

Indicaciones para la utilización y prescripción de atorvastatina en dispilidemias

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Todos los pacientes deben cumplir con cambios terapéuticos de estilos de vida nutrición y adherencia al programa de seguimiento recomendados por su médico de familia y el equipo de salud de la IPS Básica (establecidos en la guía de abordaje de manejo de lípidos de EPS SURA).

Alerta

La Food and Drug Administration (FDA) ha notificado una alerta donde informa que la utilización de los inhibidores de la HMG-CoA reductasa con inhibidores de la proteasa utilizados para tratamiento del virus de la inmunodeficiencia humana (VIH) o la hepatitis C (VHC), pueden aumentar el riesgo de miopatía o rabdomiólisis, daño renal y llevar a insuficiencia renal.

NOTA: Cuando se vaya realizar la formulación de la atorvastatina con Inhibidores de la proteasa deberá evaluar su pertinencia con el coordinador del programa de HIV/SIDA de EPS SURA.

NOMBRE: ATORVASTATINA

CATEGORÍA: Agente antilipemiente (HMG-CoA inhibidor de la reductasa)

NIVEL DE AUTORIZACIÓN: Médico general

NOMBRES SIMILARES CON LOS QUE PUEDE SER CONFUNDIDO: Atomoxetina, lovastatina, nistatina, pitavastatina, pravastatina, rosuvastatina, simvastatina.

PRESENTACIONES DISPONIBLES EN EPS SURA:

CÓDIGO POS	MEDICAMENTO	PRESENTACIÓN
280052	ATORVASTATINA	10 MG
280053	ATORVASTATINA	20 MG
280054	ATORVASTATINA	40 MG

INDICACIONES ESPECÍFICAS CUBIERTA POR EL POS:

Pacientes clasificados en riesgo:

- **ALTO** colesterol LDL: 160-189 mg/dl
- **MUY ALTO** colesterol LDL : Mayor de 190 mg/dl
- Paciente post-evento agudo coronario.
- Pacientes que hayan tomando lovastatina mínimo durante tres meses a dosis óptima (80 mg/día) sin lograr llegar a las metas.

NOTA: Si el pacientes logra y mantiene cifras óptimas de LDL, con la lovastatina, no debe ser pasado a ATORVASTATINA.

RECOMENDACIONES GENERALES

- Se debe iniciar con la dosis más baja y realizar el ajuste de la dosis cada 2-4 semanas según niveles de C-LDL y respuesta.

- Se puede hacer el cambio de lovastatina a atorvastatina de inmediato (suspendida lovastatina al día siguiente se inicia atorvastatina).
- Puede ser administrado con alimentos y a cualquier hora del día

REACCIONES ADVERSAS:

>10%:

- Diarrea (5-14%), artralgias (4%-12%), nasofaringitis (4% -13%)

2% -10%:

- Insomnio (1-5%), náuseas (4%-7%), dispepsia (3%-6%), infección urinaria (4%-8%), incremento transaminasas (2%-3% con dosis 80 mg/día) mialgia (3%-8%), espasmo muscular (2-5%), dolor muscular (2% - 5%).

CONTRAINDICACIONES:

- Hipersensibilidad a la atorvastatina, enfermedad hepática activa, elevaciones persistentes e inexplicables de las transaminasas séricas, embarazo, lactancia materna

PRECAUCIONES:

- **Ancianos:** Debe usarse con precaución en pacientes con edad avanzada, estos pacientes están predispuestos a la miopatía.
- **Pediatría:** La seguridad y eficacia no han sido establecidas en pacientes menores de diez años, o antes de la menarquia en las niñas.

MONITOREO DE PARÁMETROS DE LABORATORIO (de acuerdo con la patología de base del paciente):

- Niveles de LDL según cifras y guía de EPS SURA
- Síntomas de miopatía: seguimiento CPK
- Está recomendado realizar perfil hepático a todos los pacientes al menos doce semanas posterior a la iniciación de la atorvastatina de acuerdo con la patología de base.

