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The National Opioid Crisis: The Physicians Responsibilities and What You Need to Know About Prescribing Pain Medications

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Objectives

- Review national and regional trends regarding prescription/drug abuse
- Discuss national, state, and local initiatives for addressing the prescription/drug abuse epidemic
- Identify recent updates surrounding prescribing and dispensing practices
- Identify the psychological factors in Opioid addiction and its prevention.
- Describe connections of addiction to co-morbid mental health diagnoses and social factors.
- Review non-medical treatment modalities for addiction, associated mental illness, and pain management.
- Evaluate different routes of administration and tolerance effects of extended release/long-acting opioids
- Describe adverse effects of opioids
- Identify significant drug-drug interactions associated with opioid use

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CDC¹



91
AMERICANS

die every day from
an **opioid overdose**
(that includes prescription
opioids and heroin).

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CDC²



More than
40
PEOPLE

die every day from
overdoses involving
prescription opioids.

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Each day, more than
1,000
PEOPLE

are treated in
emergency
departments for
not using prescription
opioids as directed.



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CDC: Drug Overdose Deaths in the United States, 1999–2016⁴

- **Key findings (data from the National Vital Statistics System, Mortality)**
 - In 2016, there were more than 63,600 drug overdose deaths in the United States.
 - The age-adjusted rate of drug overdose deaths in 2016 (19.8 per 100,000) was 21% higher than the rate in 2015 (16.3).
 - West Virginia (52.0 per 100,000), Ohio (39.1), New Hampshire (39.0), the District of Columbia (38.8), and Pennsylvania (37.9) had the highest observed age-adjusted drug overdose death rates in 2016.
 - The age-adjusted rate of drug overdose deaths involving synthetic opioids other than methadone (drugs such as fentanyl, fentanyl analogs, and tramadol) doubled between 2015 and 2016, from 3.1 to 6.2 per 100,000.

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CDC Data⁵

- Overdose deaths involving prescription opioids were five times higher in 2016 than 1999, and sales of these prescription drugs have quadrupled.
- From 1999 to 2016, more than 200,000 people have died in the U.S. from overdoses related to prescription opioids.
- Sharp increases in opioid overdose deaths since 2013 are partly explained by the introduction of illicitly manufactured fentanyl or fentanyl analogs (e.g. carfentanil) into the heroin market.
- Misuse of prescription drugs is related to high levels of prescribing; in 2016 prescribers wrote 66.5 opioid and 25.2 sedative prescriptions for every 100 Americans (down from 72.4 opioid per 100 persons in 2006)

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Recent Conclusions⁵:

- Prescription opioid pain relievers were formerly driving the crisis, but by 2015 they shared equal measure with heroin, synthetic opioids (mostly illicit fentanyl), and others (e.g. cocaine)
- Declines in opioid prescribing rates since 2012 and high-dose prescribing rates since 2009 suggest that healthcare providers have responded and are more cautious in their opioid prescribing practices
- Additional measures are now urgently needed to address a diverse and evolving array of drug types
 - The pattern of drugs involved in drug overdose deaths has changed in recent years

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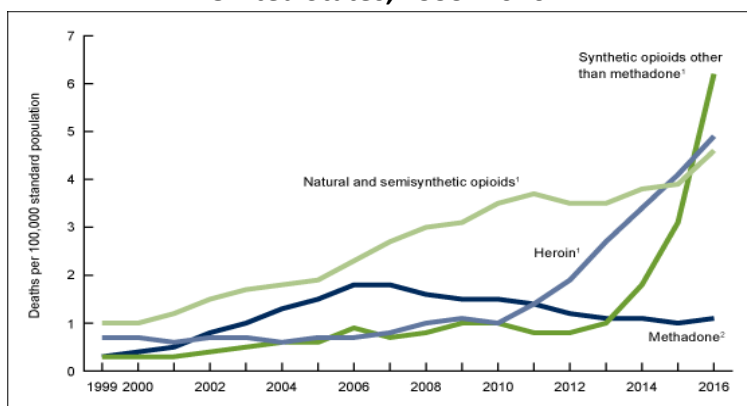
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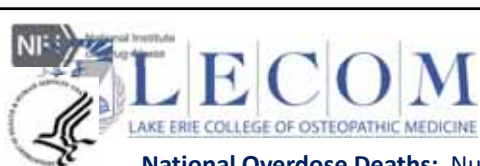


