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Medical Letter Essentials: The Basics

- Electronic Table of Contents
- Reference Tables
- Continuing Medical Education – CME/CE
- Outline & Table Box
- Summary Box
- Conclusions
- Mobile Apps

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The Medical Letter on Drugs and Therapeutics

- Published biweekly, additional online-only content
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- Consensus-based critical appraisals of **new drugs**
- **Comparative reviews** of drugs for a specific disorder
- Comprehensive **charts** for quick reference/comparison

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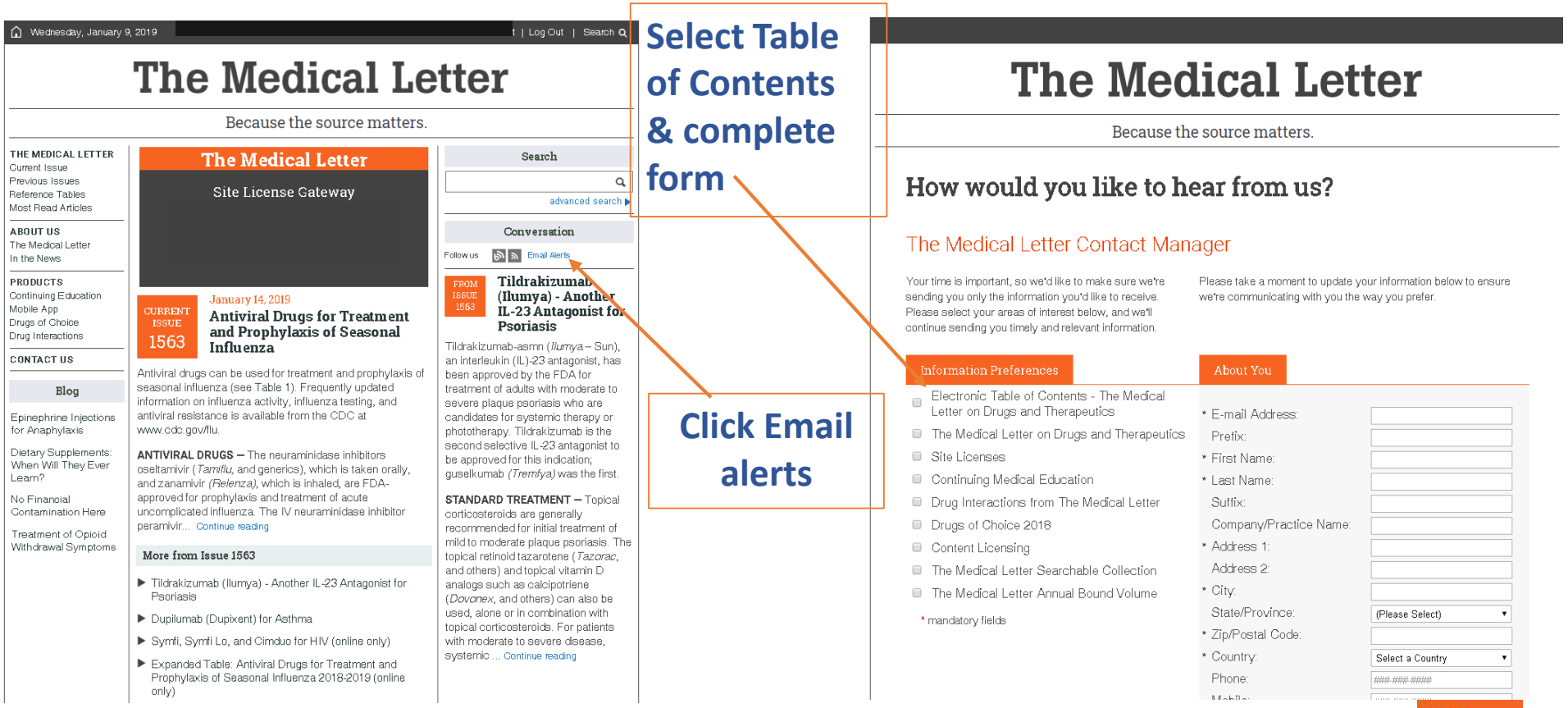
Stay current on new drugs & changes in therapeutics



