

# Panadrex Pure

## Tablets

Paracetamol 500 mg

### PACKAGE LEAFLET: INFORMATION FOR THE USER

**Read this entire leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### In this leaflet:

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### 1. What are Panadrex Pure tablets and what are they used for?

Panadrex Pure contains Paracetamol which belongs to a group of medicines called analgesics and antipyretics, it produces its effect by its action on central and peripheral prostaglandin synthesis inhibition. It is recommended for

- Mild to moderate pain associated with toothache, headache, backache, period pain, neuralgia, rheumatic ache, muscle pain, and osteoarthritis pain.
- Fever associated with cold and flu.

### 2. Before you take Panadrex Pure tablets

#### Do not take Panadrex Pure tablets in the following cases:

- If you have hypersensitivity to any component of Panadrex Pure tablets.
- If you take other paracetamol containing medication.

#### Check with your doctor or pharmacist before taking Panadrex Pure tablets if you are suffering from the following cases:

- If you have severe kidney problems or severe liver problems.
- If you have alcoholic liver disease and G6PD deficiency.

#### Taking other medicines:

Please tell your doctor or pharmacist if you are taking, or have recently taken any other medicines. This includes medicines you buy without a prescription and herbal medicines. Panadrex Pure tablets can affect the way that some medicines work and some medicines can have an effect on Panadrex Pure tablets.

Particularly the following:

- Coumarin derivatives anticoagulant (Warfarin). Chronic ingestion of large dose of paracetamol has been reported to slightly potentiate the effects of coumarin derivatives but reports are conflicting. This effect appears to be little, if any.
- Metochlopramide and domperidone (which are used for nausea and vomiting)
- Cholestyramine (used for high cholesterol)

#### Pregnancy and breast feeding:

Although there is epidemiological evidence of the safety of paracetamol in pregnancy and breast-feeding, medical advice should be sought before using this products.

### 3. How to take Panadrex Pure tablets?

Always take Panadrex Pure tablets as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual dose is as follows:

- The usual dose for adults, elderly people & children above 12 years is 2 Panadrex Pure tablets three to four times daily (maximum daily dose is 4 gm means 8 tablets)
- Children 6-12 years is ½-1 tablet three to four times daily (maximum daily dose for children 6-12 years is 2 gm means 4 tablets)
- Do not take more often than every 4 hours.
- Do not exceed the recommended dose.
- Panadrex Pure tablets are not for use in children under 6 years old, unless recommended by a doctor.

#### If you take more Panadrex Pure tablets than you should:

- contact your doctor or pharmacist for advice.
- The symptoms of the overdose include:
  - In massive over dosage exceeding 10 g of paracetamol may cause liver damage. Early symptoms may include pallor, nausea, vomiting. Clinical and laboratory evidence of liver damage may not be apparent until 48 to 72 hours past ingestion.
  - Overdose should be promptly treated by gastric lavage followed by intravenous N-acetylcysteine or methionine without waiting for the results of plasma paracetamol levels.
- Additional antidote therapy is normally considered in light of further plasma paracetamol levels and the time elapsed since ingestion.
- In all cases of suspected overdose, prompt medical attention is critical for adults as well as for children, even if you do not notice any signs or symptoms.

#### If you forgot to take Panadrex Pure tablets:

Take it as soon as you remember. However; if it is almost time for the next dose, wait until then, and take the next dose as normal. Do not take a double dose to make up for a forgotten dose.

### 4. Possible side effects

- Like all medicines, Panadrex Pure tablets can cause side effects although not everybody gets them. A small number of people have had side effects.
- Stop taking the medicine and tell your doctor immediately if you experience:
- Allergic reactions which may be severe such as skin rash and itching sometimes with swelling of the mouth or face or shortness of breath
  - Skin rash or peeling, or mouth ulcers
  - Breathing problems. These are more likely if you have experienced them before when taking other painkillers such as ibuprofen and aspirin
  - Unexplained bruising or bleeding
  - Nausea, sudden weight loss, loss of appetite and yellowing of the eyes and skin.

#### Other possible side effects

- Blood and lymphatic system disorders;
  1. Thrombocytopenia
  2. Agranulocytosis
- Immune system disorder
  1. Anaphylaxis
  2. Cutaneous hypersensitivity reactions including skin rashes, angiodema and Stevens Johnson syndrome/ toxic epidermal necrolysis
- Respiratory, thoracic and mediastinal disorders  
Bronchospasm (There have been cases of bronchospasm with Paracetamol, but there are more likely in asthmatics sensitive to Aspirin or other NSAIDs)
- Hepatobiliary disorders:  
Hepatic dysfunction

If you do get any side effects, even those not mentioned in this leaflet, tell your

doctor or pharmacist.

### 5. How to store Panadrex Pure tablets?

- Keep in safe place, out of the reach and sight of children.
- Store below 30°C.
- Do not use Panadrex Pure tablets after the expiry date which is stated on the pack. The expiry date refers to the last day of the month.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. These measures will help to protect the environment.

### 6. Further Information

#### What Panadrex Pure tablets contains?

The active substance in each tablet is: Paracetamol 500 mg.

#### The excipients are:

Microcrystalline cellulose, Maize Starch, Magnesium Stearate.

#### What Panadrex Pure tablet looks like and what are the contents of the pack?

Panadrex Pure tablet is white to off white, oblong, biconvex tablet with middle break line on one side and 'KS 112' engraved on the other side. Panadrex Pure tablets are available in pack of 12, 24, 48, 96 tablets. It is also available as Panadrex baby and infant syrup (120mg / 5ml) in glass bottles size of 100 ml with child resistant cap and as Panadrex children's suspension (250mg / 5ml) in glass bottles size of 100 ml with child resistant cap. Not all pack sizes may be marketed. This leaflet was last revised in January 2020

### 7. Adverse Drug Reaction (ADR) Reporting

**For reporting the adverse drug reactions in other countries please refer to the health authorities.**

### THIS IS A MEDICINE

- 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 instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in the 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 reach of children.

Council of Arab Health Ministers - Union of Arab Pharmacists

Marketing Authorization Holder and Manufacturer



Kuwait Saudi Pharmaceutical Industries Co. K.S.C. (Closed)  
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