Package leaflet: Information for the patient

Moventig 12.5 mg film-coated tablets
Moventig 25 mg film-coated tablets

naloxegol

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Moventig is and what it is used for

Moventig contains the active substance naloxegol. It is a medicine used in adults to treat constipation specifically caused by pain medicines, called opioids, (e.g. morphine, oxycodone, fentanyl, tramadol, codeine) taken on a regular basis. It is used when laxatives have not provided acceptable relief of constipation.

Constipation related to opioids can result in symptoms such as:

- stomach pain
- rectal straining (having to push very hard to move the stool out of the rectum, which can also cause pain in the anus during pushing)
- hard stools (stools which are hard "like a rock")
- incomplete emptying of the rectum (after having a bowel movement, the feeling as if a stool is still in the rectum which needs to come out)

In patients taking opioids with constipation, who have tried at least one laxative and had incomplete relief of constipation, Moventig has been shown in clinical trials to increase the number of bowel movements and improve symptoms of constipation caused by opioids.

2. What you need to know before you take Moventig

Do not take Moventig:

- if you are allergic to naloxegol or similar medicines or any of the other ingredients of this medicine (listed in section 6).
- if your bowels are, or may be, blocked (obstructed) or you have been warned that your bowels are at risk of becoming blocked.

- if you have cancer in your gut or 'peritoneum' (the lining of your stomach area), advanced or recurrent ovarian cancer or if you are taking medicines used to treat cancer such as "VEGF inhibitors" (e.g. bevacizumab).
- if you are taking certain other medicines such as ketoconazole or itraconazole (to treat fungal infections), clarithromycin or telithromycin (antibiotics) or ritonavir, indinavir or saquinavir (to treat HIV).

Do not use Moventig if any of the above applies to you. If you are not sure, talk to your doctor, pharmacist or nurse before taking Moventig.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Moventig:
- if you have stomach ulcers, Crohn's Disease (an illness where your gut is inflamed), diverticulitis (another illness where your gut is inflamed), cancer in your gut or 'peritoneum' (the lining of your stomach area), or any conditon that might damage the wall of your bowel
- if you currently have unusually severe, persistent or worsening stomach pain
- if the natural protective barrier between the blood vessels in the head and in the brain is damaged, for example if you have cancer in the brain or the central nervous system, or if you have a disease of the central nervous system like multiple sclerosis or Alzheimer's disease – contact your doctor immediately if you experience lack of pain relief from your opioid medicine or symptoms of opioid withdrawal syndrome (see section 4).
- if you are taking methadone (see section below "Other medicines and Moventig")
- if you have had a heart attack within the last 6 months, have heart failure with daily shortness of breath or other severe problems with your heart which cause daily symptoms
- if you have kidney problems – your doctor may tell you to take a different dose (see section below "How to take Moventig")
- if you have severe liver illness
- if you have cancer-related pain

If any of the above apply to you, or you are not sure, talk to your doctor, pharmacist or nurse before taking Moventig.

Talk to your doctor, pharmacist or nurse whilst taking Moventig:

- if you develop severe, persistent or worsening stomach pain. This could be a symptom of damage to the wall of the gut and can be life-threatening. Tell your doctor immediately, you may need a lower dose or to stop taking Moventig.
- if your opioid medicine is to be stopped for more than 24 hours
- if you experience symptoms of opioid withdrawal syndrome (see section 4 below). Tell your doctor, you may need to stop taking Moventig.

Children and adolescents
Moventig is not recommended for use in children and adolescents below 18 years of age because it has not been studied in these age-groups.

Other medicines and Moventig
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Tell your doctor what opioid pain medicines you are taking and the dose of them.

Do not take Moventig if you are taking any of the following medicines (see section "Do not take Moventig"):
- ketoconazole or itraconazole - to treat fungal infections
- clarithromycin or telithromycin - antibiotics
- ritonavir, indinavir or saquinavir – to treat HIV

Do not take Moventig if any of the above apply to you.

Tell your doctor, pharmacist or nurse if you are taking any of the following medicines:
- other medicines for constipation (any laxatives)
- methadone
- diltiazem or verapamil (for high blood pressure or angina). You may need to take a lower dose of Moventig
- rifampin (an antibiotic), carbmazepine (for epilepsy) or the herbal medicine St. John's wort (for depression). You may need to stop taking Moventig.
- medicines called 'opioid antagonists' (such as naltrexone and naloxone) which are used to counteract the effects of opioids

If any of the above apply to you, or you are not sure, talk to your doctor, pharmacist or nurse before taking Moventig.

