PharmaSuitables
October 2018

Zach Kareus, Pharm.D.
Disclosures

• Steve and Zach work for Rocky Mountain Health Plans.
• We do not have any financial interest in the medications we are discussing today.
• We have no intention to malign any person, business or product.
Ketamine

A derivative of phencyclidine (PCP)
Consensus Guidelines on the Use of Intravenous Ketamine Infusions for Chronic Pain From the American Society of Regional Anesthesia and Pain Medicine, the American Academy of Pain Medicine, and the American Society of Anesthesiologists

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Samer Narouze, MD, PhD,‡‡ Fred N. Davis, MD,§§|| Elspeth C. Ritchie, MD, MPH,**||†††
Timothy R. Lubenow, MD,§ and William M. Hooten, MD,**||†††
Drug Information

• MOAs:
  – NMDA channel blocker
  – Neuronal hyperpolarisation-activated cationic currents (HCN1)
  – Nicotinic acetyl-choline ion channels
  – Mu, kappa, sigma opioid agonist and potentiation
  – Nitric-oxide cGMP
  – Non-NMDA glutamate receptors
  – Metabotropic glutamate receptors (mGluR)
  – Increased release of dopamine/noradrenaline
  – Inhibitor of L-type calcium channels
Drug Information

• FDA approved in 1970
• Used widely during the Vietnam War for general anesthesia
• Has been referenced as possibly the most versatile drug in all of medicine
Indications

KETALAR is indicated as the sole anesthetic agent for diagnostic and surgical procedures that do not require skeletal muscle relaxation.

Off-label common uses:
– Chronic Pain (CRPS, fibromyalgia, PLP, PHN)
– Depression

• Limited data:
  – Migraine headaches
  – Chronic low-back pain
  – Cancer pain
Drug properties

- S stereoisomer is 3-4 times more potent than the R
  - The clinical benefit of this is still unknown
- Can be administered via IV, IM, intranasal, inhalation (smoked), oral, topical, and rectal
- Water and lipid soluble
  - Rapid crossing of the BBB
- Metabolized by CYP enzymes 2B6 and 2C9
- T1/2 is 2.3±0.5 hours
Administration and Dosing

<table>
<thead>
<tr>
<th>Route of Administration</th>
<th>Typical Dosing</th>
<th>Bioavailability, %</th>
<th>Time of Onset</th>
<th>Duration of Action After Dosing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intravenous</td>
<td>1–4.5 mg/kg for general anesthesia induction; 1–6 mg/kg per hour for anesthesia maintenance; 0.5–2 mg/kg for 1-d outpatient or 3- to 5-d inpatient awake ketamine infusions in chronic pain (higher dosages titrated to effect from lower doses); 0.2–0.75 mg/kg for procedural analgesia, can be repeated; 0.1 mg/kg for IV infusion test; 5- to 35-mg/h continuous infusion for acute traumatic or postoperative pain, 1–7 mg/demand dose mixed with opioids in patient-controlled analgesia</td>
<td>N/A</td>
<td>30 s</td>
<td>5–10 min for bolus doses</td>
</tr>
<tr>
<td>Intramuscular</td>
<td>2–4 times IV dosing; 5–10 mg/kg for surgical anesthesia; 0.4–2 mg/kg for procedural analgesia; bolus and treatment dosing 0.10–0.5 mg/kg for chronic pain</td>
<td>75–95</td>
<td>2–5 min</td>
<td>30–75 min</td>
</tr>
<tr>
<td>Intranasal</td>
<td>0.2–1 mg/kg for chronic pain and sedation; 3–6 mg/kg for procedural analgesia and anesthetic premedication</td>
<td>25–50</td>
<td>5–10 min</td>
<td>45–120 min</td>
</tr>
<tr>
<td>Subcutaneous</td>
<td>0.1–1.2 mg/kg per hour for chronic pain; bolus and treatment dosing 0.10–0.6 mg/kg</td>
<td>75–95</td>
<td>10–30 min</td>
<td>45–120 min</td>
</tr>
<tr>
<td>Oral</td>
<td>0.3–1.25 mg/kg for chronic pain; up to 3 mg/kg for procedural analgesia and anesthetic premedication</td>
<td>10–20</td>
<td>5–20 min</td>
<td>2–4 h</td>
</tr>
<tr>
<td>Rectal</td>
<td>5–10 mg/kg for anesthesia premedication and procedural analgesia</td>
<td>25–30</td>
<td>5–15 min</td>
<td>2–3 h</td>
</tr>
<tr>
<td>Topical</td>
<td>1%–10% cream for chronic pain</td>
<td>&lt;5</td>
<td>&lt;2 d</td>
<td>NA</td>
</tr>
</tbody>
</table>
# Contraindications

