

### 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:

1. What is PANADREX syrup and what is it used for
2. Before you take PANADREX syrup
3. How to take PANADREX syrup
4. Possible side effects
5. How to store PANADREX syrup
6. Further Information
7. Adverse Drug Reaction (ADR) Reporting

### 1. What is PANADREX syrup and what is it used for?

PANADREX syrup is analgesic and antipyretic.

- It relieves mild to moderate pain and fever associated with teething, toothache, sore throat and childhood infections.

- It also relieves fever and pain after vaccination.

PANADREX syrup has raspberry flavour.

PANADREX syrup is alcohol free and sugar free.

### 2. Before you take PANADREX syrup

Do not give PANADREX syrup for your baby in the following cases:

- If he has hypersensitivity to paracetamol or any component of PANADREX syrup.

Check with your child's doctor or pharmacist before giving PANADREX syrup in the following cases:

- Your child has severe kidney problems or severe liver problems. (Because paracetamol is metabolized in the liver and excreted by the kidney in the urine)

Check with your child's doctor if:

Your child is in a glutathione depleted state such as sepsis or your child has a severe infection as the use of paracetamol may increase the risk of metabolic acidosis.

Signs of metabolic acidosis include

- Deep, Rapid, difficult breathing
- Feeling Sick (Nausea), being sick (Vomiting)
- Loss of appetite

► Contact your child's doctor immediately if your child gets a combination of these symptoms.

► Please see your child's doctor if symptoms do not improve, get worsen or new symptoms occur because these could be signs of a serious condition.

► This product contains paracetamol. Do not use with other paracetamol containing products.

Taking other medicines:

Please tell your doctor or pharmacist if your baby is taking, or have recently taken any other medicines. This includes medicines you buy without a prescription and herbal medicines.

PANADREX syrup can affect the way that some medicines work and some medicines can have an effect on PANADREX syrup.

- The liver toxic effects of paracetamol may be increased by the use of alcohol.
- The anticoagulant effect of warfarin and other coumarin may be inhibited by prolonged regular daily use of paracetamol with increased risk of bleeding. Occasional doses have no significant effect.

Information about some ingredients: The sorbitol content of this product means that this product is unsuitable for people with inherited fructose intolerance.

### 3. How to take PANADREX syrup?

Always take PANADREX syrup as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Unless prescribed by the physician the usual dose is as follows:

For oral administration only. Do not exceed the stated dose.

Children aged 3 months and above

A dose of 10-15mg/kg to be repeated (please see the table below)

- Do not give your child more than 60 mg/kg presented in divided doses throughout 24 hours.
- Do not give to your child more frequently than every 4 hours.
- Do not give to your child more than four doses in any 24 hours period.
- Do not give to your child for longer than 3 days without asking a doctor.

Children aged 2 to 3 months

A single dose of 10-15mg/kg for symptomatic relief of reaction due to vaccination.

Medical advice should be sought if fever persists after a second dose.

For other indication, give only under medical advice.

Children aged below 2 months

Not recommended for children under 2 months.

Weight (Kg)	Age	Dose Vol (ml)*
5-6	2-3 months	3
6-7	3-4 months	3.5
7-8	4-6 months	4
8-9	6-8 months	5
9-10	8-12 months	5.5
10-12	1-2 years	6
12-14	2-3 years	7.5
14-16	3-4 years	8.5
16-18	4-5 years	10

\* Dose may be chosen based on weight or age, use weight if you know or otherwise use age.

If your child takes more PANADREX syrup than he should:(Overdose)

Paracetamol overdose may cause liver failure. Immediate medical management is required in the event of overdose, even if symptoms of overdose are not present

- In massive over dosage exceeding 10 g of paracetamol may cause liver damage. Early symptoms may include pallor, nausea, vomiting (diaphoresis) and general malaise.
- Clinical and laboratory evidence of liver damage may not be apparent until 48 to 72 hours post 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. general supportive measures must be available.
- 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 give PANADREX syrup for your child:

Give 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 give a double dose to make up for a forgotten dose.

### 4. Possible side effects

Like all medicines, PANADREX syrup can cause side effects, although not everybody gets them.

Stop this product and consult your child's doctor immediately if:

- You notice allergic reactions such as skin rash or itching, sometimes with breathing problems or swelling of the lips, tongue, throat or face.
- Your child experience angioedema or Steven Johnson syndrome.
- You notice skin rash or peeling or mouth ulcers.
- Your child previously experienced breathing problems or bronchospasm with aspirin or non

steroidal anti-inflammatory and experienced a similar reaction with this product.

- Your child experienced unexplained bruising or bleeding.

- Your child experienced liver dysfunction related symptoms or signs.

These reactions are very rare.

If you notice any side-effects not included in this leaflet please tell your doctor or pharmacist.

### 5. How to store PANADREX syrup?

- Keep in safe place, out of the reach and sight of children.
- Store below 25°C, Protect from light.
- Do not use PANADREX syrup 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 syrup contains?

The active substance in each (5ml) is: Paracetamol 120 mg.

The excipients are:

Povidone K-25, Sorbitol solution 70%, Glycerol, Dried Sodium Phosphate, Citric Acid Monohydrate, Saccharin Sodium, Potassium Sorbate, propylene glycol, Raspberry Flavor, Colour F.D & C Red No.40, and Purified Water.

What PANADREX syrup looks like and what are the contents of the pack?

PANADREX syrup is a clear red colored solution with a raspberry flavor.

PANADREX syrup is available in glass bottles size of 60 & 100 ml, with child resistant cap.

It is also available as tablets Panadrex Pure of 500mg, pack of 12, 24, 48, and 96 tablets and as suspension (250mg/5ml) 60 & 100ml bottles with child resistant cap and as suspension (120mg/5ml) 60ml & 100ml bottles with child resistant cap.

Not all pack sizes may be marketed.

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

Saudi Arabia, Saudi Food & Drug Authority: National Pharmacovigilance Center

To contact Executive Administration for Pharmacovigilance & Crisis Management.

Tel: +966-11-203-8222 ext 2340-2334-2354-2317-2356-2353

Toll Free Phone: 800 249 0000

FAX: +966112057662 E-MAIL: npc.drug@sfga.gov.sa WEBSITE: www.sfga.gov.sa/npc

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)

الشركة الكويتية للصناعات الدوائية. (مغلقة)

ص.ب: ٥٥١٢ الصفاة - الرمزا البريد: ١٣٠٥١ دولة الكويت - صبحان -

المنطقة الصناعية - هاتف: ٢٤٧٤٥٠١/٢/٣/٤ - فاكس: ٢٤٧٤٥٣١١ - ٩٦٥

P.O.Box: 5512 Safat - Postal Code: 13056 State of Kuwait - Subhan -

Industrial Area - Tel: +965 24745012/3/4 - Fax: +965 24745361

www.kspico.com

