

Package leaflet: Information for the user

PEDOL Tablets

Diclofenac Sodium and Paracetamol Tablets

Please read this leaflet carefully before using this medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

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1. What Pedol tablet is and what it is used for

Pedol tablet is a combination of two medicines: Diclofenac and Paracetamol. This medication helps in relieving pain and inflammation. It works by lowering the levels of chemical substances in the body that cause pain and inflammation. Paracetamol / Acetaminophen has an early onset of action which means that it takes very less time to start its action and it helps in relieving the symptoms till diclofenac starts working.

2. Before you take Pedol tablet

- Do not take Pedol tablets if you are allergic to diclofenac sodium, aspirin, ibuprofen and Paracetamol or any other NSAID or to any of the ingredients listed in section 6 of this leaflet.
- Take special care with Pedol tablet if you have kidney or liver problems, you ever had asthma, seasonal allergic rhinitis, swelling of the nasal mucosa (nasal polyps), chronic pulmonary diseases or infections of the respiratory tract. you have diabetes, you have Systemic Lupus Erythematosus SLE (inflammatory, auto-immune disorder which causes symptoms such as joint pain, joint inflammation, skin rashes, fever) or any similar condition.
- Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because paracetamol can affect the way some other medicines work. Also, some other medicines can affect the way paracetamol works. Any other NSAID or COX-2 (cyclo-oxygenase-2) inhibitor, for example aspirin or ibuprofen, Medicines to treat diabetes, Diuretics, Ciclosporin and tacrolimus, Mifepristone, Quinolone antibiotics.
- Tacking Pedol tablet with with food and drink: You should not drink whilst taking these tablets. Taking alcohol with paracetamol can increase your chances of getting side effects. Take this medicine with or after food.

➤ ***Pregnancy and breast feeding***

Although not common, abnormalities have been reported in babies whose mothers have taken NSAIDs during pregnancy. You should not take Pedol tablets during the last 3 months of pregnancy as it may affect the baby's circulation.

You should advise your doctor or pharmacist if you think you might be pregnant or are up to 6 months pregnant.

Taking Pedol tablets may make it more difficult to become pregnant. You should talk to your doctor if you are planning to become pregnant, or if you have problems getting pregnant.

You should avoid taking Pedol tablet whilst breast feeding.

➤ ***Driving and using machines:***

Patients experiencing visual disturbances, dizziness, vertigo, somnolence or other central nervous system disturbances while taking diclofenac, should refrain from driving or using machines.

Paracetamol has no influence on the ability to drive and use machines.

3. How to take Pedol tablet

Adult: 2 to 3 tablets daily divided doses. If gastrointestinal complaints occur, Administer Pedol tablet with meal. Or as directed by the physician.

Children: As directed by physician.

- If you take more Pedol tablet than you should concerned about an overdose you should consult your doctor or pharmacist, if possible you should take the packaging and this leaflet with you.
- If you forget to take Pedol tablet then it is safe to take it at any time before the next dose is due.

4. Possible side effects

Possible side effect of Pedol tablet is Redness of the rectal mucous membranes, allergic reactions, Exanthema, urticarial, liver damage, increase in creatinine, abdominal pain, constipation, diarrhea, dyspepsia, flatulence, gross bleeding / perforation, heartburn, nausea, GI ulcers and vomiting, abnormal renal function, anemia, dizziness, edema, elevated liver enzymes, headaches, increased bleeding time, pruritus, rashes and tinnitus, Fever, infection sepsis, congestive heart failure, hypertension, tachycardia, syncope dry mouth, esophagitis, gastric/peptic ulcer, gastritis, gastrointestinal bleeding, glossitis, hematemesis, hepatitis, jaundice, ecchymosis, eosinophilia, leukopenia, melena, purpura, rectal bleeding, stomatitis, thrombocytopenia, anxiety, asthenia, confusion, depression, dream abnormalities, drowsiness, insomnia, malaise, nervousness, paresthesia, somnolence, tremors, vertigo, asthma, dyspnea, alopecia, photosensitivity, increased sweating, blurred vision, cystitis, dysuria, hematuria, interstitial nephritis, oliguria/polyuria, proteinuria, renal failure.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

5. How to store Pedol tablet

- Keep out of the reach and sight of children.
- Do not store above 30°C, Store in the original container carton
- Do not use Pedol tablet after the expiry date which is stated on the label/Carton.
- Do not use Pedol tablet if you notice any breakage in blister.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

6. Further information

➤ What Pedol tablet contains:

Each uncoated tablet contains: Diclofenac Sodium BP 50mg & Paracetamol BP 500 mg.

In addition to the above ingredients: Maize Starch, Dibasic Calcium Phosphate, Sodium Benzoate, Colloidal Silicon Dioxide, Povidone, Magnesium Stearate, Purified Talc & Sodium Starch Glycolate

➤ What Pedol tablet look like and contents of the pack:

Pedol tablet is a white coloured, oblong shaped, biconvex uncoated tablet bisected on one side supplied in carton of 10 x 1 x 10 Tablets

➤ Supplier and Manufacturer

MERCURY LABORATORIES LTD.

Unit No. 2, Halol – Baroda Road,

Village: Jarod, Tal: Waghodia,

Dist: Vadodara – 391510, Gujarat, India.

➤ Local Representative's Name & Address

PENAK PHARMACY LTD.,

Kumasi-Ghana.

➤ Date of publication or revision

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