starch, hypromellose, potassium chloride, titanium dioxide (E171). The printing ink contains red iron oxide (E172), yellow iron

oxide (E172), FD and C Blue 2 (aluminium lake, E132), carnauba wax, white shellac, glyceryl monooleate, 1-butanol and dehydrated ethyl alcohol.

Contains sugar (lactose monohydrate 33,67 mg).

What Alecensa looks like and contents of the pack

Alecensa hard capsules are white to yellowish white, size 1 capsules with “ALE” printed in black ink on the cap and “150 mg” printed in black ink on the body.

Alecensa hard capsules are packaged in aluminium foil push-through blisters consisting of three-layered oriented polyamide/aluminium/polyvinyl chloride film and hard-tempered aluminium foil.

Each multipack pack contains 224 capsules of 4 individual packs each containing 56 capsules (7 x blisters of 8 capsules each).

Holder of Certificate of Registration

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SKEDULERINGSTATUS

S4

Alecensa® 150 mg (Harde kapsule)

Alectinib

Bevat suiker, laktosemonohidraat 33,67 mg.

Lees hierdie hele voubiljet noukeurig deur voor u begin om Alecensa te gebruik.

- Hou hierdie voubiljet. U sal dit dalk later weer moet lees.
- As u verdere vrae het, vra asseblief vir u dokter of u apteker.
- Alecensa 150 mg is vir u persoonlik voorgeskryf en u moenie u medisyne met ander mense deel nie. Dit kan skadelik vir hulle wees, selfs al stem hulle simptome met u s'n ooreen.

Wat is in hierdie voubiljet

2. Wat Alecensa is en waarvoor dit gebruik word

Alecensa is 'n kankermedisyne wat die aktiewe bestanddeel alectinib bevat.

Alecensa blokkeer die werking van 'n ensiem genaamd 'ALK-tirosienkinase'. Abnormale vorme van hierdie ensiem (as gevolg van 'n fout in die geen wat dit maak) help om kankerselgroei aan te moedig. Alecensa kan die groei van u kanker verlangsaam of stop. Dit kan ook help om u kanker te laat krimp.

Alecensa word gebruik om volwassenes met ’n tipe longkanker genaamd ‘nie-kleinsellongkanker’ (‘NSCLC’) te behandel. Dit word gebruik as u longkanker:

- ‘ALK-positief’ is – dit beteken dat u kankerselle ’n fout in ’n geen het wat ’n ensiem genaamd ALK (‘anaplastiese limfoomkinase’) maak, sien ‘Hoe Alecensa werk’ hieronder
- en gevorderd is.

Alecensa kan vir u voorgeskryf word as ’n eerste behandeling vir u longkanker of as u voorheen behandel is met ’n medisyne wat ‘crizotinib’ bevat.

2. Wat u moet weet voordat u Alecensa neem

Moenie Alecensa gebruik nie:

- As u allergies vir alectinib of enige van die ander bestanddele van hierdie medisyne is, gelys in “Wat ALECENSA bevat”. As u onseker is, gesels met u dokter of verpleegkundige voor u Alecensa neem.
- As u swanger is of u baba borsvoed.

Waarskuwings en voorsorgmaatreëls

Praat met u dokter of gesondheidsorgkundige voordat u Alecensa neem:

- as u ’n oorerflike probleem genaamd ‘galaktose-intoleransie’, ‘aangebore laktasetekort’ of ‘glukose-galaktose-wanabsorpsie’ het.

Alecensa kan newe-effekte veroorsaak waarvan u u dokter dadelik moet vertel. Dit sluit in:

- lewerbeskadiging (hepatotoksisiteit). U dokter sal bloedtoetse wil doen voordat u met behandeling begin, daarna elke 2 weke vir die eerste 3 maande van u behandeling en dan minder dikwels. Dit is om na te gaan of u enige lewerprobleme het terwyl u Alecensa neem. Vertel u dokter dadelik as u enige van die volgende tekens kry: Geelwording van u vel of die wit van u oë, pyn aan die regterkant van u maagarea, donker urien, jeukerige vel, kleiner eetlus as gewoonlik, naarheid of braking, tamheid, makliker bloeding of kneusing as wat normaal is.