## TABLE 5. Contraindications to and Precautions for Use of Subanesthetic Doses of Ketamine for Chronic Pain

<table>
<thead>
<tr>
<th>Category</th>
<th>Contraindication/Precaution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular</td>
<td>• Unstable angina&lt;br&gt;• Poorly controlled hypertension&lt;br&gt;• High-risk coronary vascular disease</td>
</tr>
<tr>
<td>Neurological and ophthalmic</td>
<td>• Elevated intracranial pressure, including secondary traumatic brain injury or tumor&lt;br&gt;• Elevated intraocular pressure, acute globe injury, or glaucoma</td>
</tr>
<tr>
<td>Endocrinological (due to possible potentiation</td>
<td>• Hyperthyroidism&lt;br&gt;• Pheochromocytoma&lt;br&gt;• Severe liver disease&lt;br&gt;• Full stomach aspiration risk&lt;br&gt;• Lack of data on safety&lt;br&gt;• Intoxication with alcohol or other substances&lt;br&gt;• Active substance abuse&lt;br&gt;• Delirium&lt;br&gt;• Psychosis&lt;br&gt;• Refusal or inability to consent of sympathomimetic effects)</td>
</tr>
</tbody>
</table>
Evidence for use in Pain

- Thought to treat nociceptive pain > non-nociceptive pain
- Potential to treat complex regional pain syndrome (CRPS) type 1
- Double-blind RCT reported pain reduction of 25% - 45% vs. Placebo in patients with mixed chronic neuropathic pain diagnoses
- 1 RCT showed significant difference during infusion but difference was no longer present 110 minutes after infusion
- 1 RCT showed superior pain relief to alfentanil but the adverse effects lasted longer than the pain relief
Fibromyalgia