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Comparison Tables

Our signature tables make comparing drugs quick and easy

Comparison Table: Some Lipid-Lowering Drugs

Comparison Table: Some Lipid-Lowering Drugs

Drug	Some Formulations	Usual Adult Dosage[1]	Average LDL-C Reduction[2]	Adverse Effects/Pregnancy/ Drug Interactions	Comments	Cost[3]
Statins[4]						
Atorvastatin – generic *Lipitor* (Pfizer)	10, 20, 40, 80 mg tabs	Initial: 10-20 mg once/day Maximum: 80 mg once/day Renal impairment: no dosage adjustment required	35-40% 50-60%	**Adverse Effects** ▸ Muscle pain and weakness with or without increased creatine kinase (CK) levels can occur ▸ Rhabdomyolysis and myoglobinemia leading to renal failure occur rarely ▸ Serum aminotransferase levels >3 times the upper limit of normal occur in 1-2% of patients receiving high-intensity statin therapy ▸ New-onset diabetes, particularly in patients with diabetes risk factors, can occur ▸ Peripheral neuropathy, memory loss, sleep disturbances, erectile dysfunction, gynecomastia, a lupus-like syndrome, and acute pancreatitis have been reported, but causal relationships are unclear	▸ Statins are the drugs of choice for treatment of hyperlipidemia and prevention of cardiovascular disease in most patients ▸ Statins can reduce the risk of a first cardiovascular event and death in patients at increased risk for ASCVD ▸ Statins can decrease the risk of major coronary events and death in patients with ASCVD ▸ High-intensity statin therapy (atorvastatin 40-80 mg/day, rosuvastatin 20-40 mg/day) reduces LDL-C levels by ≥50% ▸ Moderate-intensity statin therapy (e.g., atorvastatin 10-20 mg/day, rosuvastatin 5-10 mg/day, simvastatin 20-40 mg/day) reduces LDL-C levels by 30-49% ▸ Low-intensity statin therapy (e.g., pravastatin 10-20 mg/day, lovastatin 20 mg/day) reduces LDL-C levels by <30%	$5.60 299.40
Fluvastatin – generic *Lescol* (Novartis)	20, 40 mg caps	Initial: 40 mg bid Maximum: 40 mg bid	30-35% 30-35%			220.10 306.10
extended-release – generic *Lescol XL*	80 mg ER tabs	Initial: 80 mg once/day Maximum: 80 mg once/day Renal impairment: no dosage adjustment required	35-40% 35-40%			194.10 323.10
Lovastatin – generic	10, 20, 40 mg tabs	Initial: 20 mg once/day Maximum: 80 mg once/day or 40 mg bid Renal impairment: CrCl <30 mL/min: doses >20 mg/day use cautiously	25-30% 35-40%			6.30
extended-release – *Altoprev* (Covis)	20, 40, 60 mg ER tabs	Initial: 20 mg once/day Maximum: 60 mg once/day Renal impairment: CrCl <30 mL/min: doses >20 mg/day use cautiously	20-25% 40-45%			921.10

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Table Tip:

Quickly find manufacturer, dosage & costs for easy reference

Manufacturer

Wholesaler Acquisition Cost or Manufacturer's Publishing Pricing

Recommended Dosage

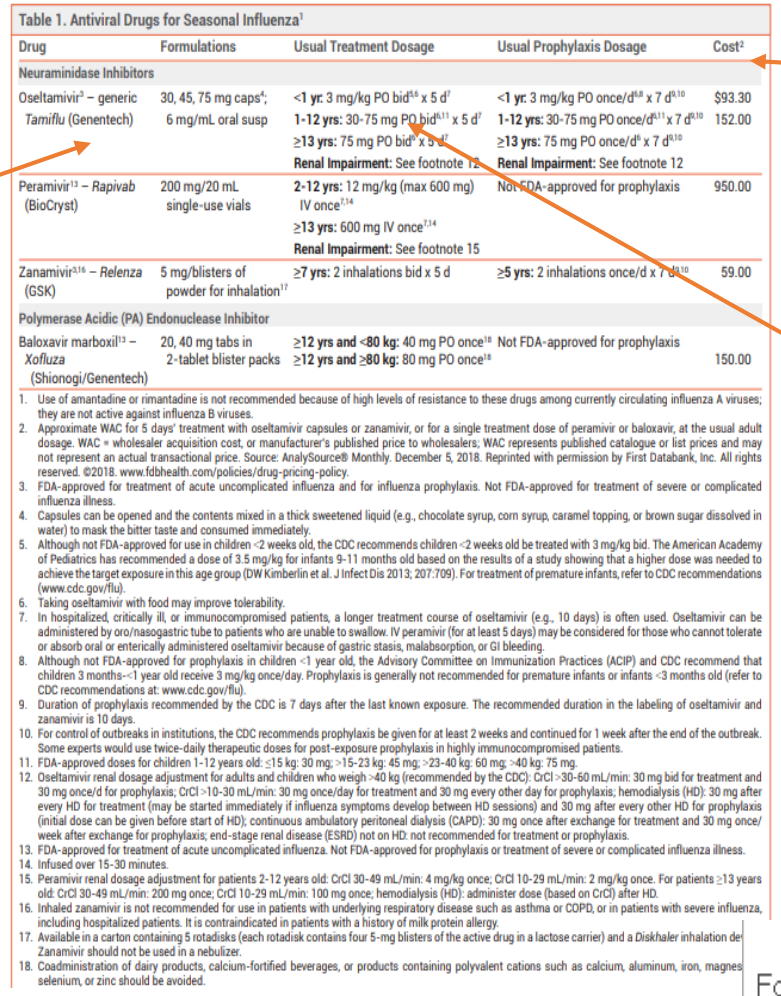

Table 1. Antiviral Drugs for Seasonal Influenza[1]

