

Final Container Label for Donepezil Hydrochloride Tablets, 23 mg - 30's Count
Label Size: 95 mm x 30 mm

NDC 55111-302-30

DR. REDDY'S

30 Tablets

Donepezil Hydrochloride Tablets, 23 mg

PHARMACIST: Dispense with Patient Package Insert

Rx Only

Each film-coated tablet contains 23 mg donepezil hydrochloride USP


Usual Dosage: See accompanying prescribing information.

Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature].

Dispense in tight containers (USP).

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Mkt. By: Dr. Reddy's Laboratories Limited
Bachupally - 500 060 INDIA



LOT

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(b) (4)

(b) (4)

Final Container Label for Donepezil Hydrochloride Tablets, 23 mg - 90's Count
Label Size: 117 mm x 37 mm

NDC 55111-302-90

90 Tablets

Donepezil Hydrochloride Tablets, 23 mg

**PHARMACIST:
Dispense with Patient
Package Insert**

Rx Only

Each film-coated tablet contains: 23 mg donepezil hydrochloride USP.


Usual Dosage: See accompanying prescribing information.

Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature].

Dispense in tight containers (USP).

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Mfg. By: Dr. Reddy's Laboratories Limited
Bachubally - 500 050 INDIA



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Final Container Label for Donepezil Hydrochloride Tablets, 23 mg - 500's Count
Label Size: 154 mm x 60 mm

NDC 55111-302-05

500 Tablets

Donepezil Hydrochloride Tablets, 23 mg

Rx Only

DR. REDDY'S

**PHARMACIST:
Dispense with Patient
Package Insert**


**Each film-coated tablet contains:
23 mg donepezil hydrochloride USP.**

Usual Dosage: See accompanying prescribing information.

Store at 20°-25°C (68°-77°F)
[see USP Controlled Room Temperature].

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Mfd. By: Dr. Reddy's Laboratories Limited
Bachupally - 500 090 INDIA



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LOT

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Final Container Label for Donepezil Hydrochloride Tablets, 23 mg - 1000's Count
Label Size: 170 mm x 90 mm

NDC 55111-302-10

DR. REDDY'S

1000 Tablets

Donepezil Hydrochloride Tablets, 23 mg

Rx Only

**PHARMACIST:
Dispense with Patient
Package Insert**


Each film-coated tablet contains: 23 mg donepezil hydrochloride USP.

Usual Dosage: See accompanying prescribing information.

Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature].

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Mfd. By: **Dr. Reddy's Laboratories Limited**
Bachupally - 500 090 INDIA



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DESCRIPTION OF THE PRODUCT
 The active ingredient is **Desogrel Hydrochloride**, a selective 5-HT_{2A} receptor antagonist. It is used for the treatment of depression and anxiety disorders. The product is available as tablets and capsules.

INDICATIONS
 - Major Depressive Disorder (MDD)
 - Generalized Anxiety Disorder (GAD)

CONTRAINDICATIONS
 - Hypersensitivity to desogrel or any of the excipients.
 - Concurrent use with other 5-HT_{2A} receptor antagonists.

WARNINGS AND PRECAUTIONS
 - Patients should be monitored for changes in mood and suicidal thoughts.
 - Desogrel may interact with other medications, particularly those affecting the cytochrome P450 system.

ADVERSE REACTIONS
 - Common side effects include dizziness, headache, and fatigue.
 - Serious side effects include changes in liver function tests and allergic reactions.

PHARMACOLOGICAL PROPERTIES
 - Desogrel is a selective 5-HT_{2A} receptor antagonist. It acts by blocking the binding of serotonin to the 5-HT_{2A} receptor, thereby modulating the serotonergic system.

PHARMACOKINETICS
 Desogrel is rapidly absorbed after oral administration. The plasma concentration increases and reaches a steady state within 24 hours. The elimination half-life is approximately 12 hours.

CLINICAL TRIALS
 In clinical trials, desogrel was shown to be effective in the treatment of MDD and GAD. The response rate was significantly higher compared to placebo.

TOXICOLOGY
 Desogrel was found to be safe and effective in acute and chronic toxicity studies. No significant changes were observed in organ function or body weight.

PHARMACEUTICAL PARTICULARS
 - **Trade Name:** Desogrel Hydrochloride
 - **Manufacturer:** [Company Name]
 - **Excipients:** Lactose, Cellulose, Povidone, Magnesium Stearate.

HOW TO TAKE THE TABLETS
 Desogrel tablets should be taken orally, with or without food, once daily. The recommended dose is 100 mg per day.

HOW TO TAKE THE CAPSULES
 Desogrel capsules should be taken orally, with or without food, once daily. The recommended dose is 100 mg per day.

DOSE ADJUSTMENT
 - **Renal Impairment:** No dose adjustment is necessary.
 - **Hepatic Impairment:** Dose adjustment may be required in patients with moderate to severe liver impairment.

DRUG INTERACTIONS
 - Desogrel may interact with other 5-HT_{2A} receptor antagonists.
 - Desogrel may interact with drugs that are metabolized by the cytochrome P450 system.