- Mixed efficacy has been found in RCTs
- 2 RCTs demonstrated a 20 to 25-point reduction in VAS pain scores 90-120 minutes following an infusion vs. placebo
- 2 RCTs showed a 0.5 to 0.9-point reduction in 10-cm VAS scores 90-180 minutes after infusion compared to placebo
- 1 RCT found no difference in pain scores or QOL during 8-week follow-up period
<table>
<thead>
<tr>
<th>First Author, Year</th>
<th>Patients</th>
<th>Ketamine Regimen</th>
<th>Follow-Up</th>
<th>Results</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amr, 2010</td>
<td>40 patients with neuropathic pain after spinal cord injury</td>
<td>80 mg over 5 h per day × 1 wk</td>
<td>4 wk</td>
<td>Ketamine better than placebo for 2 wk</td>
<td>All patients also received gabapentin</td>
</tr>
<tr>
<td>Eichenberger, 2008</td>
<td>20 patients with PLP</td>
<td>0.4 mg/kg over 1 h with 48 h minimum interval between infusions</td>
<td>48 h</td>
<td>Ketamine better than placebo and calcitonin. No difference between ketamine alone and combination for worst pain reduction, but combination superior for mean pain reduction. Mixed results for QST</td>
<td>Crossover study comparing ketamine to calcitonin to combination of both to placebo</td>
</tr>
<tr>
<td>Schwartzman, 2009</td>
<td>19 patients with CRPS types 1 and 2</td>
<td>Up to 100 mg over 4 h for 10 consecutive weekdays</td>
<td>9–12 wk</td>
<td>Ketamine better than placebo for pain, but no improvement in QST and no correlation between response and serum levels</td>
<td>Study halted at midpoint because of lack of improvement in ketamine group</td>
</tr>
<tr>
<td>Sigtermans, 2009</td>
<td>60 patients with CRPS type 1</td>
<td>0.43 mg/kg per hour continuously over 4.2 d</td>
<td>12 wk</td>
<td>Ketamine better than placebo, but results were not statistically significant beyond 11 wk</td>
<td>Blinding ineffective</td>
</tr>
<tr>
<td>Noppers, 2011</td>
<td>24 patients with fibromyalgia</td>
<td>0.5 mg/kg over 30 min</td>
<td>8 wk</td>
<td>Ketamine better than placebo only up to 3 h</td>
<td>Blinding ineffective</td>
</tr>
<tr>
<td>Mitchell, 2002</td>
<td>35 patients with ischemic limb pain</td>
<td>0.6 mg/kg over 4 h</td>
<td>2–9 d (mean, 5 d)</td>
<td>Ketamine better than placebo</td>
<td>All patients also received opioids</td>
</tr>
<tr>
<td>Salas, 2012</td>
<td>20 patients with cancer pain</td>
<td>0.5 mg/kg per day increased to 1 mg/kg per day × 2 d for persistent pain</td>
<td>48 h</td>
<td>No difference between treatment groups</td>
<td>All patients received morphine</td>
</tr>
</tbody>
</table>

QST indicates quantitative sensory testing.
# Summary of recommendations

**TABLE 6. Summary of ASRA/AAPM/ASA Recommendations for Ketamine Infusions for Chronic Pain**

<table>
<thead>
<tr>
<th>Recommendation Category</th>
<th>Recommendation</th>
<th>Level of Evidence*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications</td>
<td>(1) For spinal cord injury pain, there is weak evidence to support short-term improvement</td>
<td>(1) Grade C, low certainty</td>
</tr>
<tr>
<td></td>
<td>(2) In CRPS, there is moderate evidence to support improvement for up to 12 wk</td>
<td>(2) Grade B, low to moderate certainty</td>
</tr>
<tr>
<td></td>
<td>(3) For other pain conditions such as mixed neuropathic pain, fibromyalgia, cancer pain, ischemic pain, headache, and spinal pain, there is weak or no evidence for immediate improvement</td>
<td>(3) Grade D, low certainty</td>
</tr>
</tbody>
</table>
Summary

• Data for use in pain:
  – Small sample sizes with few RCTs with problems
  – Mixed results ranging from no difference to almost 50% reduction in VAS pain scale
  – Short duration of effect during studies
    • Duration of effect has been shown to be dose dependent
  – Lack of defined patient population currently

• Need for long-term well designed clinical trials
References


Drugs to treat Osteoporosis

OSTEOPOROSIS RISK FACTORS
- Alcohol Use
- Corticosteroid Use
- Calcium Low
- Estrogen Low
- Smoking
- Sedentary Lifestyle

“Access” (leads to) Osteoporosis

OSTEOPOROSIS

NORMAL BONE

OSTEOPOROSIS
Anti-catabolic pathway

<table>
<thead>
<tr>
<th>Bisphosphonates</th>
<th>SERM</th>
<th>RANKL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fosamax</td>
<td>Evista</td>
<td>Prolia</td>
</tr>
<tr>
<td>Boniva</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Actonel</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reclast</td>
<td></td>
<td></td>
</tr>
<tr>
<td>alendronate</td>
<td>raloxifene</td>
<td>denosumab</td>
</tr>
<tr>
<td>Ibandronate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>risedronate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>zoledronic acid</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