Drug	Formulations	Usual Treatment Dosage	Usual Prophylaxis Dosage	Cost[2]
Neuraminidase Inhibitors				
Oseltamivir[3] – generic *Tamiflu* (Genentech)	30, 45, 75 mg caps[4]; 6 mg/mL oral susp	**<1 yr:** 3 mg/kg PO bid[5,6] x 5 d[7] **1-12 yrs:** 30-75 mg PO bid[6,11] x 5 d[7] **≥13 yrs:** 75 mg PO bid[8] x 5 d[7] **Renal Impairment:** See footnote 12	**<1 yr:** 3 mg/kg PO once/d[5,8] x 7 d[9,10] **1-12 yrs:** 30-75 mg PO once/d[6,11] x 7 d[9,10] **≥13 yrs:** 75 mg PO once/d[8] x 7 d[9,10] **Renal Impairment:** See footnote 12	$93.30 152.00
Peramivir[13] – *Rapivab* (BioCryst)	200 mg/20 mL single-use vials	**2-12 yrs:** 12 mg/kg (max 600 mg) IV once[7,14] **≥13 yrs:** 600 mg IV once[7,14] **Renal Impairment:** See footnote 15	Not FDA-approved for prophylaxis	950.00
Zanamivir[3,16] – *Relenza* (GSK)	5 mg/blisters of powder for inhalation[17]	**≥7 yrs:** 2 inhalations bid x 5 d	**≥5 yrs:** 2 inhalations once/d x 7 d[9,10]	59.00
Polymerase Acidic (PA) Endonuclease Inhibitor				
Baloxavir marboxil[13] – *Xofluza* (Shionogi/Genentech)	20, 40 mg tabs in 2-tablet blister packs	**≥12 yrs and <80 kg:** 40 mg PO once[18] **≥12 yrs and ≥80 kg:** 80 mg PO once[18]	Not FDA-approved for prophylaxis	150.00

1. Use of amantadine or rimantadine is not recommended because of high levels of resistance to these drugs among currently circulating influenza A viruses; they are not active against influenza B viruses.
2. Approximate WAC for 5 days' treatment with oseltamivir capsules or zanamivir, or for a single treatment dose of peramivir or baloxavir, at the usual adult dosage. WAC = wholesaler acquisition cost, or manufacturer's published price to wholesalers; WAC represents published catalogue or list prices and may not represent an actual transactional price. Source: AnalySource® Monthly. December 5, 2018. Reprinted with permission by First Databank, Inc. All rights reserved. ©2018. www.fdbhealth.com/policies/drug-pricing-policy.
3. FDA-approved for treatment of acute uncomplicated influenza and for influenza prophylaxis. Not FDA-approved for treatment of severe or complicated influenza illness.
4. Capsules can be opened and the contents mixed in a thick sweetened liquid (e.g., chocolate syrup, corn syrup, caramel topping, or brown sugar dissolved in water) to mask the bitter taste and consumed immediately.
5. Although not FDA-approved for use in children <2 weeks old, the CDC recommends children <2 weeks old be treated with 3 mg/kg bid. The American Academy of Pediatrics has recommended a dose of 3.5 mg/kg for infants 9-11 months old based on the results of a study showing that a higher dose was needed to achieve the target exposure in this age group (DW Kimberlin et al. J Infect Dis 2013; 207:709). For treatment of premature infants, refer to CDC recommendations (www.cdc.gov/flu).
6. Taking oseltamivir with food may improve tolerability.
