

Medication Guide

Pentazocine and Naloxone (pen taz' oh seen and nal ox' one) Tablets

Pentazocine and Naloxone Tablets are:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage moderate to severe pain, when other pain treatments such as non-opioid pain medicines do not treat your pain well enough or you cannot tolerate them.
- An opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to death.

Important information about Pentazocine and Naloxone Tablets:

- **Get emergency help right away if you take too many Pentazocine and Naloxone Tablets (overdose).** When you first start taking Pentazocine and Naloxone Tablets, when your dose is changed, or if you take too much (overdose), serious or life-threatening breathing problems that can lead to death may occur. Taking Pentazocine and Naloxone Tablets with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.
- Never give anyone else your Pentazocine and Naloxone Tablets. They could die from taking it. Selling or giving away Pentazocine and Naloxone Tablets is against the law.
- Store Pentazocine and Naloxone Tablets securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home.

Do not take Pentazocine and Naloxone Tablets if you have:

- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.
- previously had an allergic reaction to pentazocine or naloxone.
- known or suspected gastrointestinal obstruction, including paralytic ileus.

Before taking Pentazocine and Naloxone Tablets, tell your healthcare provider if you have a history of:

- head injury, seizures
- liver, kidney, thyroid problems
- problems urinating
- pancreas or gallbladder problems
- abuse of street or prescription drugs, alcohol addiction, or mental health problems.

Tell your healthcare provider if you are:

- **pregnant or planning to become pregnant.** Prolonged use of Pentazocine and Naloxone Tablets during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated.
- **breastfeeding.** Pentazocine and naloxone passes into breast milk and may harm your baby.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking Pentazocine and Naloxone Tablets with certain other medicines can cause serious side effects that could lead to death.

When taking Pentazocine and Naloxone Tablets:

- Do not change your dose. Take Pentazocine and Naloxone Tablets exactly as prescribed by your healthcare provider. Use the lowest dose possible for the shortest time needed.
- Take your prescribed dose every 3 or 4 hours at the same time every day. Do not take more than your prescribed dose. If you miss a dose, take your next dose at your usual time.
- Call your healthcare provider if the dose you are taking does not control your pain.
- If you have been taking Pentazocine and Naloxone Tablets regularly, do not stop taking Pentazocine and Naloxone Tablets without talking to your healthcare provider.
- Dispose of expired, unwanted, or unused Pentazocine and Naloxone Tablets by promptly flushing down the toilet, if a drug take-back option is not readily available. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.

While taking Pentazocine and Naloxone Tablets DO NOT:

- Drive or operate heavy machinery, until you know how Pentazocine and Naloxone Tablets affect you. Pentazocine and Naloxone Tablets can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol. Using products containing alcohol during treatment with Pentazocine and Naloxone Tablets may cause you to overdose and die.

 		Proof Date: 04/16/2019 Proof Time: 02:22 PM Prepared by: suzannea	
NP Item#: NOVE-NP_41211		Size: 6 x 13.25 (folded: 4.5 x 6)	Type size:
PO No.:		Item Iss./Rev. Date: Revised: 04/2019	Cust. Part No.: MG68000203
Customer: Novel	Private Label: Lupin	Description: Pentazocine & Naloxone Tabs MG68000203 (Lupin)	
Bar code details: Type: Code:			
Notes:			
<input type="checkbox"/> Approved <input type="checkbox"/> Resubmit		Signature: _____ Date: _____	

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The possible side effects of Pentazocine and Naloxone Tablets:

- constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain. Call your healthcare provider if you have any of these symptoms and they are severe.

Get emergency medical help if you have:

- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue, or throat, extreme drowsiness, light-headedness when changing positions, feeling faint, agitation, high body temperature, trouble walking, stiff muscles, or mental changes such as confusion.

These are not all the possible side effects of Pentazocine and Naloxone Tablets. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. **For more information go to dailymed.nlm.nih.gov.**

For more information call Lupin Pharmaceuticals, Inc. at 1-866-403-7592.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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