• Work by decreasing bone turnover and preserve bone mineral density

• Different mechanisms of action to prevent bone loss
  • Decrease osteoclast activity
  • Selective estrogen receptor modulator (SERM)
  • Receptor activator of nuclear factor kappa-B ligand (RANKL) inhibitor
Anabolic pathway

<table>
<thead>
<tr>
<th>Parathyroid hormone</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Forteo</td>
<td>Tymlos</td>
</tr>
<tr>
<td>teriparatide</td>
<td>abaloparatide</td>
</tr>
</tbody>
</table>

- Work by increasing bone mineral density
- Results in new bone formation
  - Stimulates osteoblasts activity to out produce osteoclasts
- Currently limited to 2 years of total lifetime therapy with these products per package inserts
## The Drugs

<table>
<thead>
<tr>
<th>Brand</th>
<th>Indication</th>
<th>Dose</th>
<th>Cost/month</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fosamax (alendronate)</strong></td>
<td>Treatment and prevention of postmenopausal osteoporosis</td>
<td>P: 5mg PO daily/35mg weekly</td>
<td>$6.37</td>
</tr>
<tr>
<td></td>
<td></td>
<td>T: 10mg PO daily/70mg weekly</td>
<td></td>
</tr>
<tr>
<td><strong>Boniva (ibandronate)</strong></td>
<td>Treatment and prevention of postmenopausal osteoporosis</td>
<td>P: 150mg PO monthly</td>
<td>$27.21</td>
</tr>
<tr>
<td></td>
<td></td>
<td>T: 150mg PO monthly</td>
<td></td>
</tr>
<tr>
<td><strong>Actonel (risedronate)</strong></td>
<td>Treatment and prevention of postmenopausal osteoporosis</td>
<td>P: 5mg PO daily/35mg weekly</td>
<td>$150.8</td>
</tr>
<tr>
<td></td>
<td></td>
<td>T: 5mg PO daily/35mg weekly</td>
<td></td>
</tr>
<tr>
<td><strong>Reclast (zoledronic acid)</strong></td>
<td>Treatment and prevention of postmenopausal osteoporosis</td>
<td>P: 5mg IV q2years</td>
<td>$2.06</td>
</tr>
<tr>
<td></td>
<td></td>
<td>T: 5mg IV q1year</td>
<td></td>
</tr>
<tr>
<td><strong>Evista (raloxifene)</strong></td>
<td>Treatment and prevention of postmenopausal osteoporosis</td>
<td>P: 60mg PO daily</td>
<td>$118.00</td>
</tr>
<tr>
<td></td>
<td></td>
<td>T: 60mg PO daily</td>
<td></td>
</tr>
<tr>
<td><strong>Prolia (denosumab)</strong></td>
<td>Treatment of postmenopausal osteoporosis</td>
<td>P: N/A</td>
<td>$236.71</td>
</tr>
<tr>
<td></td>
<td></td>
<td>T: 60mg SC q6months</td>
<td>(AWP)</td>
</tr>
<tr>
<td><strong>Forteo (teriparatide)</strong></td>
<td>Treatment of postmenopausal osteoporosis</td>
<td>P: N/A</td>
<td>$3,953.64</td>
</tr>
<tr>
<td></td>
<td></td>
<td>T: 20mcg SC daily</td>
<td>(AWP)</td>
</tr>
<tr>
<td><strong>Tymlos (abaloparatide)</strong></td>
<td>Treatment of postmenopausal osteoporosis</td>
<td>P: N/A</td>
<td>$2,065.06</td>
</tr>
<tr>
<td></td>
<td></td>
<td>T: 80mcg SC daily</td>
<td>(AWP)</td>
</tr>
</tbody>
</table>
NNT Comparison