7. In hospitalized, critically ill, or immunocompromised patients, a longer treatment course of oseltamivir (e.g., 10 days) is often used. Oseltamivir can be administered by oro/nasogastric tube to patients who are unable to swallow. IV peramivir (for at least 5 days) may be considered for those who cannot tolerate or absorb oral or enterically administered oseltamivir because of gastric stasis, malabsorption, or GI bleeding.
8. Although not FDA-approved for prophylaxis in children <1 year old, the Advisory Committee on Immunization Practices (ACIP) and CDC recommend that children 3 months-<1 year old receive 3 mg/kg once/day. Prophylaxis is generally not recommended for premature infants or infants <3 months old (refer to CDC recommendations at: www.cdc.gov/flu).
9. Duration of prophylaxis recommended by the CDC is 7 days after the last known exposure. The recommended duration in the labeling of oseltamivir and zanamivir is 10 days.
10. For control of outbreaks in institutions, the CDC recommends prophylaxis be given for at least 2 weeks and continued for 1 week after the end of the outbreak. Some experts would use twice-daily therapeutic doses for post-exposure prophylaxis in highly immunocompromised patients.
11. FDA-approved doses for children 1-12 years old: ≤15 kg: 30 mg; >15-23 kg: 45 mg; >23-40 kg: 60 mg; >40 kg: 75 mg.
12. Oseltamivir renal dosage adjustment for adults and children who weigh >40 kg (recommended by the CDC): CrCl >30-60 mL/min: 30 mg bid for treatment and 30 mg once/d for prophylaxis; CrCl >10-30 mL/min: 30 mg once/day for treatment and 30 mg every other day for prophylaxis; hemodialysis (HD): 30 mg after every HD for treatment (may be started immediately if influenza symptoms develop between HD sessions) and 30 mg after every other HD for prophylaxis (initial dose can be given before start of HD); continuous ambulatory peritoneal dialysis (CAPD): 30 mg once after exchange for treatment and 30 mg once/week after exchange for prophylaxis; end-stage renal disease (ESRD) not on HD: not recommended for treatment or prophylaxis.
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15. Peramivir renal dosage adjustment for patients 2-12 years old: CrCl 30-49 mL/min: 4 mg/kg once; CrCl 10-29 mL/min: 2 mg/kg once. For patients ≥13 years old: CrCl 30-49 mL/min: 200 mg once; CrCl 10-29 mL/min: 100 mg once; hemodialysis (HD): administer dose (based on CrCl) after HD.
16. Inhaled zanamivir is not recommended for use in patients with underlying respiratory disease such as asthma or COPD, or in patients with severe influenza, including hospitalized patients. It is contraindicated in patients with a history of milk protein allergy.
17. Available in a carton containing 5 rotadisks (each rotadisk contains four 5-mg blisters of the active drug in a lactose carrier) and a *Diskhaler* inhalation de Zanamivir should not be used in a nebulizer.
18. Coadministration of dairy products, calcium-fortified beverages, or products containing polyvalent cations such as calcium, aluminum, iron, magnes selenium, or zinc should be avoided.