INTERACCIONES MÁS FRECUENTES:

- **Antiácidos:** Puede disminuir la concentración sérica de la HMG-CoA reductasa
- **Ciclosporina:** Puede aumentar la concentración sérica de atorvastatina
- **Digoxina:** Puede aumentar la concentración sérica de digoxina
- **Diltiazem:** Pueden aumentar las concentraciones séricas de atorvastatina
- **Fenofibrato:** Pueden aumentar los efectos adversos / tóxicos de los inhibidores de la HMG-CoA reductasa
- **Ácido fusídico:** Puede aumentar el efecto adverso / toxicidad de atorvastatina. Específicamente, el riesgo de rabdomiolisis.
- **Gemfibrozil:** Puede aumentar la concentración sérica de atorvastatina (evitar la combinación).
- **Antibióticos macrólidos:** Puede disminuir el metabolismo de los inhibidores de la HMG-CoA reductasa. Manejo: evite lovastatina o simvastatina con eritro, claritromicina.
- **Fenitoína:** Puede disminuir la concentración sérica de la HMG-CoA reductasa
- **Verapamilo:** Puede aumentar la concentración sérica de atorvastatina. Considere el uso de dosis bajas de atorvastatina cuando se utiliza junto con verapamilo.

Referencias bibliográficas

1. Adams JA, Albers G, Alberts JS, et al, "Update to the AHA/ASA Recommendations for the Prevention of Stroke on Patients With Stroke and Transient Ischemic Attack," *Stroke*, 2008, 39(5):1647-52. [PubMed 18322260].
2. Amarenco P, Bogousslavsky J, Callahan A 3rd, et al, "High-Dose Atorvastatin After Stroke or Transient Ischemic Attack. The Stroke Prevention by Aggressive Reduction in Cholesterol Levels (SPARCL) Investigators," *N Engl J Med*, 2006, 355(6):549-59. [PubMed16899775].
3. American Diabetes Association, "Standards of Medical Care in Diabetes Mellitus-2011," *Diabetes Care*, 2011, 34(Suppl 1):11-61. [PubMed 21193625].
4. Anderson JL, Adams CD, Antman EM, et al, "2011 ACCF/AHA Focused Update Incorporated Into the ACC/AHA 2007 Guidelines for the Management of Patients With Unstable Angina/Non-ST-Elevation Myocardial Infarction: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines," *Circulation*, 2011, 123(18):e426-579. [PubMed 21444888].
5. Antman EM, Anbe DT, Armstrong PW, et al. "ACC/AHA Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the 1999 Guidelines for the Management of Patients With Acute Myocardial Infarction)," *J Am Coll Cardiol*, 2004, 44(3):671-719. [PubMed 15358045].
6. Antman EM, Hand M, Armstrong PW, et al, "2007 Focused Update of the ACC/AHA 2004 Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction. A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines," *J Am Coll Cardiol*, 2008, 51(2):210-49. [PubMed 18191746].
7. Briguori C, Visconti G, Focaccio A, et al, "Novel Approaches for Preventing or Limiting Events (Naples) II trial: Impact of a Single High Loading Dose of Atorvastatin on Periprocedural Myocardial Infarction," *J Am Coll Cardiol*, 2009, 54(23):2157-63. [PubMed19664895].
8. Cannon CP, Braunwald E, McCabe CH, et al, "Intensive Versus Moderate Lipid Lowering With Statins After Acute Coronary Syndromes. Pravastatin or Atorvastatin Evaluation and Infection Therapy-Thrombolysis in Myocardial Infarction 22 Investigators," *N Engl J Med*, 2004, 350(15):1495-504. [PubMed 15007110].
9. Davidson MH and Robinson JG, "Safety of Aggressive Lipid Management," *J Am Coll Cardiol*, 2007, 49(17):1753-62. [PubMed 17466224].
10. de Denus S and Spinler SA, "Early Statin Therapy for Acute Coronary Syndromes," *Ann Pharmacother*, 2002, 36(11):1749-58. [PubMed 12398573].
11. de Lemos JA, Blazing MA, Wiviott SD, et al, "Early Intensive vs a Delayed Conservative Simvastatin Strategy in Patients with Acute Coronary Syndromes," *JAMA*, 2004, 292(11):1307-16. [PubMed 15337732].
12. Di Sciascio G, Patti G, Pasceri V, et al, "Efficacy of Atorvastatin Reload in Patients on Chronic Statin Therapy Undergoing Percutaneous Coronary Intervention: Results of the ARMYDA-RECAPTURE (Atorvastatin for Reduction of Myocardial Damage During Angioplasty) Randomized Trial," *J Am Coll Cardiol*, 2009, 54(6):558-65. [PubMed 19643320].
13. "Executive Summary of The Third Report of The National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III)," *JAMA*, 2001, 285(19):2486-97. [PubMed 11368702].
14. Fernández AB, Karas RH, Alsheikh-Ali AA, et al, "Statins and Interstitial Lung Disease: A Systematic Review of the Literature and of Food and Drug Administration Adverse Event Reports," *Chest*, 2008, 134(4):824-30. [PubMed 18689579].
15. Fleisher LA, Beckman JA, Brown KA, et al, "ACC/AHA 2007 Guidelines on Perioperative Cardiovascular Evaluation and Care for Noncardiac Surgery: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the 2002 Guidelines on Perioperative Cardiovascular Evaluation for Noncardiac Surgery) Developed in Collaboration With the American Society of Echocardiography, American Society of Nuclear Cardiology, Heart Rhythm Society,