• Assumptions
  – Inclusion criteria differs for all trials
    • Age
    • Cut off for DEXA scan
  – Definition of non-vertebral is inconsistent
  – Dx is Osteoporosis in postmenopausal women

https://bmcmusculoskeletdisord.biomedcentral.com/articles/10.1186/1471-2474-12-209
<table>
<thead>
<tr>
<th>Brand (generic)</th>
<th>↑ BMD</th>
<th>Duration</th>
<th>NNT</th>
<th>Recommendation*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fosamax (alendronate)</td>
<td>5-6%/year</td>
<td>3 years</td>
<td>Vertebral: 15 Hip: 91 Non-vertebral: 50-60</td>
<td>Initial therapy</td>
</tr>
<tr>
<td>Boniva (ibandronate)</td>
<td>5-6%/year</td>
<td>3 years</td>
<td>Vertebral: 21 Hip: NSD Non-vertebral: NSD</td>
<td>High spine fracture risk</td>
</tr>
<tr>
<td>Actonel (risedronate)</td>
<td>5-6%/year</td>
<td>3 years</td>
<td>Vertebral: 20 Hip: 77-91 Non-vertebral: 50-60</td>
<td>Initial therapy</td>
</tr>
<tr>
<td>Reclast (zoledronic acid)</td>
<td>5-6%/year</td>
<td>3 years</td>
<td>Vertebral: 14 Hip: 23-107 Non-vertebral: 50-60</td>
<td>Initial therapy for higher fracture risk</td>
</tr>
<tr>
<td>Evista (raloxifene)</td>
<td>Up to 4% over 2 years</td>
<td>3 years</td>
<td>Vertebral: 46 Hip: NSD Non-vertebral: NSD</td>
<td>High spine fracture risk</td>
</tr>
<tr>
<td>Prolia (denosumab)</td>
<td>Up to 15% over 6 years</td>
<td>3 years</td>
<td>Vertebral: 21 Hip: 200 Non-vertebral: 71</td>
<td>Initial therapy for higher fracture risk</td>
</tr>
<tr>
<td>Forteo (teriparatide)</td>
<td>Up to 13% in 1.5 years</td>
<td>1.5 years</td>
<td>Vertebral: 11 Hip: NSD Non-vertebral: 50-60</td>
<td>Initial therapy for higher fracture risk</td>
</tr>
<tr>
<td>Tymlos (abaloparatide)</td>
<td>Up to 9% in 1.5 years</td>
<td>1.5 years</td>
<td>Vertebral: 28 Hip: NSD Non-vertebral: 50</td>
<td>No recommendation at this time</td>
</tr>
</tbody>
</table>

NSD = No Statistical Difference  
*Per AACE/ACE 2016 postmenopausal osteoporosis recommendations
Failure of bisphosphonates

• GERD
  – Relative contraindication for bisphosphonates
  – Take with 6-8oz of plain water after overnight fast
  – Can the patient stay upright for 30 – 60 minutes after taking medication
    • Sitting/standing/active
  – IV formulations reduce GI upset
  – Not recommended for patients with Barrett’s esophagus

• Renal function needs to be monitored
  – Not recommended:
    • Ibandronate/risedronate CrCL < 30 mL/min
    • Alendronate CrCL < 35 mL/min
  – Contraindicated
    • Zoledronic acid CrCL < 35 mL/min
Serious Adverse Event rates - NNH

- Osteonecrosis of the jaw – NNH 2500
  - Prolia may have less rates vs. bisphosphonates
- Atypical femoral fracture risk increase with duration. Increasing 10.7% per year while on therapy. NNH 1250-2000
- Tymlos/Forteo are limited to 2 years due to increase risk of sarcoma in mice
  - 7 year follow up study for Forteo has found no occurrences in humans so far
Lucemyra (lofexidine)
Lucemyra

- First non-opioid, non-addictive treatment for multiple symptoms of opioid withdrawal
- Facilitates abrupt opioid discontinuation
- FDA approved May 6th, 2018
- MOA: Alpha-2 adrenergic agonist
  - Same MOA as clonidine
Lucemyra

- Treatment duration: 3 – 14 days (depending on opioid being discontinued)
- Dosing: Take three 0.18mg tablets PO 4 times/day at 5-6 hour intervals.
  - Taper over 2-4 days depending on treatment duration
- AE: Orthostatic hypotension, bradycardia, hypotension, dizziness
Cost of Lucemyra vs. Clonidine

What is the cost of a 14 day treatment of Lucemyra compared to clonidine?