For a more detailed table, click here.

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Table Tip: View the Expanded Table
for Adverse Effects and Valuable Comments

Table 1. Antiviral Drugs for Seasonal Influenza[1]

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Zanamivir[3,16] – *Relenza* (GSK)	5 mg/blisters of powder for inhalation[17]	**≥7 yrs:** 2 inhalations bid x 5 d	**≥5 yrs:** 2 inhalations once/d x 7 d[9,10]	59.00
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2. Approximate WAC for 5 days' treatment with oseltamivir capsules or zanamivir, or for a single treatment dose of peramivir or baloxavir, at the usual adult dosage. WAC = wholesaler acquisition cost, or manufacturer's published price to wholesalers; WAC represents published catalogue or list prices and may not represent an actual transactional price. Source: AnalySource® Monthly. December 5, 2018. Reprinted with permission by First Databank, Inc. All rights reserved. ©2018. www.fdbhealth.com/policies/drug-pricing-policy.
3. FDA-approved for treatment of acute uncomplicated influenza and for influenza prophylaxis. Not FDA-approved for treatment of severe or complicated influenza illness.
4. Capsules can be opened and the contents mixed in a thick sweetened liquid (e.g., chocolate syrup, corn syrup, caramel topping, or brown sugar dissolved in water) to mask the bitter taste and consumed immediately.
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6. Taking oseltamivir with food may improve tolerability.
7. In hospitalized, critically ill, or immunocompromised patients, a longer treatment course of oseltamivir (e.g., 10 days) is often used. Oseltamivir can be administered by oro/nasogastric tube to patients who are unable to swallow. IV peramivir (for at least 5 days) may be considered for those who cannot tolerate or absorb oral or enterically administered oseltamivir because of gastric stasis, malabsorption, or GI bleeding.
8. Although not FDA-approved for prophylaxis in children <1 year old, the Advisory Committee on Immunization Practices (ACIP) and CDC recommend that children 3 months-<1 year old receive 3 mg/kg once/day. Prophylaxis is generally not recommended for premature infants or infants <3 months old (refer to CDC recommendations at: www.cdc.gov/flu).
9. Duration of prophylaxis recommended by the CDC is 7 days after the last known exposure. The recommended duration in the labeling of oseltamivir and zanamivir is 10 days.
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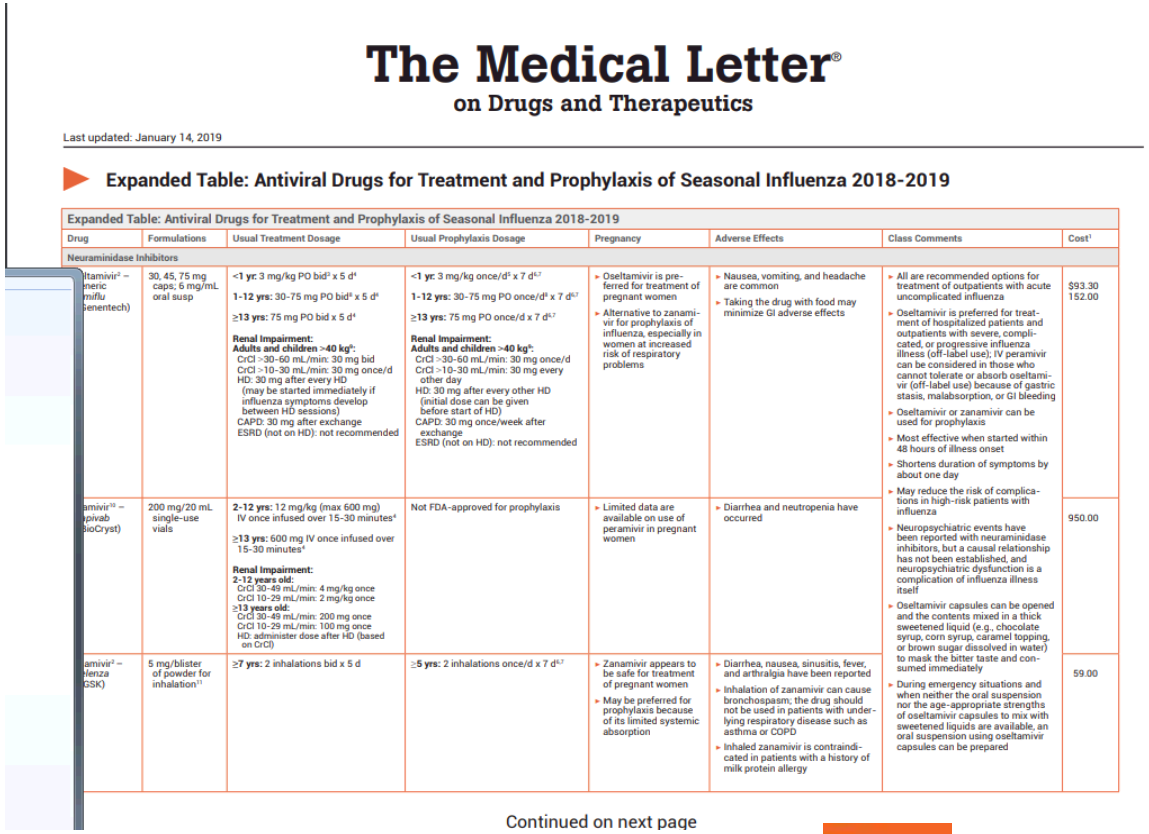
18. Coadministration of dairy products, calcium-fortified beverages, or products containing polyvalent cations such as calcium, aluminum, iron, magnesium, selenium, or zinc should be avoided.



The Medical Letter®
on Drugs and Therapeutics

Last updated: January 14, 2019

Expanded Table: Antiviral Drugs for Treatment and Prophylaxis of Seasonal Influenza 2018-2019

Expanded Table: Antiviral Drugs for Treatment and Prophylaxis of Seasonal Influenza 2018-2019

