



Leter drejtuar profesionisteve te kujdesit shendetesor

17 dhjetor 2025

ALECENSA/ALECENSARO (alektinib), Udhëzime për menaxhimin e hipertrigliceridemisë së rëndë

Të nderuar profesionist të kujdesit shëndetësor,
Hoffmann-La Roche Ltd në marrëveshje me Agjencinë e Kosovës për Produkte dhe Pajisje Medicinale (AKPPM) do të dëshirojnë t'ju informojnë si vijon:

Përmbledhja

- **Hipertrigliceridemia, duke përfshirë episodet e rënda dhe kërcënuese për jetën, është identifikuar si një reaksion i ri i padëshiruar i barit Alecensa.**
- **Hipertrigliceridemia e rëndë konsiderohet urgjencë mjekësore, pasi mund të çojë në pankreatit akut. Pankreatiti i shkaktuar nga hipertrigliceridemia u raportua në periudhën pas tregtimit për Alecensa, prandaj do të shtohet një paralajmërim dhe masë e re paraprake në informacionin e produktit të Alecensa.**
- **Pacientëve duhet t'u bëhet një matje paraprake e triglicerideve në gjak përpara se të nisin përdorimin e Alecensa, si dhe periodikisht gjatë trajtimit.**
- **Pacientët duhet të monitorohen për simptomat që janë treguese të pankreatitit akut, veçanërisht te pacientët me rrezik të shtuar për pankreatit.**
- **Nëse ndodhin rritje të rënda ose kërcënuese për jetën të triglicerideve në gjak, Alecensa duhet të ndërpritet përkohësisht deri sa të kthehet të paktën në hipertrigliceridemi të moderuar (trigliceridet në gjak > 300–500 mg/dL ose > 3,42 – 5,7 mmol/L).**
- **Te këta pacientë duhet të vlerësohen faktorët e rrezikut për pankreatitin dhe faktorët e trajtueshëm të rrezikut duhet të adresohen para fillimit të trajtimit me Alecensa. Alecensa mund të rifillohet në të njëjtën dozë, me monitorim të rregullt të niveleve të triglicerideve te këta pacientë.**



Informacionet për shqetësimet lidhur me sigurinë

Alecensa (alektinib, RO5424802, CH5424802) indikohet si trajtim ndihmës pas rezektimit të tumorit për pacientët me kancer të mushkërive me qeliza jo të vogla (NSCLC), pozitiv për kinazën e limfomës anaplastike (ALK), për trajtimin e linjës së parë të pacientëve me NSCLC ALK-pozitive lokalisht të avancuar ose metastatike dhe për trajtimin e pacientëve me NSCLC ALK-pozitive, lokalisht të avancuar ose metastatike që kanë avancuar te krizotinibi ose janë intolerantë ndaj tij.

Të dhënat kumulative nga studimet klinike dhe burimet pas tregtimit e identifikuan hipertriglicerideminë si një rrezik të ri për Alecensa, me episode të padëshiruara të hipertrigliceridemisë të çdo shkalle intensiteti të raportuara për 4,3% të pacientëve nga studimet klinike kryesore dhe episode të padëshiruara të rënda të hipertrigliceridemisë të raportuara për 1,5% të pacientëve nga studimet kryesore. Trigliceridet nuk u monitoruan vazhdimisht në provat klinike. Të dhënat laboratorike nga 3 prova klinike në të cilat u matën trigliceridet treguan një rritje nga pika e nisjes dhe shumica e shmangieve nga pika e nisjes ishin nga normalja deri në gradën 1 (150 mg/dL- 300 mg/dL; 1,71 mmol/L-3,42 mmol/L), megjithatë, në këto prova klinike u raportuan edhe episode të rritjeve të vlerave laboratorike të gradës ≥ 3 .