• A) 130x more expensive
• B) 1300x more expensive
• C) 13x more expensive
• D) 130,000x more expensive
TRIVIA
Question

There was recently an age increase for the HPV shot – Gardasil. What is the new age range approved by the FDA?

A) 9-45
B) 9-26
C) 9-65
D) Give it to anyone that is willing
FDA News Release

FDA approves expanded use of Gardasil 9 to include individuals 27 through 45 years old

For Immediate Release  October 5, 2018
Question

Which formulation of Calcium requires an acid environment for absorption?

A) Citrate
B) Gluconate
C) Lactate
D) Carbonate
Table 3

Characteristics of various calcium preparations. Data from Wickersham and Novak (2002)

<table>
<thead>
<tr>
<th>Calcium salt</th>
<th>% elemental calcium</th>
<th>Elemental calcium in example dosage forms</th>
<th>Absorption acid dependent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbonate</td>
<td>40%</td>
<td>1500 mg tablet contains 500 mg</td>
<td>Yes</td>
</tr>
<tr>
<td>Triphosphate</td>
<td>39%</td>
<td>1565.2 mg tablets contain 600 mg elemental calcium</td>
<td>Yes</td>
</tr>
<tr>
<td>Citrate</td>
<td>21%</td>
<td>950 mg tablets contain 200 mg elemental calcium</td>
<td>No</td>
</tr>
<tr>
<td>Lactate</td>
<td>13%</td>
<td>650 mg tablets contain 84.5 mg elemental calcium</td>
<td>No</td>
</tr>
<tr>
<td>Gluconate</td>
<td>9.3%</td>
<td>500 mg tablets contain 45 mg elemental calcium</td>
<td>No</td>
</tr>
</tbody>
</table>

Published online 2006 Sep.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1936264/
Question

What drug was recently recalled due to NDMA contamination? N-nitrosodimethylamine is a potential carcinogen

A) Lisinopril (Prinivil/Zestril)
B) Amlodipine (Norvasc)
C) Valsartan (Diovan)
D) Candesartan (Atacand)
FDA News Release

FDA announces voluntary recall of several medicines containing valsartan following detection of an impurity

For Immediate Release
July 13, 2018

Angiotensin Receptor Blocker (ARB) Antihypertensive Dose Comparison

NOTE: When switching products consider indication, liver function, renal function, other medical conditions, and allergies. Dose equivalencies are approximate; individual responses may vary. Monitor blood pressure, potassium, and renal function.