Drug	Formulations	Usual Treatment Dosage	Usual Prophylaxis Dosage	Pregnancy	Adverse Effects	Class Comments	Cost[1]
Neuraminidase Inhibitors							
ltamivir[2] – neric miflu enentech)	30, 45, 75 mg caps; 6 mg/mL oral susp	**<1 yr:** 3 mg/kg PO bid[3] x 5 d[4] **1-12 yrs:** 30-75 mg PO bid[3] x 5 d[4] **≥13 yrs:** 75 mg PO bid x 5 d[4] **Renal Impairment:** **Adults and children >40 kg[5]:** CrCl >30-60 mL/min: 30 mg bid CrCl >10-30 mL/min: 30 mg once/d HD: 30 mg after every HD (may be started immediately if influenza symptoms develop between HD sessions) CAPD: 30 mg after exchange ESRD (not on HD): not recommended	**<1 yr:** 3 mg/kg once/d[3] x 7 d[6,7] **1-12 yrs:** 30-75 mg PO once/d[4] x 7 d[6,7] **≥13 yrs:** 75 mg PO once/d x 7 d[6,7] **Renal Impairment:** **Adults and children >40 kg[5]:** CrCl >30-60 mL/min: 30 mg once/d CrCl >10-30 mL/min: 30 mg every other day HD: 30 mg after every other HD (initial dose can be given before start of HD) CAPD: 30 mg once/week after exchange ESRD (not on HD): not recommended	▸ Oseltamivir is preferred for treatment of pregnant women ▸ Alternative to zanamivir for prophylaxis of influenza, especially in women at increased risk of respiratory problems	▸ Nausea, vomiting, and headache are common ▸ Taking the drug with food may minimize GI adverse effects	▸ All are recommended options for treatment of outpatients with acute uncomplicated influenza ▸ Oseltamivir is preferred for treatment of hospitalized patients and outpatients with severe, complicated, or progressive influenza illness (off-label use); IV peramivir can be considered in those who cannot tolerate or absorb oseltamivir (off-label use) because of gastric stasis, malabsorption, or GI bleeding ▸ Oseltamivir or zanamivir can be used for prophylaxis ▸ Most effective when started within 48 hours of illness onset ▸ Shortens duration of symptoms by about one day ▸ May reduce the risk of complications in high-risk patients with influenza ▸ Neuropsychiatric events have been reported with neuraminidase inhibitors, but a causal relationship has not been established, and neuropsychiatric dysfunction is a complication of influenza illness itself ▸ Oseltamivir capsules can be opened and the contents mixed in a thick sweetened liquid (e.g., chocolate syrup, corn syrup, caramel topping, or brown sugar dissolved in water) to mask the bitter taste and consumed immediately ▸ During emergency situations and when neither the oral suspension nor the age-appropriate strengths of oseltamivir capsules to mix with sweetened liquids are available, an oral suspension using oseltamivir capsules can be prepared	$93.30 152.00
amivir[10] – pivab ioCryst)	200 mg/20 mL single-use vials	**2-12 yrs:** 12 mg/kg (max 600 mg) IV once infused over 15-30 minutes[4] **≥13 yrs:** 600 mg IV once infused over 15-30 minutes[4] **Renal Impairment:** **2-12 years old:** CrCl 30-49 mL/min: 4 mg/kg once CrCl 10-29 mL/min: 2 mg/kg once **≥13 years old:** CrCl 30-49 mL/min: 200 mg once CrCl 10-29 mL/min: 100 mg once HD: administer dose after HD (based on CrCl)	Not FDA-approved for prophylaxis	▸ Limited data are available on use of peramivir in pregnant women	▸ Diarrhea and neutropenia have occurred		950.00
amivir[2] – lenza GSK)	5 mg/blister of powder for inhalation[11]	**≥7 yrs:** 2 inhalations bid x 5 d	**≥5 yrs:** 2 inhalations once/d x 7 d[6,7]	▸ Zanamivir appears to be safe for treatment of pregnant women ▸ May be preferred for prophylaxis because of its limited systemic absorption	▸ Diarrhea, nausea, sinusitis, fever, and arthralgia have been reported ▸ Inhalation of zanamivir can cause bronchospasm; the drug should not be used in patients with underlying respiratory disease such as asthma or COPD ▸ Inhaled zanamivir is contraindicated in patients with a history of milk protein allergy		59.00

Continued on next page

For a more detailed table, click here.

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- Clinical Studies
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- Drug Interactions
- Pregnancy and Lactation
- Dosage and Administration
- Conclusion

Tables

- Pharmacology
- Lefamulin Clinical Trial Results
- Lefamulin Drug Interactions
- Some Drugs for Empiric Treatment of CABP