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**Age-adjusted drug overdose death rates, by opioid category:
United States, 1999–2016⁴**

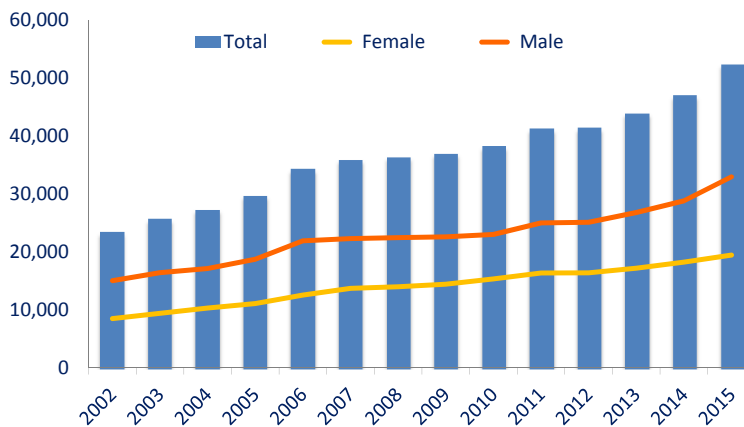


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National Overdose Deaths: Number of Deaths from All Drugs



Source: National Center for Health Statistics, CDC Wonder

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Comparing the size of lethal doses of heroin, fentanyl, and carfentanyl. The vials here contain an artificial sweetener for illustration. (New Hampshire State Police Forensic Laboratory)

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PA Coroners Report⁶

- 2016 Report
 - 2016 – 4,884; 2015 – 3,505; 2014 – 2,489
 - 13 people die everyday from drug related causes; not known are those that overdose and survive
 - Opioids (prescription painkillers and heroin) are still found in most overdose deaths; cocaine on the rise, and fentanyl with its synthetic versions is very commonly found, frequently with heroin or cocaine
 - Erie 95; Allegheny Co 648; Philadelphia 907

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RX to Illicit Trend⁷

Of those who began abusing opioids in the 2000s, 75 percent reported that their first opioid was a prescription drug



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Federal Initiatives

- Fed – FDA, CDC, DEA, SAMSHA...
 - DEA – disposal, rescheduling, increased inspections, ongoing enforcements
 - CARA 2016 – increased funding for naloxone, treatment, MAT, DATA expansion / mid level and patients, partial fills, education
 - FDA – abuse deterrent meds, REMS, withdrawal of med
 - CDC – prescribing guidelines
 - CDC – RX Awareness campaign (“it only takes a little to lose a lot”) education on opioid use disorder/risks of opioids
 - Other proposed laws – acute care prescribing guidelines

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CARA 2016

- Partial Fills of CII
 - Up to 30 day permitted from date issued; up to total qty prescribed
 - For call in ER can give partial up to 72 hours
 - Replaces long standing rule of pharmacy “unable to supply” could give 72 hour then remainder

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State Initiatives

- States
 - PDMPs, naloxone access, prescribing and dispensing guidelines and laws, CEs, increased treatment, disposal options,
 - PA Dept of Health guidelines
 - PA example 4 hours education for newly licensed, 2 hours for licensed per renewal
 - Mandatory medical education
 - Limits on CII in ER; age limits; first fills
 - Lawsuits against pharma, charges against distributors / pharmacies / prescribers / “dealers”
 - Increased enforcement actions (criminal and administrative)

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Civil Cases/Malpractice Trend??

- The “patient” (one that became addicted); or their family (if the “patient” is deceased from an overdose) sues in CIVIL court (basically malpractice) against the prescriber and pharmacy/pharmacist
 - Basics of Claim – the prescriber prescribed, which led to my addiction, and continued to provide the med(s), and pharmacy/pharmacist continued to dispense
 - Various courts have allowed these cases to proceed (WVa SC also determined cases can continue despite “patient” potentially being involved in criminal behavior (multiple docs, pharmacies, etc)
- My experiences from regional cases – NY/NJ/PA law firm; Pgh law firm
 - \$\$ Damages for becoming addicted, time spent recovering, problems that occurred as a result (e.g. socially, job, family, etc)
 - Most have involved “patient” going to multiple docs and pharmacies, maybe even internet (was there a PDMP available to help with these?), or pill mill prescribers
 - Counter claim (if state allows) – ok, maybe the defendant didn’t prescribe or dispense the best they could have (e.g. pharmacy red flags), but the “patient” is partly responsible, thus damages decreased