Abbreviations: BID=twice daily, MI=myocardial infarction, QD=once daily

<table>
<thead>
<tr>
<th>Drug</th>
<th>Comparable dose based on therapeutic interchange studies, comparative clinical trials, and manufacturers’ recommended dosing for hypertension</th>
</tr>
</thead>
<tbody>
<tr>
<td>Azilsartan (Edarbi)</td>
<td>40 mg QD² 40 mg QD³ 40 mg QD⁴ 40 mg QD⁵ 40 mg QD⁶ 80 mg QD</td>
</tr>
<tr>
<td>Candesartan (Atacand)</td>
<td>4 mg QD⁷ 8 mg QD or divided BID 16 mg QD or divided BID⁸ 16 mg QD or divided BID⁹ to 32 mg QD or divided BID</td>
</tr>
<tr>
<td>Eprosartan (Teveten)</td>
<td>400 mg QD 800 mg QD³ 800 mg QD⁴ 800 mg QD⁵ 800 mg QD⁶ 800 mg QD⁷</td>
</tr>
<tr>
<td>Irbesartan (Avapro)</td>
<td>75 mg QD⁷ 150 mg QD 300 mg QD 300 mg QD</td>
</tr>
<tr>
<td>Losartan (Cozaar)</td>
<td>25 mg QD⁷ 50 mg QD or divided BID⁸ 100 mg QD or divided BID⁹</td>
</tr>
<tr>
<td>Olmesartan (Benicar)</td>
<td>10 mg QD 20 mg QD 20 mg QD⁹ to 40 mg QD</td>
</tr>
<tr>
<td>Telmisartan (Micardis)</td>
<td>20 mg QD 40 mg QD⁷ 40 mg QD⁸ to 80 mg QD</td>
</tr>
<tr>
<td>Valsartan (Diovan)</td>
<td>40 mg QD or 20 mg BID⁹ 80 mg QD⁴ or 40 mg BID⁴⁰ 160 mg QD 320 mg QD⁵²</td>
</tr>
</tbody>
</table>

(See footnotes regarding lower doses)
Question

True or False: The most recent drug approved by the FDA is a new treatment for influenza?

A) True
B) False
FDA News Release

FDA approves new drug to treat influenza

For Immediate Release

October 24, 2018

Today, the U.S. Food and Drug Administration approved Xofluza (baloxavir marboxil) for the treatment of acute uncomplicated influenza (flu) in patients 12 years of age and older who have been symptomatic for no more than 48 hours.

"This is the first new antiviral flu treatment with a novel mechanism of action approved by the FDA in nearly 20 years. With thousands of people getting the flu every year, and many people becoming seriously ill, having safe and effective treatment alternatives is critical. This novel drug provides an important, additional treatment option," said FDA Commissioner Scott Gottlieb, M.D. "While there are several FDA-approved antiviral drugs to treat flu, they’re not a substitute for yearly vaccination. Flu season is already well underway, and the U.S. Centers for Disease Control and Prevention recommends getting vaccinated by the end of October, as seasonal flu vaccine is one of the most effective and safest ways to protect yourself, your family and your community from the flu and serious flu-related complications, which can result in hospitalizations. Yearly vaccination is the primary means of preventing and controlling flu outbreaks."
Question

For fiscal year 2018, the FDA approved how many generic drugs?

A) 300-450
B) 451-600
C) 601-750
D) 751-900
E) Not Enough
Answer – Daily Double

FDA sets new record for generic drug approvals

- Tentative approvals
- Approvals

<table>
<thead>
<tr>
<th>Year</th>
<th>Approvals per year</th>
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<tbody>
<tr>
<td>FY 2013</td>
<td>535</td>
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<td>FY 2014</td>
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<td>FY 2018</td>
<td>971</td>
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Question

The term “authorized generic” means what?

A) The manufacturer of the brand name drug has given permission for the generic to be made

B) The manufacturer of the brand name drug is now making the generic version

C) The FDA prefers the authorized generic over others
What is an authorized generic drug?

An Authorized Generic is the brand company's own product repackaged and marketed as a generic drug either through a subsidiary or a third party. An Authorized Generic is a brand-name drug - already approved as a New Drug Application (NDA) by the FDA - and marketed as a generic product under a private label.
Question

Which drug below recently went generic?

A) Cialis
B) Humira
C) Advair
D) Lantus
E) Myrbetriq
Question

What actor worked at a pharmacy before becoming famous?

A) Chris Hemsworth
B) Robert De Niro
C) Chevy Chase
D) Robert Downey Jr.
Trivia

What is the best Halloween candy?

A) Butterfinger
B) Nerds
C) Skittles
D) Milky Way
E) An apple to keep the doctor away
That’s all folks

Thanks for your time and attention!