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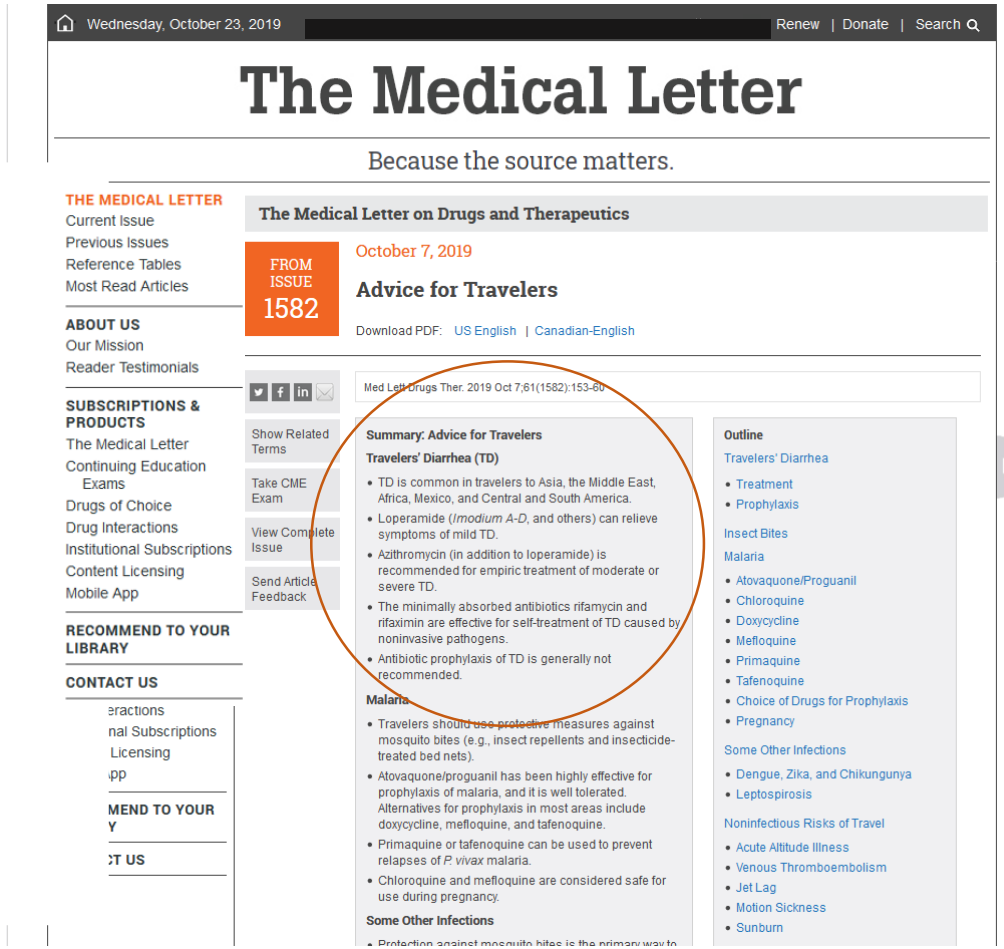
Summary Box

What You Need to Know At a Glance



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Conclusions

Evidence-based, peer-reviewed evaluations and recommendations reached by a consensus of experts

Providing healthcare professionals with unbiased, time-saving recommendations to improve prescribing for better outcomes.

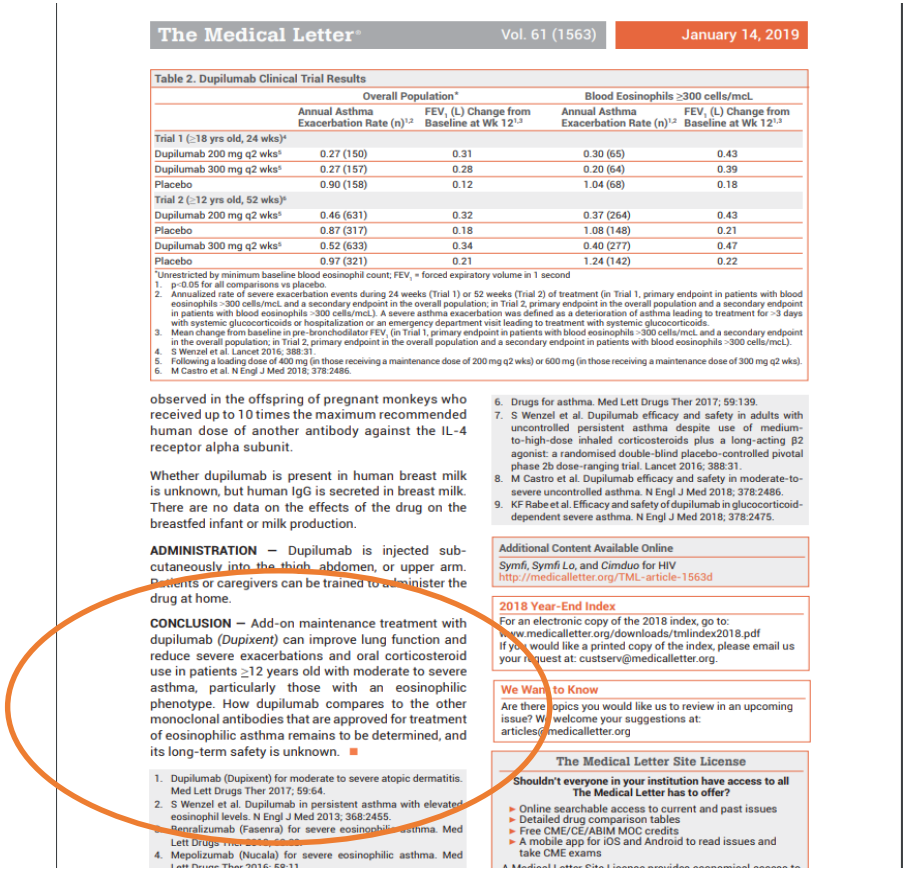

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Table 2. Dupilumab Clinical Trial Results