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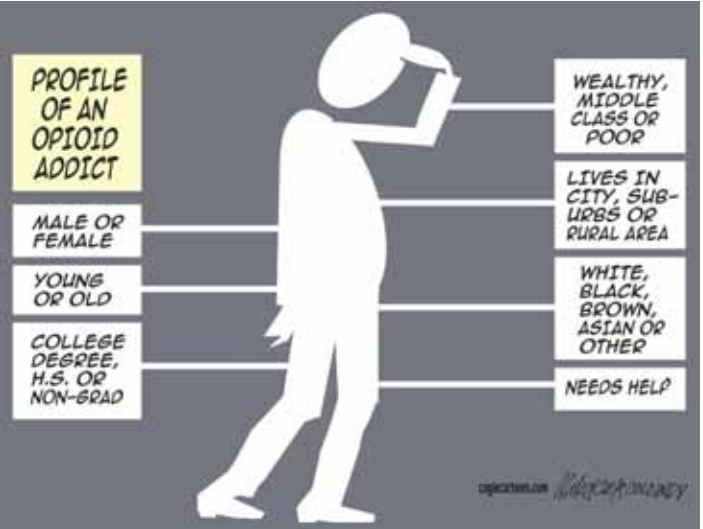
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The cartoon depicts a white silhouette of a person standing and holding their hand to their forehead in a thinking pose. To the left of the person are four yellow boxes with black text, and to the right are four white boxes with black text. Lines connect the boxes to the person's head. The boxes contain the following text:

- Left side boxes:**
 - PROFILE OF AN OPIOID ADDICT
 - MALE OR FEMALE
 - YOUNG OR OLD
 - COLLEGE DEGREE, H.S. OR NON-GRAD
- Right side boxes:**
 - WEALTHY, MIDDLE CLASS OR POOR
 - LIVES IN CITY, SUBURBS OR RURAL AREA
 - WHITE, BLACK, BROWN, ASIAN OR OTHER
 - NEEDS HELP

At the bottom right of the cartoon, there is a signature and the text 'opportunity.com'.

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DSM-5 Criteria for Opioid Use Disorder
Description:

The following are the DSM-5 diagnostic criteria for Opioid Use Disorder

1. A problematic pattern of opioid use leading to clinically significant impairment or distress, as manifested by at least two of the following, occurring within a 12-month period:
 - Opioids are often taken in larger amounts or over a longer period than was intended.
 - There is a persistent desire or unsuccessful efforts to cut down or control opioid use.
 - A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects.
 - Craving, or a strong desire or urge to use opioids.

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- Recurrent opioid use resulting in a failure to fulfill major role obligations at work, school, or home.
- Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids.
- Important social, occupational, or recreational activities are given up or reduced because of opioid use.
- Recurrent opioid use in situations in which it is physically hazardous.
- Continued opioid use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance.-

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Tolerance, as defined by either of the following:

A need for markedly increased amounts of opioids to achieve intoxication or desired effect.

A markedly diminished effect with continued use of the same amount of an opioid. (Note: This criterion is not considered to be met for those taking opioids solely under appropriate medical supervision.)

Withdrawal, as manifested by either of the following:

The characteristic opioid withdrawal syndrome (refer to Criteria A and B of the criteria set for opioid withdrawal).

Opioids (or a closely related substance) are taken to relieve or avoid withdrawal symptoms. (Note: This criterion is not considered to be met for those individuals taking opioids solely under appropriate medical supervision.)

Specify if:

In early remission (3 months of no criteria being met (with the exception of cravings) or sustained remission (12 months or longer (with the exception of cravings).

On maintenance therapy

In a controlled environment (where access to opioids is restricted).

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See the DSM-5 manual for details on specifications.

Specify current severity:

305.50 (F11.10) Mild: Presence of 2–3 symptoms.

304.00 (F11.20) Moderate: Presence of 4–5 symptoms.

304.00 (F11.20) Severe: Presence of 6 or more symptoms.

