

adol[®]

PM

Caplets, Granules for Hot Therapy (in Sachets)

What is the composition of Adol PM?

Caplets

Each caplet contains:

Active ingredients:	Paracetamol	325mg
	Diphenhydramine HCl	25mg
Excipients:	Cellulose, stearic acid, magnesium stearate, cross linked starch, starch, povidone, aerosil, glycerol, gelatin, hypromellose, polyethylene glycol, titanium dioxide, FD&C blue 1, FD&C blue 2, and talc.	

Granules for Hot Therapy (in Sachets)

Each sachet contains:

Active ingredients:	Paracetamol	650mg
	Diphenhydramine HCl	50mg
Excipients:	Sucrose, aspartame, citric acid, sodium citrate, sodium chloride, starch, D&C yellow 10, FD&C red no. 40, lemon dry flavour, and honey dry flavour.	

What should you know about Adol PM?

Paracetamol is an effective pain reliever and fever reducer. It relieves pain by elevating the pain threshold centrally and, to a lesser extent, by blocking pain-impulse generation through a peripheral action. Paracetamol reduces fever through its effect on the hypothalamic heat-regulating centre, resulting in peripheral vasodilation, increased blood flow through the skin, sweating, and heat loss. The central and peripheral actions of paracetamol are mainly due to the inhibition of prostaglandins biosynthesis.

Diphenhydramine is an ethanolamine antihistamine that acts by competitively antagonising histamine at the H₁ receptors. It is also known to have a non-narcotic cough suppressant property where it acts directly on the cough centre in the medulla of the brain and thereby suppresses the cough reflex. In addition, diphenhydramine has also antimuscarinic (anticholinergic) and central sedative properties.

Adol PM caplets are easy to swallow because they are specially coated and shaped, and for those who do not like or are unable to swallow caplets, sachets can be used. The "hot therapy" provided by sachets also helps assuring rapid absorption and rapid and effective symptomatic relief.

What is Adol PM used for?

Adol PM is used for the temporary relief of night-time pain associated with difficulty in sleep. This pain may be due to cough, cold, headache, minor aches and fever.

How should you take Adol PM?

Adults and children over 12 years: Take 2 caplets or one sachet about 20 minutes before bedtime.

Adol PM is not recommended for children aged 12 years except on medical advice.

For "hot therapy" sachets: Tear or cut open the sachet as indicated. Dissolve the contents of one sachet in 6 ounces (180mL) cup of hot water. Sip while hot. If desired, sweeten to taste.

When should you avoid using Adol PM?

- If you are sensitive to paracetamol, diphenhydramine, or to any of the excipients.
- If you are suffering from severe liver disease, since sedation is inappropriate.

What should you be aware of?

Do not take more than 2 caplets at one time.

Other products containing paracetamol may be taken for daytime pain relief but the total maximum dose should not exceed 4 grams in 24 hours. Further doses of paracetamol should not be taken within 4 hours of a dose of **Adol PM**.

Do not take this medicine more than 7 consecutive nights without consulting your doctor.

Do not give to children below 12 years old without consulting your doctor or pharmacist.

Adol PM is thought to be safe in porphyria.

Be aware if you are alcoholic or if you suffer from epilepsy, glaucoma, pyloroduodenal obstruction, mild to moderate liver disease, kidney dysfunction, prostatic enlargement or urinary retention.

Since **Adol PM** contains diphenhydramine, it may cause drowsiness; therefore, be aware when you intend to drive motor vehicles or to operate hazardous machinery.

It is recommended to stop using **Adol PM** at least 72 hours before performing skin tests for allergy due to possible false-negative results.

Pregnancy: Although there are no known risks associated with the use of the active ingredients during pregnancy, it is

better not to be used unless your doctor tells you to.

Lactation: As it is assumed that diphenhydramine may inhibit breastfeeding, as well as it may be secreted in breast-milk, this medicine is better not to be used unless your doctor tells you to. Individuals suffering from phenylketonuria or those who should avoid protein foods should use **Adol PM** sachets with caution due to the presence of phenylalanine in the excipient aspartame.

Is there any undesired effects?

Side effects are usually mild and infrequent. However, some people may rarely feel more alert especially with high doses or in elderly.

Other side effects which have been reported less frequently include headache, difficulty of muscle coordination, difficulty in passing urine, dry mouth, blurred vision, and gastrointestinal disturbances.

Hypersensitivity reactions including swelling of the face, lips, mouth, tongue or throat, thickened phlegm, chest tightness, anaphylaxis, rashes, and sensitivity of skin to sunlight have also been reported less frequently.

Very rarely, dizziness, confusion, depression, sleep disturbances, tremor, convulsions, palpitations, changes to heart rhythm, low blood pressure, blood disorders, liver dysfunction and extrapyramidal effects have been reported.

What to do in case of overdose?

Massive overdose of paracetamol (exceeding 10g for adults) should be avoided to avoid the possibility of hepatotoxicity.

Refer immediately to the doctor if you experience diarrhoea, loss of appetite, nausea or vomiting, stomach cramps or pain, increased sweating, sedation, alertness, psychosis, convulsions, anticholinergic effects and changes to heart rhythm. Pain, tenderness, and/or swelling in upper abdominal area may occur 2 - 4 days after ingesting the overdose.

Is there any drug interactions?

Talk to your doctor or pharmacist if you are taking any other medicines, particularly:

- Alcohol, anxiolytics and hypnotics as they may intensify the sedative effect of **Adol PM**.
- Anticholinergics (antimuscarinics), as they may enhance the anticholinergic side effects.
- Antidepressants (monoamine oxidase inhibitors and tricyclic antidepressants), as they may enhance both the sedative and the anticholinergic (antimuscarinic) effects of **Adol PM**.
- Betahistine (histamine analogue), as it is expected to antagonise the effects of **Adol PM**.
- Cholestyramine (used to treat high blood cholesterol), as it may reduce the absorption of paracetamol.
- Metoclopramide (used to treat nausea and vomiting), as it increases the rate of absorption of paracetamol.
- If you are taking coumarins (anticoagulants), you may take occasional doses of paracetamol. If you need to take pain killers on a daily basis over a long period, talk to your doctor.
- Intravenous busulfan (used to treat leukaemia) should be used with caution if administered within 72 hours of taking paracetamol, as paracetamol may possibly inhibit its metabolism.

What are the available packs of Adol PM?

Adol PM caplets: Pack of 24 caplets.

Adol PM granules for hot therapy: Pack of 6 sachets.

* Store at a temperature not exceeding 25°C, in a dry place.

THIS IS A MEDICAMENT

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children.

Council of Arab Health Ministers,
Union of Arab Pharmacists.

Any information? Call Toll Free No. (971) 800-4994



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