- Society of Cardiovascular Anesthesiologists, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine and Biology, and Society for Vascular Surgery," *J Am Coll Cardiol*, 2007, 50(17):e159-241. [PubMed 17950140].
16. Fonarow GC, French WJ, Parsons LS, et al, "Use of Lipid-Lowering Medications at Discharge in Patients With Acute Myocardial Infarction: Data From the National Registry of Myocardial Infarction 3," *Circulation*, 2001, 103(1):38-44. [PubMed 11136683].
 17. Fraker TD, Fihn SD, Gibbons RJ, et al, "2007 Chronic Angina Focused Update of the ACC/AHA 2002 Guidelines for the Management of Patients With Chronic Stable Angina: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines Writing Group to Develop the Focused Update of the 2002 Guidelines for the Management of Patients With Chronic Stable Angina," *Circulation*, 2007, 116(23):2762-72. [PubMed 17998462].
 18. Gibbons RJ, Abrams J, Chatterjee K, et al, "ACC/AHA 2002 Guideline Update for the Management of Patients With Chronic Stable Angina - Summary Article: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines [Committee on the Management of Patients With Chronic Stable Angina]," *Circulation*, 2003, 107(1):149-58. [PubMed 12515758].
 19. Grundy SM, Cleeman JI, Merz CN, et al, "Implications of Recent Clinical Trials for the National Cholesterol Education Program Adult Treatment Panel III Guidelines," *J Am Coll Cardiol*, 2004, 44(3):720-32. [PubMed 15358046].
 20. Heeschen C, Hamm CW, Laufs U, et al, "Withdrawal of Statins Increases Event Rates in Patients With Acute Coronary Syndromes," *Circulation*, 2002, 105(12):1446-52. [PubMed 11914253].
 21. Hillis LD, Smith PK, Anderson JL, et al, "2011 ACCF/AHA Guideline for Coronary Artery Bypass Graft Surgery: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines," *Circulation*, 2011, 124(23):2610-42. [PubMed 22064600].
 22. Koren MJ, Smith DG, Hunninghake DB, et al, "The Cost of Reaching National Cholesterol Education Program (NCEP) Goals in Hypercholesterolaemic Patients. A Comparison of Atorvastatin, Simvastatin, Lovastatin, and Fluvastatin," *Pharmacoeconomics*, 1998, 14(1):59-70. [PubMed 10182195].
 23. LaRosa JC, Grundy SM, Waters DD, et al, "Intensive Lipid Lowering With Atorvastatin in Patients With Stable Coronary Disease," *N Engl J Med*, 2005, 352(14):1425-35. [PubMed 15755765].
 24. LeManach Y, Godet G, Coriat P, et al, "The Impact of Postoperative Discontinuation or Continuation of Chronic Statin Therapy on Cardiac Outcome After Major Vascular Surgery," *Anesth Analg*, 2007, 104(6):1326-33. [PubMed 17513620].
 25. Levine GN, Bates ER, Blankenship JC, et al, "2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions," *Circulation*, 2011, 124(23):e574-651. [PubMed 22064601].
 26. McPherson R, Frohlich J, Fodor G, et al, "Canadian Cardiovascular Society Position Statement-Recommendations for the Diagnosis and Treatment of Dyslipidemia and Prevention of Cardiovascular Disease," *Can J Cardiol*, 2006, 22(11):913-27; published erratum appears in *Can J Cardiol*, 2006, 22(12):1077. [PubMed 16971976].
 27. "MRC/BHF Heart Protection Study of Cholesterol Lowering With Simvastatin in 20,536 High-Risk Individuals: A Randomised Placebo-Controlled Trial. Heart Protection Study Collaborative Group," *Lancet*, 2002, 360(9326):7-22. [PubMed 12114036].
 28. Pasceri V, Patti G, Nusca A, et al, "Randomized Trial of Atorvastatin for Reduction of Myocardial Damage During Coronary Intervention: Results from the ARMYDA (Atorvastatin for Reduction of MYocardial Damage during Angioplasty) Study," *Circulation*, 2004, 110(6):674-8. [PubMed 15277322].
 29. Pasternak RC, Smith SC Jr, Bairey-Merz CN, et al, "ACC/AHA/NHLBI Clinical Advisory on the Use and Safety of Statins," *Stroke*, 2002, 33(9):2337-41. Available at <http://stroke.ahajournals.org/cgi/content/short/33/9/2337> [PubMed 12215610].