Moventig with drink
You should not drink large amounts of grapefruit juice whilst taking Moventig. This is because large amounts can affect how much of the naloxegol medicine gets into the body.

Pregnancy and breast-feeding
If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before taking this medicine. As there are additional data from the use of this medicine in pregnant women, the use of Moventig during pregnancy is not recommended.

As it is not known whether this medicine is excreted in human milk, do not use Moventig during breast-feeding.

Driving and using machines
Moventig is not expected to affect you being able to drive a car or use any tools or machines.

Moventig contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per 12.5 mg / 25 mg tablet, that is to say essentially 'sodium-free'.

3. How to take Moventig

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is 1 tablet of 25 mg each day.

Take Moventig in the morning, to avoid bowel movements in the middle of the night. Moventig should be taken on an empty stomach at least 30 minutes before the first meal of the day or 2 hours after the first meal.

When treatment with Moventig is started, all currently used laxatives should be stopped, until instructed by your doctor to restart.

Your doctor may tell you to take a lower dose of 12.5 mg
- if you have kidney problems
- if you take diltiazem or verapamil (for high blood pressure or angina)

Your doctor may tell you to increase the dose to 25 mg depending on how you respond to the medicine.

If you have trouble swallowing the tablet
If you have trouble swallowing the tablet you can crush it and mix with water as follows:

- Crush the tablet to a powder
- Pour the powder into half a glass of water (120 ml)
- Stir and drink immediately
- To make sure there is no medicine left, rinse the empty glass with another half a glass of water (120 ml), and drink it

If you take more Moventig than you should
If you take more Moventig than you should, talk to a doctor or go to hospital.

If you forget to take Moventig

- If you miss a dose of Moventig, take it as soon as you remember. However, if it is less than 12 hours until your next dose, skip the missed dose.
- Do not take a double dose to make up for a missed dose.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking the medicine and tell your doctor straight away if you develop opioid withdrawal symptoms (if you have a combination of three or more of these symptoms: feeling depressed, nausea, vomiting, muscle aches, increased tearing, runny nose, dilation of the pupils, goosebumps, excess sweating, diarrhoea, yawning, fever or insomnia) which would usually occur within the first few days after starting naloxegol. Opioid withdrawal symptoms may affect up to 1 in 100 people.

Other possible side effects:
Very common (may affect more than 1 in 10 people):

- stomach pain
- diarrhoea (passing of frequent, watery stools)

Common (may affect up to 1 in 10 people):

- passing wind
- nausea (feeling sick to the stomach)
- vomiting
- nasopharyngitis (runny or stuffy nose)
- headache
- excessive sweating

Not known (frequency cannot be estimated from the available data):

- allergic reaction
- gastrointestinal perforation (a hole developing in the bowel wall)

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Moventig

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after "EXP". The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Moventig contains

- The active substance is naloxegol.

-Each Moventig 12.5 mg film-coated tablet (tablet) contains 12.5 mg naloxegol as naloxegol oxalate.
-Each Moventig 25 mg film-coated tablet (tablet) contains 25 mg naloxegol as naloxegol oxalate.

- The other ingredients are:

-tablet core: mannitol (E421), cellulose microcrystalline (E460), croscarmellose sodium (E468) – see section 2 under 'Moventig contains sodium', magnesium stearate (E470b), propyl gallate (E310)
-film-coating: hypromellose (E464), titanium dioxide (E171), macrogol (E1521), iron oxide red (E172) and iron oxide black (E172).

What Moventig looks like and contents of the pack
Moventig 12.5 mg: a mauve coloured, oval, dimensions 10.5 x 5.5 mm film-coated tablet, marked "nGL" on one side and "12.5" on the other side.
Moventig 25 mg: a mauve coloured, oval, dimensions 13 x 7 mm, film-coated tablet, marked "nGL" on one side and "25" on the other side.

Moventig 12.5 mg tablets are available in aluminium blisters in pack sizes of 30 or 90 film-coated tablets in non-perforated blisters and 30x 1 or 90x1 film-coated tablets in perforated unit dose blisters.

Moventig 25 mg tablets are available in aluminium blisters in pack sizes of 10, 30 or 90 film--coated tablets in non-perforated blisters and 10x1, 30x, 90x1 or 100x1 film-coated tablets in perforated unit dose blisters.

Not all pack sizes may be marketed in your country.

Marketing Authorisation Holder

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Manufacturer

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Detailed information on this medicine is available on the European Medicines Agency website: http://www.ema.europa.eu.