	Overall Population*		Blood Eosinophils ≥300 cells/mcL	
	Annual Asthma Exacerbation Rate (n)[1,2]	FEV$_1$ (L) Change from Baseline at Wk 12[1,3]	Annual Asthma Exacerbation Rate (n)[1,2]	FEV$_1$ (L) Change from Baseline at Wk 12[1,3]
Trial 1 (≥18 yrs old, 24 wks)[4]				
Dupilumab 200 mg q2 wks[5]	0.27 (150)	0.31	0.30 (65)	0.43
Dupilumab 300 mg q2 wks[5]	0.27 (157)	0.28	0.20 (64)	0.39
Placebo	0.90 (158)	0.12	1.04 (68)	0.18
Trial 2 (≥12 yrs old, 52 wks)[6]				
Dupilumab 200 mg q2 wks[5]	0.46 (631)	0.32	0.37 (264)	0.43
Placebo	0.87 (317)	0.18	1.08 (148)	0.21
Dupilumab 300 mg q2 wks[5]	0.52 (633)	0.34	0.40 (277)	0.47
Placebo	0.97 (321)	0.21	1.24 (142)	0.22

*Unrestricted by minimum baseline blood eosinophil count; FEV$_1$ = forced expiratory volume in 1 second
1. p<0.05 for all comparisons vs placebo.
2. Annualized rate of severe exacerbation events during 24 weeks (Trial 1) or 52 weeks (Trial 2) of treatment (in Trial 1, primary endpoint in patients with blood eosinophils >300 cells/mcL and a secondary endpoint in the overall population; in Trial 2, primary endpoint in the overall population and a secondary endpoint in patients with blood eosinophils >300 cells/mcL). A severe asthma exacerbation was defined as a deterioration of asthma leading to treatment for >3 days with systemic glucocorticoids or hospitalization or an emergency department visit leading to treatment with systemic glucocorticoids.
3. Mean change from baseline in pre-bronchodilator FEV$_1$ (in Trial 1, primary endpoint in patients with blood eosinophils >300 cells/mcL and a secondary endpoint in the overall population; in Trial 2, primary endpoint in the overall population and a secondary endpoint in patients with blood eosinophils >300 cells/mcL).
4. S Wenzel et al. Lancet 2016; 388:31.
5. Following a loading dose of 400 mg (in those receiving a maintenance dose of 200 mg q2 wks) or 600 mg (in those receiving a maintenance dose of 300 mg q2 wks).
6. M Castro et al. N Engl J Med 2018; 378:2486.

observed in the offspring of pregnant monkeys who received up to 10 times the maximum recommended human dose of another antibody against the IL-4 receptor alpha subunit.

Whether dupilumab is present in human breast milk is unknown, but human IgG is secreted in breast milk. There are no data on the effects of the drug on the breastfed infant or milk production.

ADMINISTRATION — Dupilumab is injected subcutaneously into the thigh, abdomen, or upper arm. Patients or caregivers can be trained to administer the drug at home.

CONCLUSION — Add-on maintenance treatment with dupilumab *(Dupixent)* can improve lung function and reduce severe exacerbations and oral corticosteroid use in patients ≥12 years old with moderate to severe asthma, particularly those with an eosinophilic phenotype. How dupilumab compares to the other monoclonal antibodies that are approved for treatment of eosinophilic asthma remains to be determined, and its long-term safety is unknown. ■

1. Dupilumab (Dupixent) for moderate to severe atopic dermatitis. Med Lett Drugs Ther 2017; 59:64.
2. S Wenzel et al. Dupilumab in persistent asthma with elevated eosinophil levels. N Engl J Med 2013; 368:2455.
3. Benralizumab (Fasenra) for severe eosinophilic asthma. Med Lett Drugs Ther 2016; 58:93.
4. Mepolizumab (Nucala) for severe eosinophilic asthma. Med Lett Drugs Ther 2016; 58:11.
6. Drugs for asthma. Med Lett Drugs Ther 2017; 59:139.
7. S Wenzel et al. Dupilumab efficacy and safety in adults with uncontrolled persistent asthma despite use of medium-to-high-dose inhaled corticosteroids plus a long-acting β2 agonist: a randomised double-blind placebo-controlled pivotal phase 2b dose-ranging trial. Lancet 2016; 388:31.
8. M Castro et al. Dupilumab efficacy and safety in moderate-to-severe uncontrolled asthma. N Engl J Med 2018; 378:2486.
9. KF Rabe et al. Efficacy and safety of dupilumab in glucocorticoid-dependent severe asthma. N Engl J Med 2018; 378:2475.

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Drug Interactions

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Search and find potentially life-threatening interactions between prescription drugs, over-the-counter drugs, herbs, supplements, and lifestyle factors.

The Medical Letter®

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- Manufacturer as well as competing manufacturers review drafts and submit input. This ensures a balanced representation of a drug's benefits and shortcomings.
- All articles are reviewed by the FDA.

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