- stadige hartklop (bradikardie).
- longinflammasie (pneumonitis). Alecensa kan erge of lewensbedreigende swelling (inflammasie) van die longe tydens behandeling veroorsaak. Die tekens kan soortgelyk aan dié van u longkanker wees. Vertel u dokter dadelik as u enige nuwe of erger tekens het, insluitende moeilike asemhaling, kortasemheid, hoes met of sonder mukus of koors.
- erge spierpyn, teerheid en swakheid (mialgie). U dokter sal minstens elke 2 weke vir die eerste maand en soos nodig tydens behandeling met Alecensa bloedtoetse doen. Vertel u dokter dadelik as u nuwe of erger tekens van spierprobleme het, insluitende spierpyn wat nie verklaar kan word nie of spierpyn wat nie weggaan nie, teerheid of swakheid.

Wys op die uitkyk hiervoor terwyl u Alecensa neem. Sien ‘Newe-effekte’ vir nog inligting.

Sensitiwiteit vir sonlig

Moenie uself vir lang tye aan die son blootstel terwyl u Alecensa neem en vir 7 dae nadat u dit gestaak het nie. U moet sonskerm en lipsalf met ’n sonbeskermingsfaktor van 50 of hoër aanwend om sonbrand te help voorkom.

Kinders en adolessente

Alecensa is nie in kinders of adolessente bestudeer nie. Moenie hierdie medisyne aan kinders of adolessente jonger as 18 jaar gee nie.

Toetse en ondersoeke

Wanneer u Alecensa neem, sal u dokter bloedtoetse doen voordat u met behandeling begin, daarna elke 2 weke vir die eerste 3 maande van u behandeling en dan minder dikwels. Dit is om na te gaan of u enige lewer- of spierprobleme het terwyl u Alecensa neem.

Ander medisyne en Alecensa

Neem van ander medisyne saam met Alecensa:

Vertel altyd u gesondheidsorgkundige as u enige ander medisyne neem. (Dit sluit aanvullende of tradisionele medisyne in.)

Stel asseblief u dokter of apteker in kennis indien u onlangs enige ander medisynes geneem het. Die rede hiervoor is dat Alecensa die manier kan affekteer waarop sommige ander medisynes werk. Daar is ook sekere ander medisyne wat die manier waarop Alecensa werk, kan beïnvloed.

Praat met u dokter voordat u Alecensa neem as u die volgende neem:

- digoksien, ’n medisyne wat gebruik word om hartprobleme te behandel
- dabigatraan eteksilaat, ’n medisyne wat gebruik word om bloedklonte te behandel
- metotreksaat, ’n medisyne wat gebruik word om sekere tipes kanker te behandel of om outo-immuunsiektes (bv. rumatoïedartritis) te behandel
- nilotinib, ’n medisyne wat gebruik word om sekere tipes kanker te behandel
- lapatinib, ’n medisyne wat gebruik word om sekere tipes borskanker te behandel
- mitoksantroon, ’n medisyne wat gebruik word om sekere tipes kanker of outo-immuunsiektes (bv. meervoudige sklerose) te behandel
- everolimus, ’n medisyne wat gebruik word om sekere tipes kanker te behandel of gebruik word om te voorkom dat die liggaam se immuunstelsel ’n oorgeplante nier, hart of lewer verwerp
- sirolimus, ’n medisyne wat gebruik word om te voorkom dat die liggaam se immuunstelsel ’n oorgeplante nier, hart of lewer verwerp
- topotekaan, ’n medisyne wat gebruik word om sekere tipes kanker te behandel
- medisynes wat gebruik word om vigs/MIV te behandel (bv. ritonavir, sakwinavir)
- medisynes wat gebruik word om infeksies te behandel. Dit sluit medisynes in wat fungusinfeksies behandel (antifungale middels soos as ketokonasool, itrakonasool, vorikonasool, posakonasool) en medisynes wat gebruik word om sekere tipes bakteriële infeksies te behandel (antibiotika soos telitromisien)

