Zurnai™ (nalmefene) – New drug approval

- On August 7, 2024, the FDA announced the approval of Purdue Pharma's Zurnai (nalmefene), for the emergency treatment of known or suspected opioid overdose induced by natural or synthetic opioids in adults and pediatric patients aged 12 years and older, as manifested by respiratory and/or central nervous system depression.
    - Zurnai is intended for immediate administration as emergency therapy in settings where opioids may be present.
    - Zurnai is not a substitute for emergency medical care.
- Drug overdose persists as a major public health issue in the U.S., with more than 107,000 reported fatal overdoses occurring in 2023, primarily driven by synthetic opioids like illicit fentanyl.
    - Nalmefene and naloxone are two available options to reverse opioid overdose. The FDA has worked to increase availability and accessibility of both options to encourage harm reduction and reduce overdose death.
- Zurnai is the first nalmefene auto-injector formulation. The FDA approved the first nasal spray formulation of nalmefene (Opvee®) in May 2023.
- The approval of Zurnai is supported by safety and pharmacokinetic studies, as well as a study in healthy individuals who use opioids recreationally, to assess how quickly the product works.
- Warnings and precautions for Zurnai include risk of recurrent respiratory and central nervous system depression; risk of limited efficacy with partial agonists or mixed agonist/antagonists; precipitation of severe opioid withdrawal; and risk of opioid overdose from attempts to overcome the blockade.
- The most common adverse reactions (≥ 5%) with Zurnai use were feeling hot, nausea, headache, dizziness, chills, vomiting, allodynia, palpitations, tinnitus, ear discomfort, feeling abnormal, burning sensation, hot flush, and irritability.
- The recommended dose of Zurnai in adults and pediatric patients aged 12 years and older is 1.5 mg delivered by intramuscular or subcutaneous injection into the anterolateral aspect of the thigh, through clothing if necessary.
    - Emergency medical assistance should be sought as soon as possible after administration of the first dose of Zurnai. The requirement for repeat doses of Zurnai depends upon the amount, type, and route of administration of the opioid being antagonized.
    - If the patient responds to Zurnai and subsequently relapses back into respiratory depression before emergency assistance arrives, an additional dose of Zurnai should be administered using a new auto-injector and surveillance of the patient should be continued.
    - If the desired response is not obtained after 2 to 5 minutes, an additional dose of Zurnai should be administered using a new auto-injector. If there is still no response and additional doses are available, additional doses of Zurnai should be administered every 2 to 5 minutes using a new Zurnai auto-injector for each dose until emergency medical assistance arrives.

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- Purdue Pharma’s launch plans for Zurnai are pending. Zurnai will be available as a 1.5 mg nalmefene base/0.5 mL prefilled, single-dose autoinjector.