Në përgjithësi, rastet e vëzhguara të hipertrigliceridemisë ishin kryesisht me intensitet të lehtë dhe të moderuar, megjithatë, nga burimet pas tregtimit, u raportuan pesë raste, të konfirmuara nga ana mjekësore, të rënda deri në kërcënuese për jetën nën trajtimin Alecensa. Tre nga këto raste rezultuan në ndërlikimin e pankreatitit kërcënues për jetën, të cilat të gjitha u shëruan përfundimisht pas trajtimit. Një nga këto raste pati një rikthim pozitiv të hipertrigliceridemisë kërcënuese për jetën pas rifillimit të Alecensa. Shfaqja e parë e këtyre rasteve serioze varioi midis 6 javëve dhe 1 viti pas fillimit të trajtimit me Alecensa.

Në kuadër të këtyre vëzhgimeve, do të lëshohen udhëzimet e mëposhtme:

- Pacientët duhet të bëjnë një matje paraprake të triglicerideve në gjak përpara se të fillojnë përdorimin e Alecensa, si dhe periodikisht gjatë trajtimit.
- Pacientët duhet të monitorohen për simptoma që janë treguese të pankreatitit akut, veçanërisht te pacientët me rrezik të shtuar për pankreatit.
- Nëse ndodhin rritje të rënda (trigliceridet në gjak >500 deri në 1000 mg/dL ose $>5,7$ deri në $11,4$ mmol/L) ose kërcënuese për jetën (trigliceridet në gjak >1000 mg/dL ose $>11,4$ mmol/L) të triglicerideve në gjak, Alecensa duhet të ndërpritet përkohësisht deri në kthimin në të paktën në hipertrigliceridemi të moderuar (trigliceridet në gjak >300 – 500 mg/dL ose $>3,42$ – $5,7$ mmol/L).
- Te këta pacientë duhet të vlerësohen faktorët e rrezikut për pankreatitin dhe faktorët e trajtueshëm të rrezikut duhet të trajtohen para fillimit të trajtimit me Alecensa. Alecensa mund të rifillohet në të njëjtën dozë, me monitorim të rregullt të niveleve të triglicerideve te këta pacientë.

Në përgjithësi, profili përfitim-rrezik i Alecensa vazhdon të jetë i favorshëm.

Informacioni i produktit do të përditësohet për të përfshirë hipertriglicerideminë në seksionin "Efektet e padëshiruara", si dhe për të përfshirë rekomandimet e mësipërme në seksionet "Paralajmërime dhe masa paraprake të veçanta për përdorimin" dhe "Pozologjia dhe mënyra



e administrimit". Nuk propozohen aktivitete të mëtejshme për minimizimin e rrezikut përveç udhëzimeve të dhëna në etiketë.

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Të gjitha efektet anësore të dyshuara duhet të raportohen në Agjencinë e Kosovës për Produkte dhe Paisje dhe Medicinale (AKPPM). AKPPM inkurajon punonjësit e kujdesit shëndetësor të raportojnë efektet anësore të dyshuara duke plotësuar formularin e raportimit për efekte anësore që mund ta shkarkoni në webfaqen e AKPPM-së (<https://akppm.rks-gov.net>) dhe ta dërgoni në njërën nga mënyrat e mëposhtme:

Në mënyrë elektronike: info.akppm@rks-gov.net

Me postë: Agjencia e Kosovës për Produkte dhe Paisje Medicinale- Lagjia e Spitalit (Q.K.U.K), 10000 Prishtinë, Kosovë.

Raportimi i efekteve anësore mund të bëhet edhe direkt te personat lokal përgjegjës për farmakovigjilencë për produktet e regjistruara në Republikën e Kosovës.

Pika e kontaktit të kompanisë

Hoffmann - La Roche Ltd.
Zyra përfaqësuese Kosovë
Rr. Tirana, Icon Tower, kati i 16të
10000 Prishtinë, Republika e Kosovës
Tel: +38338609217
Web: www.roche.com

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17. decembar 2025.