- Sintjanskruid, ’n kruiemedisyne wat gebruik word om depressie te behandel
- medisynes wat gebruik word om stuiptrekkings of toevalle te stop (anti-epileptika soos fenitoïen, karbamasepien of fenobarbitoon)
- medisynes wat gebruik word om tuberkulose te behandel (bv. rifampisien, rifabutien)
- nefasodoon, ’n medisyne wat gebruik word om depressie te behandel

Mondelikse voorbehoedmiddels

As u Alecensa neem terwyl u mondelikse voorbehoedmiddels gebruik, kan die mondelikse voorbehoedmiddels minder doeltreffend wees.

Wanneer Alecensa met kos en drank geneem word

U moet versigtig wees wanneer u pomelosap drink of Seville-lemoene eet terwyl u op behandeling met Alecensa is aangesien dit die hoeveelheid Alecensa in u liggaam kan verander. Sien ook afdeling 3 "Hoe om Alecensa te neem".

Swangerskap en borsvoeding

Alecensa is nie vir gebruik vir vroue wat swanger is, swanger kan raak of beplan om hulle babas te borsvoed nie.

As u swanger is of borsvoed, dink dat u swanger kan wees of beplan om ’n baba te hê, vra u dokter of apteker se raad voordat u hierdie medisyne neem.

Voorbehoeding

- U moenie swanger raak terwyl u hierdie medisyne neem nie. As u swanger kan raak, moet u ’n uiters doeltreffende voorbehoedmiddel gebruik terwyl u op behandeling is en vir minstens 3 maande nadat behandeling gestaak is. Praat met u dokter oor die regte voorbehoedmiddels vir u en u seksmaat. As u Alecensa neem terwyl u mondelikse voorbehoedmiddels gebruik, kan die mondelikse voorbehoedmiddels minder doeltreffend wees.

- Manlike pasiënte wat Alecensa kry, wat vroulike seksmaat het wat kinders kan kry. Die vroulike seksmaat moet uiters doeltreffende voorbehoedmiddels tydens behandeling en vir minstens 3 maande na die laaste dosis Alecensa gebruik.

Swangerskap

- Moenie Alecensa gebruik as u swanger is nie. Die rede hiervoor is dat dit u baba kan benadeel.
- As u swanger raak terwyl u die medisyne neem of gedurende die 3 maande nadat u u laaste dosis geneem het, moet u u dokter dadelik vertel.

Borsvoeding

- Moenie borsvoed terwyl u hierdie medisyne neem nie.

As u swanger is of u baba borsvoed, raadpleeg asseblief u dokter of ander gesondheidsorgkundige vir raad voordat u hierdie medisyne neem.

Motorbestuur en die gebruik van masjinerie

Wees besonder versigtig wanneer u bestuur en masjiene gebruik aangesien u probleme met sig of stadiger hartklop of laer bloeddruk kan ontwikkel wat floutes of duiseligheid tot gevolg kan hê terwyl u Alecensa neem.

Belangrike inligting oor ’n aantal bestanddele in Alecensa:

Alecensa bevat laktosemonohidraat. Pasiënte met seldsame oorerflike toestande van laktose-intoleransie, bv. galaktosemie, moet nie Alecensa neem nie.

Alecensa bevat natrium. Die aanbevole daaglikse dosis Alecensa (1 200 mg) bevat 48 mg natrium. Neem hierdie hoeveelheid asseblief in ag as u op ’n beheerde natriumdieet is.

3. Hoe om Alecensa te neem

Moenie medisynes wat vir u voorgeskryf is, met enigiemand anders deel nie.

Neem Alecensa altyd presies volgens u dokter se aanwysings. U moet u dokter of apteker raadpleeg as u nie seker is nie.

