

Standard

Drug Facts

General information about MIRAPEX

MIRAPLEX (pramipexole hydrochloride tablets, USP) 0.5

Read the Medication Guide that comes with MIRAPEX before you or your child starts taking it and each time you or your child takes it. There may be new information. This Medication Guide has been updated to reflect the most recent information about MIRAPEX.

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

The following have been reported with use of MIRAPEX and other dopamine agonists:

- **Heart-related problems:**
 - **Low blood pressure** (a problem that has been reported in some people)
 - **Increased heart effects on adults:**
 - **Increased blood pressure and heart rate**

Tell your doctor if you or your child has any heart problems, heart disease, high blood pressure, or is taking medicine for these problems.

Some people should avoid use of pramipexole tablets for these reasons before starting MIRAPEX:

- Heart disease (heart attack, angina, chest pain, heart failure, coronary artery disease, irregular heart rhythm, or other heart conditions)
- Low or high blood pressure
- Use of other dopamine agonists
- Use of other medicines that may affect MIRAPEX

Tell your doctor right away if you or your child has any of the following symptoms while taking MIRAPEX:

- **Heart-related symptoms:**
 - **Low or high blood pressure** (dizziness, fainting, or other symptoms)
 - **Increased heart effects on adults:**
 - **Increased blood pressure and heart rate**

Tell your doctor right away if you or your child has any of the following symptoms while taking MIRAPEX:

- **Heart-related symptoms:**
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 - **Increased blood pressure and heart rate**

MIRAPEX is also used for the treatment of a sleep disorder called REM sleep behavior disorder.

MIRAPEX is a dopamine agonist. It works by stimulating dopamine receptors in the brain. It may be used to treat Parkinson's disease, restless leg syndrome, and other conditions.

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Column

Health Literacy

MIRAPLEX (pramipexole hydrochloride)

Important Warning about MIRAPEX

- You can develop serious side effects including:
 - Heart-related problems
 - Mental (psychiatric) problems

Uses

MIRAPEX is a central nervous system stimulant that helps increase alertness and decrease impulsiveness and hyperactivity.

- MIRAPEX helps treat:
 - Attention-Deficit/Hyperactivity Disorder (ADHD)
 - A sleep disorder called narcolepsy

How to take MIRAPEX

- MIRAPEX is taken by mouth (pill). Take MIRAPEX as prescribed by your doctor.
- Take MIRAPEX 30 to 60 minutes before eating.
- MIRAPEX is usually taken 2 to 3 times a day.
- Store MIRAPEX at room temperature, 68°F to 86°F, away from light.

Serious side effects

Stop taking this medicine and call your doctor right away if you have:

- a stroke or heart attack (heart failure)
- increased blood pressure or heart rate
- low or high blood pressure
- low or high appetite
- new psychiatric or mental symptoms
- slowing of growth in children
- weight changes or blurred vision

Common side effects

- Headache, stomach ache, trouble sleeping, dizziness, decreased appetite, constipation, dryness, and heart palpitations
- There may be other common side effects of MIRAPEX. Tell your doctor about any side effect that does not go away or gets worse.

Ask your doctor before use

- Tell your doctor if you:
- have heart problems, heart defects, or high blood pressure
 - have mental problems including psychosis, mania, or depression
 - have been or have had an abnormal brain wave test (EEG)
 - are pregnant, planning to become pregnant, or breastfeeding
 - are taking anti-depression medicines including MAOIs, tricyclic antidepressants, blood thinners, heart medicine, or use of allergy medicines that contain decongestants

Specific Groups

- MIRAPEX should not be used in children less than 6 years old because it has not been studied in this age group.

More information

- Talk to your doctor or pharmacist about any questions you may have about this medicine.
- For more information about MIRAPEX call Novartis Laboratories at 1-888-662-6622.
- You may report side effects to the FDA at 1-800-FDA-1088.

Notes

Active ingredient	pramipexole hydrochloride	
Uses	<ul style="list-style-type: none"> • Attention-Deficit/Hyperactivity Disorder (ADHD) • A sleep disorder called narcolepsy 	
Warnings	<p>Important warnings about MIRAPEX</p> <ul style="list-style-type: none"> • You can develop serious side effects including heart-related problems or mental (psychiatric) problems. • MIRAPEX should not be used in children less than 6 years old because it has not been studied in this age group. 	
Ask your doctor before use if you:	<ul style="list-style-type: none"> • have heart problems, heart defects, or high blood pressure • have mental problems including psychosis, mania, or depression • have been or have had an abnormal brain wave test (EEG) • are pregnant, planning to become pregnant, or breastfeeding • are taking anti-depression medicines including MAOIs, tricyclic antidepressants, blood thinners, blood pressure medicine, or use of allergy medicines that contain decongestants 	
Stop use and call your doctor right away if you:	<ul style="list-style-type: none"> • have a stroke or heart attack (heart failure) • have increased blood pressure or heart rate • have low or high blood pressure • have low or high appetite • have new psychiatric or mental symptoms • have slowing of growth in children • have weight changes or blurred vision 	
When using this medicine you may get:	<ul style="list-style-type: none"> • headache • stomach ache • trouble sleeping • dizziness • decreased appetite • constipation • dryness • heart palpitations 	
There can be common side effects of MIRAPEX. Tell your doctor about any side effect that does not go away or gets worse.		
Directions	<ul style="list-style-type: none"> • MIRAPEX is taken by mouth (pill). Take MIRAPEX as prescribed by your doctor. • Take MIRAPEX 30 to 60 minutes before eating. MIRAPEX is usually taken 2 to 3 times a day. • Store MIRAPEX at room temperature, 68°F to 86°F, away from light. 	
Questions	<ul style="list-style-type: none"> • Talk to your doctor or pharmacist about any questions you may have about this medicine. • For more information about MIRAPEX call Novartis Laboratories at 1-888-662-6622. 	

SOME IMPORTANT THINGS TO KNOW ABOUT YOUR MEDICATION

Brand Name(s)	MIRAPEX	
Active ingredient(s)	pramipexole hydrochloride	
Purpose(s)	MIRAPEX helps treat Attention-Deficit/Hyperactivity Disorder (ADHD) and a sleep disorder called narcolepsy.	
Warnings	<p>MIRAPEX is a central nervous system stimulant that helps increase alertness and decrease impulsiveness and hyperactivity.</p> <p>Important warnings about MIRAPEX</p> <ul style="list-style-type: none"> • You can develop serious side effects including heart-related problems or mental (psychiatric) problems. • MIRAPEX should not be used in children less than 6 years old because it has not been studied in this age group. 	
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Ask before use	<p>Ask your doctor before use if you:</p> <ul style="list-style-type: none"> • have heart problems, heart defects, or high blood pressure • have mental problems including psychosis, mania, or depression • have been or have had an abnormal brain wave test (EEG) • are pregnant, planning to become pregnant, or breastfeeding • are taking anti-depression medicines including MAOIs, tricyclic antidepressants, blood thinners, heart medicine, or use of allergy medicines that contain decongestants 	
Common side effects	<p>There can be common side effects of MIRAPEX. Tell your doctor about any side effect that does not go away or gets worse.</p> <ul style="list-style-type: none"> • headache • stomach ache • trouble sleeping • dizziness • decreased appetite • constipation • dryness • heart palpitations 	
Serious side effects	<p>Stop taking this medicine and call your doctor right away if you:</p> <ul style="list-style-type: none"> • have a stroke or heart attack (heart failure) • have increased blood pressure or heart rate • have low or high blood pressure • have low or high appetite • have new psychiatric or mental symptoms • have slowing of growth in children • have weight changes or blurred vision 	
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