HOW TO STORE THE TABLETS
 Desogrel tablets should be stored in their original packaging, protected from light and moisture. The storage temperature should be between 15°C and 30°C.

HOW TO STORE THE CAPSULES
 Desogrel capsules should be stored in their original packaging, protected from light and moisture. The storage temperature should be between 15°C and 30°C.

EXPIRY DATE
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LOT NUMBER
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Component	Quantity	Strength
Desogrel Hydrochloride	100 mg	100 mg
Lactose	100 mg	-
Cellulose	100 mg	-
Povidone	100 mg	-
Magnesium Stearate	100 mg	-

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55111-302-01

PATIENT PACKAGE INSERT
Donepezil Hydrochloride Tablets

Read the Patient Information that comes with donepezil hydrochloride tablets before the patient starts taking it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with the doctor about Alzheimer's disease or treatment for it. If you have questions, ask the doctor or pharmacist.

What is donepezil hydrochloride?

Donepezil hydrochloride comes as donepezil hydrochloride film coated tablets in dosage strengths of 5 mg, 10 mg, and 23 mg.

Donepezil hydrochloride tablet is prescription medicine to treat mild, moderate and severe Alzheimer's disease. Donepezil hydrochloride tablets can help with mental function and with doing daily tasks. Donepezil hydrochloride tablets does not work the same in all people. Some people may:

- Seem much better
- Get better in small ways or stay the same
- Get worse over time but slower than expected
- Not change and then get worse as expected

Donepezil hydrochloride tablets does not cure Alzheimer's disease. All patients with Alzheimer's disease get worse over time, even if they take donepezil hydrochloride tablets.

Donepezil hydrochloride tablets have not been approved as a treatment for any medical condition in children.

Who should not take donepezil hydrochloride tablets?

The patient should not take donepezil hydrochloride tablets if allergic to any of the ingredients in donepezil hydrochloride tablets or to medicines that contain piperidine. Ask the patient's doctor if you are not sure. See the end of this leaflet for a list of ingredients in donepezil hydrochloride tablets.

What should I tell the doctor before the patient takes donepezil hydrochloride tablets?

Tell the doctor about all the patient's present or past health problems.

Include:

- Any heart problems including problems with irregular, slow, or fast heartbeats
- Asthma or lung problems
- A seizure
- Stomach ulcers
- Difficulty passing urine

- Liver or kidney problems
- Trouble swallowing tablets
- Present pregnancy or plans to become pregnant. It is not known if donepezil hydrochloride tablets can harm an unborn baby.
- Present breast feeding. It is not known if donepezil hydrochloride passes into breast milk. Donepezil hydrochloride tablets is not for women who are breast feeding.

Tell the doctor about all the medicines the patient takes, including prescription and non prescription medicines, vitamins, and herbal products. Donepezil hydrochloride tablets and other medicines may affect each other.

Be particularly sure to tell the doctor if the patient takes aspirin or medicines called nonsteroidal anti-inflammatory drugs (NSAIDs). There are many NSAID medicines, both prescription and non prescription. Ask the doctor or pharmacist if you are not sure if any of the patient's medicines are NSAIDs. Taking NSAIDs and donepezil hydrochloride tablets together may make the patient more likely to get stomach ulcers.

Donepezil hydrochloride tablets taken with certain medicines used for anesthesia may cause side effects. Tell the responsible doctor or dentist that the patient takes donepezil hydrochloride tablets before the patient has:

- surgery
- medical procedures
- dental surgery or procedures

Know the medicines that the patient takes. Keep a list of all the patient's medicines. Show it to the doctor or pharmacist before the patient starts a new medicine.

How should the patient take donepezil hydrochloride tablets?

Give donepezil hydrochloride tablets exactly as prescribed by the doctor. Do not stop donepezil hydrochloride tablets or change the dose yourself. Talk with the doctor first.

Give donepezil hydrochloride tablets one time each day. Donepezil hydrochloride tablets can be taken with or without food.

Donepezil hydrochloride 23 mg tablets should be swallowed whole without the tablets being split, crushed or chewed.

If you miss giving the patient a dose of donepezil hydrochloride tablets, just wait. Give only the next dose at the usual time. Do not give 2 doses at the same time.

(Continued on other side)



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(Continued on other side)

(Continued from previous side)

- If donepezil hydrochloride tablets is missed for 7 days or more, talk with the doctor before starting again
- If the patient takes too much donepezil hydrochloride tablets at one time, call the doctor or poison control center, or go to the emergency room right away

What are the possible side effects of donepezil hydrochloride tablets?

Donepezil hydrochloride tablets may cause the following serious side effects:

- slow heartbeat and fainting. This happens more often in people with heart problems. Call the doctor right away if the patient faints while taking donepezil hydrochloride tablets
 - more stomach acid. This raises the chance of ulcers and bleeding, especially when taking donepezil hydrochloride tablets 23 mg. The risk is higher for patients who had ulcers, or take aspirin or other NSAIDs
 - worsening of lung problems in people with asthma or other lung disease
 - seizures
 - difficulty passing urine
- Call the doctor right away if the patient has:
- fainting
 - heartburn or stomach pain that is new or won't go away
 - nausea or vomiting, blood in the vomit, dark vomit that looks like coffee grounds
 - bowel movements or stools that look like black tar
 - new or worse asthma or breathing problems
 - seizures
 - difficulty passing urine

The most common side effects of donepezil hydrochloride tablets are:

- nausea
- diarrhea
- not sleeping well
- vomiting
- muscle cramps
- feeling tired
- not wanting to eat

These side effects may get better after the patient takes donepezil hydrochloride tablets for a while. This is not a complete list of side effects with donepezil hydrochloride tablets. For more information, ask the doctor or pharmacist.