ALECENSA/ALECENSARO (alektinib), Uputstvo za lečenje teške hipertrigliceridemije

Poštovani zdravstveni radnici,
Hoffmann La Roche LTD u dogovoru sa AKPPM-Kosovska Agencija za Lekove i
Medicinska Sredstva želi da vas obavesti o sledećem:

Sažetak

- **Hipertrigliceridemija, uključujući teške i po život opasne događaje, identifikovana je kao nova neželjena reakcija leka Alecensa.**
- **Teška hipertrigliceridemija se smatra hitnim medicinskim slučajem jer može dovesti do akutnog pankreatitisa. Pankreatitis izazvan hipertrigliceridemijom prijavljen je u postmarketinškom periodu za lek Alecensa, tako da će novo upozorenje i mere opreza biti dodati u Informacije o proizvodu za lek Alecensa.**
- **Pacijentima treba obaviti početno merenje triglicerida u krvi pre početka lečenja lekom Alecensa, a treba ga obavljati i redovno tokom lečenja.**
- **Pacijente treba pratiti u pogledu simptoma koji ukazuju na akutni pankreatitis, posebno one sa povećanim rizikom od pankreatitisa.**
- **Ukoliko dođe do teškog ili po život opasnog povećanja nivoa triglicerida u krvi, uzimanje leka Alecensa treba privremeno prekinuti do oporavka, barem do nastupanja umerene hipertrigliceridemije (trigliceridi u krvi >300–500 mg/dl ili >3,42–5,7 mmol/l).**
- **Kod takvih pacijenata treba proceniti faktore rizika za pankreatitis, a faktore rizika koji se mogu lečiti treba rešiti pre početka lečenja lekom Alecensa. Lečenje lekom Alecensa se može nastaviti u istoj dozi, pri čemu kod takvih pacijenata treba redovno pratiti nivo triglicerida.**

Osnovne informacije o bezbednosnom riziku



Lek Alecensa (alektinib, RO5424802, CH5424802) indikovano je kao adjuvantna terapija nakon resekcije tumora kod pacijenata sa nemikrocelularnim karcinomom pluća (NSCLC) pozitivnim na anaplastičnu limfomsku kinazu (ALK), za prvu liniju lečenja pacijenata sa ALK-pozitivnim lokalno uznapredovalim ili metastatskim NSCLC i za lečenje pacijenata sa ALK-pozitivnim, lokalno uznapredovalim ili metastatskim NSCLC kod kojih je došlo do progresije bolesti tokom lečenja krizotinibom ili koji su intolerantni na njega.

Kumulativni podaci iz kliničkih studija i postmarketinških izvora identifikovali su hipertrigliceridemiju kao novi rizik leka Alecensa, pri čemu je hipertrigliceridemija bilo koje težine kao neželjeni događaj prijavljena kod 4,3% pacijenata iz ključnih kliničkih ispitivanja, dok je ozbiljna hipertrigliceridemija kao neželjeni događaj prijavljena kod 1,5% pacijenata iz ključnih ispitivanja. Trigliceridi nisu dosledno praćeni u kliničkim ispitivanjima. Laboratorijski podaci iz 3 klinička ispitivanja u kojima su mereni trigliceridi pokazali su povećanje u odnosu na početnu vrednost, a većina odstupanja od početne vrednosti bila je od normale do 1. stepena (150–300mg/dl; 1,71–3,42 mmol/l). Međutim, u ovim kliničkim ispitivanjima zabeleženi su i događaji povećanja laboratorijskih rezultata stepena ≥ 3 .

Sve u svemu, uočeni slučajevi hipertrigliceridemije uglavnom su bili blage i umerene težine, međutim, iz postmarketinških izvora prijavljeno je pet medicinski potvrđenih slučajeva teške do po život opasne hipertrigliceridemije tokom lečenja lekom Alecensa. Tri od ovih slučajeva rezultirala su komplikacijom u vidu pankreatitisa opasnog po život, od kojih su se svi na kraju oporavili nakon lečenja. U jednom slučaju je ponovno uvođenje terapije lekom Alecensa dovelo do ponovne pojave hipertrigliceridemije opasne po život. Početak ovih ozbiljnih slučajeva kretao se između 6 nedelja i 1 godine nakon početka lečenja lekom Alecensa.