See the DSM-5 manual for details on specifications and how to code when there are other disorders.

(Reprinted with permission from APA. *Diagnostic and Statistical Manual of Mental Disorders* 2000 and updated to: American Psychiatric Association. (2013). *Diagnostic and statistical manual of mental disorders* (5th ed.). Arlington, VA: American Psychiatric Publishing.

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Psychological Factors in Opioid Addiction



- Opiate Addiction generally has greater devastation than addiction to other drugs due to the severity of mental and physical effects.
- Family History
- Social History
- Shared risk factors between Mental Illness and Opioid Addiction:
 - Overlapping genetic vulnerabilities
 - Overlapping environmental triggers
 - Involvement of similar brain systems (reward and stress systems)
 - Both are developmental disorders (often begin in adolescence.)

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Chronic pain can lead to mental health issues.

Medical History

-Use of opiates with cancer and pain patients increases risk of depression.

Legal Involvement

Prior Mental Health History:

Moderate to severe mental illness is a substantial predictor of development of opiate addiction.

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Behavioral Considerations in Addiction to Opioids

- Substances can create mental health symptoms (paranoia, delusions, depression, etc.) when under the influence.
- When these symptoms continue after influence of substances wears off, it can indicate a co-occurring disorder.
- Substance use increases the risk of sexual assault or violent crime. This can lead to development of PTSD, other anxiety disorders, depression, and eating disorders.
- Poor decision-making is common when intoxicated. (ie. Breaking the law, unprotected sex, sharing needles, etc..) This can in turn cause depression and grief over consequences of these behaviors.

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Opioid Addiction and Suicide Risk

- 13x greater risk of death
- 14X greater risk of suicide
- Normal risk factors apply (gender, MI, family, social factors)
- Required targeted intervention with this population

Risk factors: Use of alcohol

Depression

Stress

Peers

Employment issues

Short treatment duration

Leaving treatment before completion

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Opioid Addiction and Co-Morbid Psychiatric Disorders

Comorbidity- 2 disorders occurring simultaneously in one individual

- Individuals who suffer from addiction are twice as likely to also suffer from mood and anxiety disorders.
- Symptoms of one disorder trigger the other.
- Addiction is a mental health disorder.
- It fundamentally changes the brain and impacts hierarchy of needs and desires. The drug becomes priority and impulsive, harmful behaviors may result in order to get it. Affects thinking and functioning.

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Opioid Addiction and Co-Morbid Psychiatric Disorders

Substance Abuse Secondary to a Mental Health Diagnosis

* **Self-medication:** using substance to help manage symptoms that are disruptive or uncomfortable

* **Connection to Depression:**

-Opiate abuse has a very strong correlation with clinical depression. This makes recovery even more difficult if not addressed and treated. (Bi-directional relationship.)

-Use of opiates (not necessarily abuse) increases risk of Depression.

-Increased relapse risk.



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Opioid Addiction and Co-Morbid Psychiatric Disorders

Substance Abuse Secondary to Other Mental Health Diagnoses:

-Anxiety Disorders

- Generalized Anxiety Disorder
- Obsessive Compulsive Disorder
- Social Anxiety
- Post-Traumatic Stress Disorder

-Adult Attention Deficit Hyperactivity Disorder

-Bipolar Disorder

-Psychotic Symptoms/Thought Disorders/Schizophrenia



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Non-Medical Treatment Modalities

- Can decrease risk of relapse
- Psychotherapy is best when combined with MAT and drug counseling
- Most effective with those with moderate or severe MI
- Can be very difficult to separate therapy and therapist effects
- Effectiveness strongly associated with perception of the helping relationship
- Increased effectiveness when completely integrated into treatment/recovery

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Non-Medical Treatment Modalities

Most effective with:

- new clients with no treatment history
- successful graduates of intensive programs.
- Family therapy aids retention.