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

How should donepezil hydrochloride tablets be stored?
Storage: Store at 20°-25°C (68°-77°F); [see USP Controlled Room Temperature]

Keep donepezil hydrochloride tablets and all medicines out of the reach of children.

General information about donepezil hydrochloride tablets
Medicines are sometimes prescribed for conditions that are not mentioned in this Patient Information Leaflet. Do not use donepezil hydrochloride tablets for a condition for which it was not prescribed. Do not give donepezil hydrochloride tablets to people other than the patient, even if they have the same symptoms as the patient, as it may harm them.

This leaflet summarizes the most important information about donepezil hydrochloride tablets. If you would like more information, talk with the patient's doctor. You can ask your pharmacist or doctor for information about donepezil hydrochloride tablets that is written for health professionals. For more information, call 1 888 375 3784 (toll free).

What are the ingredients in donepezil hydrochloride tablets?

Active ingredient: donepezil hydrochloride USP
Inactive ingredients: hydroxypropyl cellulose, hypromellose, lactose monohydrate, magnesium stearate and methacrylic acid copolymer. The film coating includes iron oxide red, iron oxide yellow and Opadry OY 58900. White contains hypromellose, polyethylene glycol and titanium dioxide. To reorder additional Patient Package Inserts contact Dr. Reddy's Customer Service at 1 888 733 3962.

Rx Only

Manufactured by
Dr. Reddy's Laboratories Limited
Bachupally 500 090 INDIA

Issued May 2013

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- feeling tired
- not wanting to eat

These side effects may get better after the patient takes donepezil hydrochloride tablets for a while. This is not a complete list of side effects with donepezil hydrochloride tablets. For more information, ask the doctor or pharmacist.

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

How should donepezil hydrochloride tablets be stored?
Storage: Store at 20°-25°C (68°-77°F); [see USP Controlled Room Temperature]

Keep donepezil hydrochloride tablets and all medicines out of the reach of children.

General information about donepezil hydrochloride tablets
Medicines are sometimes prescribed for conditions that are not mentioned in this Patient Information Leaflet. Do not use donepezil hydrochloride tablets for a condition for which it was not prescribed. Do not give donepezil hydrochloride tablets to people other than the patient, even if they have the same symptoms as the patient, as it may harm them.

This leaflet summarizes the most important information about donepezil hydrochloride tablets. If you would like more information, talk with the patient's doctor. You can ask your pharmacist or doctor for information about donepezil hydrochloride tablets that is written for health professionals. For more information, call 1 888 375 3784 (toll free).

What are the ingredients in donepezil hydrochloride tablets?

Active ingredient: donepezil hydrochloride USP
Inactive ingredients: hydroxypropyl cellulose, hypromellose, lactose monohydrate, magnesium stearate and methacrylic acid copolymer. The film coating includes iron oxide red, iron oxide yellow and Opadry OY 58900. White contains hypromellose, polyethylene glycol and titanium dioxide. To reorder additional Patient Package Inserts contact Dr. Reddy's Customer Service at 1 888 733 3962.

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(Continued from previous side)

- If donepezil hydrochloride tablets is missed for 7 days or more, talk with the doctor before starting again
- If the patient takes too much donepezil hydrochloride tablets at one time, call the doctor or poison control center, or go to the emergency room right away

What are the possible side effects of donepezil hydrochloride tablets?

Donepezil hydrochloride tablets may cause the following serious side effects:

- slow heartbeat and fainting. This happens more often in people with heart problems. Call the doctor right away if the patient faints while taking donepezil hydrochloride tablets
 - more stomach acid. This raises the chance of ulcers and bleeding, especially when taking donepezil hydrochloride tablets 23 mg. The risk is higher for patients who had ulcers, or take aspirin or other NSAIDs
 - worsening of lung problems in people with asthma or other lung disease
 - seizures
 - difficulty passing urine
- Call the doctor right away if the patient has:
- fainting
 - heartburn or stomach pain that is new or won't go away
 - nausea or vomiting, blood in the vomit, dark vomit that looks like coffee grounds
 - bowel movements or stools that look like black tar
 - new or worse asthma or breathing problems
 - seizures
 - difficulty passing urine

The most common side effects of donepezil hydrochloride tablets are:

- nausea
- diarrhea
- not sleeping well
- vomiting
- muscle cramps
- feeling tired
- not wanting to eat

These side effects may get better after the patient takes donepezil hydrochloride tablets for a while. This is not a complete list of side effects with donepezil hydrochloride tablets. For more information, ask the doctor or pharmacist.

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