30. Patti G, Pasceri V, Colonna G, et al, "Atorvastatin Pretreatment Improves Outcomes in Patients With Acute Coronary Syndromes Undergoing Early Percutaneous Coronary Intervention: Results of the ARMYDA-ACS Randomized Trial," *J Am Coll Cardiol*, 2007, 49(12):1272-8. [PubMed 17394957].
31. Pearson TA, Mensah GA, Alexander RW, et al, "Markers of Inflammation and Cardiovascular Disease: Application to Clinical and Public Health Practice: A Statement for Healthcare Professionals From the Centers for Disease Control and Prevention and the American Heart Association," *Circulation*, 2003, 107(3):499-511. [PubMed 12551878].
32. Pederson TR, Faergeman O, Kastelein JJ, et al, "High-Dose Atorvastatin vs Usual-Dose Simvastatin for Secondary Prevention After Myocardial Infarction: The IDEAL Study: A Randomized Controlled Trial," *JAMA*, 2005, 294(19):2437-45. [PubMed 16287954].
33. Pitt B, Waters D, Brown WV, et al, "Aggressive Lipid-Lowering Therapy Compared With Angioplasty in Stable Coronary Artery Disease. Atorvastatin Versus Revascularization Treatment Investigators," *N Engl J Med*, 1999, 341(2):70-6. [PubMed 10395630].
34. Poldermans D, Bax JJ, Kertai MD, et al, "Statins Are Associated With a Reduced Incidence of Perioperative Mortality in Patients Undergoing Major Noncardiac Vascular Surgery," *Circulation*, 2003, 107(14):1848-51. [PubMed 12695283].
35. Ridker PM, Danielson E, Fonseca FAH, et al, "Rosuvastatin to Prevent Vascular Events in Men and Women With Elevated C-Reactive Protein," *N Engl J Med*, 2008, 359(21):2195-207. [PubMed 18997196].
36. Schwartz GG, Olsson AG, Ezekowitz MD, et al, "Effects of Atorvastatin on Early Recurrent Ischemic Events in Acute Coronary Syndromes: The MIRACL Study: A Randomized Controlled Trial," *JAMA*, 2001, 285(13):1711-8. [PubMed 11277825].
37. Sever PS, Dahlof B, Poulter NR, et al, "Prevention of Coronary and Stroke Events With Atorvastatin in Hypertensive Patients Who Have Average or Lower-Than-Average Cholesterol Concentrations, in the Anglo-Scandinavian Cardiac Outcomes Trial-Lipid-Lowering Arm (ASCOT-LLA): A Multicentre Randomised Controlled Trial," *Lancet*, 2003, 361(9364):1149-58. [PubMed 12686036].
38. Shepherd J, Cobbe SM, Ford I, et al, "Prevention of Coronary Heart Disease With Pravastatin in Men With Hypercholesterolemia. West of Scotland Coronary Prevention Study Group," *N Engl J Med*, 1995, 333(20):1301-7. [PubMed 7566020].
39. Smith SC Jr, Benjamin EJ, Bonow RO, et al, "AHA/ACCF Secondary Prevention and Risk Reduction Therapy for Patients With Coronary and Other Atherosclerotic Vascular Disease: 2011 Update: A Guideline From the American Heart Association and American College of Cardiology Foundation," *Circulation*, 2011, 124(22):2458-73. [PubMed 22052934].
40. Waters DD, LaRosa JC, Barter P, et al, "Effects Of High-Dose Atorvastatin On Cerebrovascular Events In Patients With Stable Coronary Disease In The TNT (Treating To New Targets) Study," *J Am Coll Cardiol*, 2006, 48(9):1793-9. [PubMed 17084252].

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