Focus on: Coping skills
Past Trauma
Self-care



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Non-Medical Treatment Modalities

Contingency Management Interventions: Tangible reinforcement

- Voucher based reinforcement
- Prize incentives
- Increases retention and abstinence

Therapeutic Communities:

- Comprehensive, include recreational, family, social, and vocational components
- Patients are used as the treatment modality

Group Psychotherapy- improved outcomes, less use of opiates (at 6 month follow-up)

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Non-Medical Treatment Modalities

CBT- identify unhealthy, negative thinking and behaviors and replace with healthier more positive ones

DBT- type of CBT, teaches behavioral skills to cope with stress, manage emotions, and improve relationships with others

- significantly greater reductions in substance use
- greater gains in functioning and social adjustment

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Non-Medical Treatment Modalities

ACT - develop awareness and acceptance of thoughts and feelings
-commit to making change
-increases ability to cope and adjust to life situations

Psychodynamic Therapy

-increase awareness of unconscious thoughts and behaviors
-gaining new insights into motivations, and resolve conflicts

Interpersonal Therapy- addresses issues with current relationships with others to improve interpersonal skills

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Future Directions and Needs

- Fostering easy and broad access to treatment.
- Keeping addict alive so treatment can happen.
- Collaboration of all entities involved, particularly the medical and behavioral health communities.
- EDUCATION!
- RESEARCH!
- Addressing underlying issues such as mental illness, socio-economic disparity, educational/occupational challenges, preventative health care.



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Pharmacology of Opioid Use/Abuse

- Buprenorphine
- Fentanyl
- Hydrocodone
- Levorphanol
- Methadone
- Morphine
- Oxycodone
- Tapentadol
- Tramadol

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Pharmacology of Opioid Use/Abuse

- Immediate release form:
 - Buccal tablet
 - Sublingual or nasal spray
 - Capsule/tablet
 - Infusion/injection
 - Suppositories
- Extended release/Long-acting
 - Buccal film
 - Transdermal system
 - Capsule/tablet

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Pharmacology of Opioid Use/Abuse

- Solid oral dosage forms
 - Crushing, chewing, breaking, cutting or dissolving may result in rapid release/absorption
- Buccal film
- Transdermal systems
 - Never be cut or torn before use
 - Exposure to heat can increase release and absorption, resulting in inadvertent overdose
- IV/IM

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Opioid tolerance

- Considered opioid tolerant if receiving:
 - 60mg oral morphine/day
 - 25 µg transdermal fentanyl/hour
 - 30 mg oral oxycodone/day
 - 60 mg oral hydroxymorphone/day
 - 25 mg oral oxymorphone/day
- Tolerance typically develops after taking an opioid for 1 week or more at a morphine-equivalent dose of 60 mg/day

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Opioid tolerance

- Switching to different opioid or non-opioid treatment
- Tolerance does not indicate addiction

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Common Opioid Drug Interactions

- Concomitant use of benzodiazepines or other CNS depressants (alcohol)
- Skeletal muscle relaxants
 - Increased degree of respiratory depression
- Anticholinergic medications
 - Increases risk of urinary retention and severe constipation → paralytic ileus

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Common Opioid Drug Interactions

- Diuretics
 - Opioids induce ADH release
- CYP450 enzyme inducers/inhibitors
 - 3A4: metabolism of codeine, oxycodone, fentanyl, methadone, and tramadol
 - 2D6: influences metabolism of codeine, hydrocodone, oxycodone, and tramadol

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Common CYP inhibitors

- Antidepressants (including bupropion, fluoxetine, and paroxetine)
- Acyclovir
- Amiodarone
- Duloxetine (Cymbalta)
- Fluoroquinolone antibiotics
- Proton pump inhibitors

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Drug Interactions

- CYP3A4 inhibitors
 - Cimetidine
 - Fluconazole and ketoconazole
 - Grapefruit juice
 - Protease inhibitors
 - Indinavir [Crixivan]
 - Nelfinavir [Viracept]
 - Ritonavir [Norvir]
 - Verapamil and diltiazem
- CYP2D6 inhibitors
 - Bupropion
 - Celecoxib
 - Chlorpromazine
 - Diphenhydramine

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Drug Interactions

- CYP450 inducers
 - 3A4
 - Carbamazepine
 - Dexamethasone
 - Isoniazid
 - Phenobarbital
 - Phenytoin
 - Tobacco
 - Rifampin
 - St. John's wort

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Adverse Effects

- Sedation
- Respiratory depression
- Alterations in gut motility
 - As high as 29% patients experience constipation
- Rash
 - Due to histamine release, not a hypersensitivity reaction
- QT prolongation

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Adverse Effects

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