U svetlu ovih zapažanja, biće izdate sledeće smernice:

- Pacijentima treba obaviti početno merenje triglicerida u krvi pre početka lečenja lekom Alecensa, a treba ga obavljati i redovno tokom lečenja.
- Pacijente treba pratiti u pogledu simptoma koji ukazuju na akutni pankreatitis, posebno one sa povećanim rizikom od pankreatitisa.
- Ukoliko dođe do teškog (trigliceridi u krvi od >500 do 1000 mg/dl ili od $>5,7$ do $11,4$ mmol/l) ili po život opasnog (trigliceridi u krvi >1000 mg/dl ili $>11,4$ mmol/l) povećanja nivoa triglicerida u krvi, uzimanje leka Alecensa treba privremeno prekinuti do oporavka, barem do umerene hipertrigliceridemije (trigliceridi u krvi >300 – 500 mg/dl ili $>3,42$ – $5,7$ mmol/l).
- Kod takvih pacijenata treba proceniti faktore rizika za pankreatitis, a faktore rizika koji se mogu lečiti treba lečiti pre početka lečenja lekom Alecensa. Lečenje lekom Alecensa se može nastaviti u istoj dozi, pri čemu kod ovih pacijenata treba redovno pratiti nivo triglicerida.

Sve u svemu, profil koristi i rizika leka Alecensa i dalje je povoljan.

Informacije o proizvodu će biti ažurirane kako bi se hipertrigliceridemija dodala u odeljak „Neželjena dejstva“, kao i da bi se gorenavedene preporuke dodale u odeljke „Posebna upozorenja i mere predostrožnosti za upotrebu“ i „Doziranje i način primene“. Nisu predložene nikakve druge aktivnosti za smanjenje rizika osim smernica navedenih na etiketi.



Poziv za prijavljivanje

Zdravstveni radnici treba da prijave neželjene događaje za koje se sumnja da su povezani sa upotrebom leka Alecensa na adresu:

Elektronski: info.akppm@rks-gov.net

Poštom: Agencija za lekove i uređaje Kosova - Bolnički okrug
(Q.K.U.K), 10000
Proshtina, Kosova

Osoba za kontakt u kompaniji


<Podaci osobe za kontakt za pristup dodatnim informacijama, uključujući relevantne adrese veb-sajtova, brojeve telefona i poštansku adresu:

Kontakt osoba kompanije
Hoffmann - La Roche Ltd. Predstavništvo na Kosovu
Rr. Tirana, ICON Tower, 16. sprat
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Letter to healthcare professionals

17 December 2025

ALECENSA/ALECENSARO (alectinib), Guidance for Management of Severe Hypertriglyceridaemia

Dear Healthcare professional,
Hoffmann-La Roche Ltd in agreement with AKPPM would like to inform you of the following:

Summary

- **Hypertriglyceridaemia, including severe and life-threatening events, has been identified as a new Adverse Drug Reaction of Alecensa.**
- **Severe hypertriglyceridaemia is considered a medical emergency, as it may lead to acute pancreatitis. Hypertriglyceridaemia-induced pancreatitis was reported in the postmarketing period for Alecensa, therefore a new Warning and Precaution will be added in the Alecensa Product Information.**
- **Patients should have a baseline blood triglyceride measurement before starting Alecensa, as well as periodically while on treatment.**
- **Patients should be monitored for symptoms indicative of acute pancreatitis, particularly in patients at increased risk for pancreatitis.**
- **If severe or life-threatening elevations of blood triglycerides occur, Alecensa should be temporarily withheld until recovery to at least moderate hypertriglyceridaemia (blood triglycerides > 300-500 mg/dL or > 3.42 – 5.7 mmol/L).**



