

MEDICATION GUIDE
MOVANTIK® (mo-van-tic)
(naloxegol)
tablets, for oral use

Read this Medication Guide before you start taking MOVANTIK and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about MOVANTIK?

MOVANTIK may cause serious side effects, including:

- **Opioid withdrawal.** You may have symptoms of opioid withdrawal during treatment with MOVANTIK including sweating, chills, diarrhea, stomach pain, anxiety, irritability, and yawning. If you take methadone to treat your pain, you may be more likely to have stomach pain and diarrhea than people who do not take methadone. Tell your health care provider if you have any of these symptoms.
- **Severe stomach pain or diarrhea, or both severe stomach pain and diarrhea.** Severe stomach pain and diarrhea can happen when you take MOVANTIK. These problems can happen within a few days after you start taking MOVANTIK and can lead to hospitalization. Stop taking MOVANTIK and call your healthcare provider right away if you have severe stomach pain or diarrhea, or both severe stomach pain and diarrhea.
- **Tear in your stomach or intestinal wall (perforation).** Stomach pain that is severe can be a sign of a serious medical condition. If you have stomach pain that gets worse or does not go away, stop taking MOVANTIK and get emergency medical help right away.

What is MOVANTIK?

MOVANTIK is a prescription medicine used to treat constipation that is caused by prescription pain medicines called opioids, in adults with long-lasting (chronic) pain that is not caused by active cancer. It is not known if MOVANTIK is safe and effective in children.

Who should not take MOVANTIK?

Do not take MOVANTIK if you:

- have a bowel blockage (intestinal obstruction) or have a history of bowel blockage.
- are allergic to MOVANTIK or any of the ingredients in MOVANTIK. See the end of this Medication Guide for a complete list of ingredients in MOVANTIK.

MOVANTIK can interact with certain other medicines and cause side effects, including opioid withdrawal symptoms such as sweating, chills, diarrhea, stomach pain, anxiety, irritability, and yawning. Tell your healthcare provider or pharmacist before you start or stop any medicines during treatment with MOVANTIK.

What should I tell my healthcare provider before taking MOVANTIK?

Before you take MOVANTIK, tell your healthcare provider about all of your medical conditions, including if you:

- have any stomach or bowel (intestines) problems, including stomach ulcer, Crohn's disease, diverticulitis, cancer of the stomach or bowel, or Ogilvie's syndrome.
- have kidney problems.
- have liver problems.
- are pregnant or plan to become pregnant. Taking MOVANTIK during pregnancy may cause opioid withdrawal symptoms in you or your unborn baby. Tell your healthcare provider right away if you become pregnant during treatment with MOVANTIK.
- are breastfeeding or plan to breastfeed. It is not known if MOVANTIK passes into your breast milk.
- taking MOVANTIK while you are breastfeeding may cause opioid withdrawal in your baby. You and your healthcare provider should decide if you will take MOVANTIK or breastfeed. You should not breastfeed if you take MOVANTIK.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Other medicines may affect the way MOVANTIK works.

How should I take MOVANTIK?

- Take MOVANTIK exactly as your healthcare provider tells you.
- Take your prescribed dose of MOVANTIK one time each day, on an empty stomach, at least 1 hour before your first meal of the day or 2 hours after the meal.
- **If you cannot swallow MOVANTIK tablets whole**, MOVANTIK can be mixed with water and taken by mouth or given through a nasogastric (NG) tube. To take MOVANTIK by mouth:

- crush the tablet to a powder
- place your dose of MOVANTIK in a glass that contains 4 ounces (120 mL) of water and stir
- swallow MOVANTIK and water mixture right away
- add 4 more ounces (120 mL) of water to the glass and drink right away, to make sure that you take your full dose of MOVANTIK.
- **If you cannot swallow MOVANTIK tablets and have a nasogastric (NG) tube**, MOVANTIK may be given as follows:
 - draw up 1 ounce (30 mL) of water into a 60 mL syringe and flush the NG tube
 - crush the tablet to a powder
 - place your dose of MOVANTIK in a container and mix with approximately 2 ounces (60 mL) of water
 - draw up the MOVANTIK and water into the 60 mL syringe and give the mixture through the NG tube
 - add approximately 2 ounces (60 mL) of water to the same container you used to prepare your dose of MOVANTIK
 - draw up the water using the same 60 mL syringe and use all the water to flush the NG tube and any remaining medicine from the NG tube into the stomach
- Stop taking other laxatives before you start treatment with MOVANTIK. Your healthcare provider may prescribe other laxatives if MOVANTIK does not work after 3 days of treatment.
- MOVANTIK has been shown to be effective in people who have taken opioid pain medicines for at least 4 weeks.
- Tell your healthcare provider if you stop taking your opioid pain medicine. If you stop taking your opioid pain medicine, you should also stop taking MOVANTIK.
- If you take too much MOVANTIK, call your healthcare provider or go to the nearest emergency room right away.

What should I avoid while taking MOVANTIK?

- Avoid eating grapefruit or drinking grapefruit juice during treatment with MOVANTIK.

What are the possible side effects of MOVANTIK?

See “**What is the most important information I should know about MOVANTIK?**”

The most common side effects of MOVANTIK include: stomach (abdomen) pain, diarrhea, nausea, gas, vomiting, and headache.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of MOVANTIK.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store MOVANTIK?

- Store MOVANTIK at room temperature between 68°F to 77°F (20°C to 25°C).
- Safely throw away medicine that is out of date or that you no longer need.

Keep MOVANTIK and all medicines out of the reach of children.

General information about the safe and effective use of MOVANTIK

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use MOVANTIK for a condition for which it was not prescribed. Do not give MOVANTIK to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about MOVANTIK that is written for health professionals.

What are the ingredients in MOVANTIK?

Active ingredient: naloxegol oxalate

Inactive ingredients: The tablet core contains mannitol, cellulose microcrystalline, croscarmellose sodium, magnesium stearate, and propyl gallate. The tablet coat contains hypromellose, titanium dioxide, polyethylene glycol, iron oxide red, and iron oxide black.

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