

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 does not take the place of talking to your doctor about you or your child's condition or treatment.

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)
- **Swollen blood vessels** and **leg pain**

Call your doctor if you or your child has any of these problems. Your doctor, health care provider, or health care team should know if you have any of these problems.

Some people should avoid you or your child's activities for some periods before starting MIRAPEX[®].

Some people should avoid you or your child's driving, operating machinery, or hazardous activities until you or your child knows how MIRAPEX[®] affects you or your child.

Some people should avoid you or your child's taking any other drugs, including over-the-counter drugs, until you or your child knows how MIRAPEX[®] affects you or your child.

Some people should avoid you or your child's taking any other medicines, including over-the-counter medicines, until you or your child knows how MIRAPEX[®] affects you or your child.

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MIRAPEX[®] is also used for the treatment of a sleep disorder called **narcolepsy**.

MIRAPEX[®] is a dopamine agonist. It is used to treat Parkinson's disease, restless leg syndrome, and some forms of depression. MIRAPEX[®] may also be used to treat some forms of depression.

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Column

Health Literacy

MIRAPLEX (pramipexole hydrochloride)

Important Warning about MIRAPEX

- You can develop serious side effects including:
- Heart-related problems
- Swollen blood vessels

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)
- swollen blood vessels or heart rate
- low or uneven blood pressure
- new or worse leg pain
- new or worse appetite problems
- new psychiatric or mental symptoms
- slowing of growth in children
- weight changes or blurred vision

Common side effects

- Headache, stomach ache, trouble sleeping, nausea, decreased appetite, constipation, dizziness, 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 medical problems including asthma, stroke, 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

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

Warnings

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

Important warnings about MIRAPEX

- 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:

- have heart problems, heart defects, or high blood pressure
- have medical problems including asthma, stroke, 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 medicines, or use of allergy medicines that contain decongestants

Stop use and call your doctor right away if you:

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

You may report side effects to the FDA at 1-800-FDA-1088.

When using this medicine you may get:

- headache
- stomach ache
- trouble sleeping
- nausea
- decreased appetite
- constipation
- dizziness
- 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

- 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?

- 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	MIRAPEX is a central nervous system stimulant that helps increase alertness and decrease impulsiveness and hyperactivity.
How to take	<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.
Warnings	<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 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 medical problems including asthma, stroke, 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 nausea decreased appetite constipation dizziness 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 uneven blood pressure • have new or worse leg pain • have new or worse appetite problems • have new psychiatric or mental symptoms • have slowing of growth in children • have weight changes or blurred vision
Questions?	<p>You may report side effects to the FDA at 1-800-FDA-1088.</p> <p>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.</p>

Fda Medication Guide List

Katrin Zwirgmaier



Fda Medication Guide List:

Embracing the Beat of Term: An Emotional Symphony within **Fda Medication Guide List**

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