- **Risk factors for pancreatitis should be evaluated in such patients, and treatable risk factors should be addressed before starting treatment with Alecensa. Alecensa may be resumed at the same dose, with triglyceride levels monitored regularly in such patients.**

Background on the safety concern

Alecensa (alectinib, RO5424802, CH5424802) is indicated as adjuvant treatment following tumor resection for patients with anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC), for the first-line treatment of patients with ALK-positive locally advanced or metastatic NSCLC and for the treatment of patients with ALK-positive, locally advanced or metastatic NSCLC who have progressed on or are intolerant to crizotinib.

Cumulative data from clinical studies and postmarketing sources identified hypertriglyceridaemia as a new risk for Alecensa, with hypertriglyceridaemia adverse events of any grade severity reported for 4.3% of patients from pivotal clinical trials, and severe hypertriglyceridaemia adverse events reported for 1.5% of patients from pivotal trials. Triglycerides were not consistently monitored in clinical trials. Laboratory data from 3 clinical trials in which triglycerides were measured showed an increase from baseline, and the majority of shifts from baseline were from normal to grade 1 (150mg/dL- 300mgdL; 1.71mmol/L-3.42mmol/L), however, events of grade ≥ 3 laboratory elevations were also reported in these clinical trials.

Overall, the observed hypertriglyceridaemia cases were mostly of mild and moderate severity, however from postmarketing sources, five severe to life-threatening medically confirmed cases were reported under Alecensa treatment. Three of these cases resulted in the complication of life-threatening pancreatitis, all of which ultimately recovered upon treatment. One of these cases had a positive rechallenge of life-threatening hypertriglyceridemia upon Alecensa resumption. The onset of these serious cases ranged between 6 weeks and 1 year after the start of Alecensa treatment.

In light of these observations, the following guidance will be issued:

- Patients should have a baseline blood triglyceride measurement before starting Alecensa, as well as periodically while on treatment.
- Patients should be monitored for symptoms indicative of acute pancreatitis, particularly in patients at increased risk for pancreatitis.
- If severe (blood triglycerides >500 to 1000 mg/dL or >5.7 to 11.4 mmol/L) or life-threatening (blood triglycerides >1000 mg/dL or >11.4 mmol/L) elevations of blood triglycerides occur, Alecensa should be temporarily withheld until recovery to at least moderate hypertriglyceridaemia (blood triglycerides >300 - 500 mg/dL or >3.42 - 5.7 mmol/L).
- Risk factors for pancreatitis should be evaluated in such patients, and treatable risk factors should be treated before starting treatment with Alecensa. Alecensa may be resumed at the same dose, with triglyceride levels monitored regularly in these patients.



Overall, the benefit-risk profile of Alecensa continues to be favourable.

The Product Information will be updated to include Hypertriglyceridaemia into the 'Undesirable Effects' section, as well as to include above recommendations into the 'Special warnings and precautions for use' and 'Posology and method of administration' sections. No further risk minimisation activities other than the guidance provided in the label are proposed.

Call for reporting

All suspected adverse reactions should be reported to the Kosovo Medicines Agency (KMA). KMA encourages healthcare professionals to report suspected adverse reactions by completing the adverse reaction reporting form that can be downloaded from the KMA website (<https://akppm.rks-gov.net>) and sending it in one of the following ways:

Electronically: info.akppm@rks-gov.net

By post: Kosovo Agency for Medicinal Products and Devices - Hospital District (Q.K.U.K),
10000

Pristina, Kosovo.

Reporting of adverse reactions can also be done directly to the local person responsible for pharmacovigilance for products registered in the Republic of Kosovo.

OCREVUS is not subject to additional monitoring in any country.

Company contact point

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Web: www.roche.com

Yours sincerely,

Krenar Jelliqi

PV local responsible

Kosovo

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