Hoeveel om te neem

- Die aanbevole dosis is 4 kapsules (600 mg) twee keer per dag.
- Dit beteken dat u altesaam 8 kapsules (1 200 mg) elke dag neem.
- U dokter kan u dosis soms verlaag, u behandeling vir ’n kort rukkie staak of u behandeling heeltemal staak as u nie goed voel nie.

Hoe om te neem

- Alecensa word mondeliks geneem. Sluk elke kapsule heel in. Moenie die kapsules oopmaak of oplos nie.
- U moet Alecensa met kos neem.

U dokter sal u inlig hoe lank u behandeling met Alecensa sal duur. Moenie behandeling vroeg staak as u siek is (braak) nadat u Alecensa geneem het nie. Moenie daardie dag ’n ekstra dosis Alecensa neem nie. Gaan voort om Alecensa die volgende dag soos gewoonlik te neem. Indien u van mening is dat die effek van Alecensa te sterk of te swak is, vertel u dokter of apteker.

As u meer Alecensa neem as wat u moet

As u meer Alecensa neem as wat u moet, praat dadelik met ’n dokter. Neem die medisyneverpakking en hierdie voubiljet saam met u.

In die geval van oordosering, raadpleeg u dokter of apteker. As nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

As u vergeet om Alecensa te neem

- As dit meer as 6 ure voor u volgende dosis is, neem die dosis wat u oorgeslaan het sodra u onthou.

- As dit minder as 6 ure voor u volgende dosis is, slaan die oorgeslane dosis heeltemal oor. Neem die volgende dosis dan op die gewone tyd.
- Moenie ’n dubbele dosis neem om vir die oorgeslane dosis op te maak nie.

Effekte wanneer behandeling met Alecensa gestaak word

Dit is belangrik om voort te gaan om Alecensa twee keer per dag te neem vir so lank as wat u dokter dit voorskryf.

As u enige verdere vrae oor die gebruik van hierdie medisyne het, vra u dokter, apteker of verpleegkundige.

4. Moontlike newe-effekte

Alecensa kan newe-effekte hê.

Nie alle newe-effekte wat vir Alecensa aangemeld is, is by hierdie voubiljet ingesluit nie. As u algemene gesondheid vererger of as u enige ongunstige effekte ondervind terwyl u hierdie medisyne neem, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgkundige vir raad.

Vertel u dokter dadelik of gaan na ongevalle of ’n hospitaal as u enige van die volgende newe-effekte opmerk:

- Geelwording van u vel of die wit van u oë, pyn aan die regterkant van u maagarea, donker urien, jeukerige vel, kleiner eetlus as gewoonlik, naarheid of braking, tamheid, makliker bloeding of kneusing as wat normaal is (potensiële tekens van lewerprobleme)
- Nuwe of erger tekens van spierprobleme, insluitende spierpyn wat nie verklaar kan word nie of spierpyn wat nie weggaan nie, teerheid of swakheid (potensiële tekens van spierprobleme).
- Floutes, duiseligheid en lae bloeddruk (potensiële tekens van stadige hartklop)
- Nuwe of erger tekens, insluitende moeilike asemhaling, kortasemheid, hoes met of sonder mukus, of koors – die tekens kan soortgelyk aan dié van u longkanker wees (potensiële tekens van longinflammasie – pneumonitis). Alecensa kan erge of lewensbedreigende inflammasie van die longe tydens behandeling veroorsaak.

Dit is almal baie ernstige newe-effekte. U sal dalk dringende mediese aandag nodig hê.

Ander newe-effekte

Laat u dokter, apteker of verpleegkundige weet as u enige van die volgende newe-effekte opmerk:

Gereeld:

- abnormale uitslae van bloedtoetse wat kyk vir lewerprobleme (hoë vlakke van alanien-aminotransferase, aspartaat-aminotransferase en bulirubien)
- abnormale uitslae van bloedtoetse wat kyk vir spierskade (hoë vlakke van kreatienfosfokinase)
- u kan moeg, swak of kortasem voel as gevolg van ’n afname in die aantal rooibloedselle, as anemie bekend
- braking – as u braak nadat u ’n dosis Alecensa geneem het, moenie ’n ekstra dosis neem nie, neem net u volgende dosis op die gewone tyd
- hardlywigheid
- diarree
- naarheid
- uitslag
- swelling veroorsaak deur die opbou van vloeistof in die liggaam (edeem)
- gewigstoename
- abnormale uitslae van bloedtoetse wat kyk na nierfunksie (hoë vlak van kreatinien)
- dowwe sig, verlies aan sig, swart stippels of wit kolle in u sig en dubbelsig (probleme met u oë)
- abnormale resultate van bloedtoetse om vir lewersiekte of beensteurnisse te toets (hoë vlakke van alkalienfosfatase)
- inflammasie van die mukeuse membraan van die mond
- sensitiwiteit vir sonlig – moenie uself vir lang tye aan die son blootstel terwyl u Alecensa neem en vir 7 dae nadat u dit gestaak het nie. U moet sonskerm en lipsalf met ’n sonbeskermingsfaktor van 50 of hoër aanwend om sonbrand te help voorkom.
- verandering in smaaksin

- vinnige verlies van nierfunksie (nierprobleme).

Indien u enige newe-effekte opmerk wat nie in hierdie voubiljet genoem word nie, stel asseblief u dokter of apteker in kennis.

Aanmelding van newe-effekte

As u newe-effekte ondervind, praat met u dokter of verpleegster. Dit sluit enige moontlike newe-effekte in wat nie in hierdie voubiljet genoem word nie. U kan ook newe-effekte aanmeld by SAHPRA via die aanmeldingsvorm vir ongewenste reaksie op middels ("6.04 Adverse Drug Reaction Reporting Form"), wat aanlyn onder SAHPRA se publikasies gevind kan word: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van Alecensa te voorsien.

5. Hoe om Alecensa te stoor

Bêre alle medisyne buite die bereik van kinders.

Stoor by of onder 30 ºC.

Stoor in die oorspronklike verpakking.

Bêre die houer in die buitenste karton om dit teen lig en vog te beskerm.

Moenie gebruik na die vervaldatum wat op die karton aangedui word nie.

Vat alle ongebruikte medisyne terug na u apteker.

Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pakkie en ander inligting

Wat Alecensa bevat

Die aktiewe bestanddeel is alectinib. Elke tablet bevat 150 mg alectinib.

Die ander bestanddele is:

- karboksimetielsellulosekalsium, hidroksipropielsellulose, laktosemonohidraat, magnesiumstearaat, natriumlourielsulfaat.

- Die kapsuledop bevat karnoubawas, karrageenien, mielieblom, hipromellose, kaliumchloried, titaandioksied (E171). Die drukkersink bevat rooi-ysteroksied (E172), geelysteroksied (E172), FD en C Blue 2 (aluminiumlak, E132), karnoubawas, wit skellak, gliserielmonooleaat, 1-butanol en gedehidreerde etielalkohol.

Bevat suiker (laktosemonohidraat 33,67 mg).

Hoe Alecensa lyk en die inhoud van die verpakking

Alecensa harde kapsules is wit tot gelerigwit, grootte 1-kapsules met “ALE” in swart ink op die dop gedruk en “150 mg” in swart ink op die houer gedruk.

Alecensa harde kapsules word verpak in aluminiumfoelie deurdrukstulppakke wat bestaan uit drielaag-geöriënteerde poliamied/aluminium/polivinielchloriedfilm en verharde aluminiumfoelie.

Elke multipak-verpakking bevat 224 kapsules van 4 individuele pakke wat elkeen 56 kapsules bevat (7 x stulppakke van 8 kapsules elk).

Houer van registrasiesertifikaat

Roche Products (Pty) Ltd

Bekkerweg 90

Hertford Office Park

Geboi E, Vorna Vallei

Midrand

Suid-Afrika

Roche etiekhulplyn (Ethical Assistance Line), tolvry: 0800 21 21 25

Hierdie voubiljet is laas hersien in

Registrasienommers

53/32.16/0183