PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S0

PANADO® PAEDIATRIC SYRUP

Paracetamol 120 mg/5 ml Syrup

Contain sweetener:

Sodium cyclamate 7,50 mg

Sorbitol 280 mg

Sodium saccharin 1,55 mg

Contains sugar: Sucrose 807 mg

Tartrazine free

Read all of this leaflet carefully because it contains important information for you:

PANADO® PAEDIATRIC SYRUP is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use PANADO® PAEDIATRIC SYRUP carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share PANADO® PAEDIATRIC SYRUP with any other person
- Ask your health care provider or pharmacist if you need more information or advice
- You must see a doctor if your child's pain symptoms worsen or do not improve after 5 days

What is in this leaflet:

1. What PANADO® PAEDIATRIC SYRUP is and what it is used for
2. What you need to know before you take PANADO® PAEDIATRIC SYRUP
3. How to take PANADO® PAEDIATRIC SYRUP
4. Possible side effects
5. How to store PANADO® PAEDIATRIC SYRUP

6. Contents of the pack and other information

1. WHAT PANADO® PAEDIATRIC SYRUP IS AND WHAT IT IS USED FOR:

The active ingredient paracetamol acts as an analgesic (painkiller) and as an antipyretic (reduces fever).

PANADO® PAEDIATRIC SYRUP is therefore used for the relief of mild to moderate pain and fever.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE PANADO® PAEDIATRIC SYRUP

Do not use PANADO® PAEDIATRIC SYRUP if:

- the child is hypersensitive (allergic) to paracetamol or to any of the other ingredients of PANADO® PAEDIATRIC SYRUP (listed in section 6)
- the child has serious problems with the liver function

Warnings and precautions:

Take special care with PANADO® PAEDIATRIC SYRUP

PANADO® PAEDIATRIC SYRUP contains paracetamol which may be fatal in overdose. In the event of an overdose or suspected overdose, even if your child may not be showing or experiencing any symptoms, the nearest doctor, hospital or poison centre must be contacted immediately. Prompt specialized treatment is essential as soon as possible.

- If the child suffers from liver or kidney disease, a doctor must monitor his/her condition while he/she is taking this medicine.
- Be sure to give the correct dosage of this medicine. Severe liver damage may occur if the child is given doses higher than those recommended.
- Do not use continuously for more than 10 days without consulting the doctor.
- If no pain relief is achieved or if the fever persists with the recommended doses, please consult your doctor.

- Excessive and prolonged use of PANADO® PAEDIATRIC SYRUP may be dangerous.
- If your child suffers from hepatitis (disease of the liver) or recovering from any form of liver disease, do not give excessive quantities of PANADO® PAEDIATRIC SYRUP.
- Use with caution if your child has kidney disease, chronic malnutrition or dehydration or if your child has not eaten in a few days.
- Serious skin reactions such as acute generalized exanthematous pustulosis (AGEP), Stevens - Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN), have been reported in patients receiving paracetamol. If your child experiences any signs of serious skin reactions such as swelling, itching, red severe rash, stop using PANADO® PAEDIATRIC SYRUP immediately and contact your doctor.
- PANADO® PAEDIATRIC SYRUP contains sorbitol and may cause gastrointestinal discomfort and mild laxative effect
- Patients with the rare hereditary condition of sorbitol intolerance should not be given PANADO® PAEDIATRIC SYRUP.
- PANADO® PAEDIATRIC SYRUP contains sucrose. Patients with rare hereditary problems of glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not be given PANADO® PAEDIATRIC SYRUP**.**
- PANADO® PAEDIATRIC SYRUP contains sucrose which may have an effect on the glycaemic control of patients with diabetes mellitus.

Other medicines and PANADO® PAEDIATRIC SYRUP

Always tell your health care provider if your child is taking any other medicine. (This includes all complementary or traditional medicines).

- The risk of side effects with paracetamol may be increased in patients taking other medicines that may be harmful to the liver or medicines that can influence the functioning of the liver.

- The absorption of paracetamol may be increased by metoclopramide
- Excretion of paracetamol may be affected and plasma (blood) concentrations altered when taken together with probenecid.
- Cholestyramine reduces the absorption of paracetamol.
- Prolonged concurrent use of PANADO® PAEDIATRIC SYRUP with salicylates (e.g. aspirin) increases the risk of adverse kidney effects.
- If your child is taking Warfarin or other blood thinning medicines (anticoagulants) PANADO® PAEDIATRIC SYRUP may increase the anticoagulant effect and there is an increased risk of bleeding if your child takes regular or high doses of paracetamol while on an oral anticoagulants.
- Use of PANADO® PAEDIATRIC SYRUP and certain antibacterials used for the treatment of tuberculosis (a disease affecting the lungs) such as rifampicin or isoniazid can cause toxic damage to the liver.
- Taking PANADO® PAEDIATRIC SYRUP together with certain antiviral medicines such as zidovudine can cause severe toxic damage to the liver.
- The antiviral effect of interferon alfa may be increased if taken with PANADO® PAEDIATRIC SYRUP.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Safety and efficacy in pregnancy and breastfeeding have not been established.

Driving and using machines

PANADO PAEDIATRIC SYRUP has no or negligible influence on the ability to drive and use machines.

3. HOW TO TAKE PANADO® PAEDIATRIC SYRUP

Do not share medicines prescribed for your child with any other person.

Always take the medicine as recommended to you and **do not exceed the recommended dose**. If you are unsure or have any questions on how to take this product, please check with your pharmacist.

The recommended doses are as follows:

Infants:	
Under 3 months:	10 mg/kg (0,41 ml/kg)
3 months to 1 year:	2,5 to 5 ml (60 to 120 mg)
Children:	
1 to 5 years:	5 to 10 ml (120 to 240 mg)
6 to 12 years:	10 to 20 ml (240 to 480 mg)

Shake the bottle before use.

PANADO ® PAEDIATRIC SYRUP – 5 ml Sachet

Always administer using a medicine measure or a syringe.

For single use only. Discard remaining contents of sachet after administration of the correct dose.

While symptoms persist, to be repeated every 4 hours if needed to a maximum of 4 doses per 24 hours for not longer than 5 days.

Consult a doctor if your child's symptoms persist.

If more than the recommended dosage of PANADO® PAEDIATRIC SYRUP is given:

PANADO PAEDIATRIC SYRUP contains paracetamol which may be fatal in overdose. In the event of an overdose or suspected overdose, even if your child may not be showing or experiencing any symptoms, the nearest doctor, hospital or poison control center must be contacted immediately. Prompt specialized treatment is essential as soon as possible.

The initial symptoms of paracetamol overdose (within the first 24 hours) may include pallor (pale appearance), nausea, vomiting, anorexia (loss of appetite) and abdominal pain.

Even though these initial symptoms may appear mild, paracetamol overdosage is a serious condition, as liver damage may only become apparent 12 to 48 hours after the paracetamol overdose.

Abnormalities of glucose metabolism and metabolic acidosis may occur. Cardiac arrhythmias have been reported.

If a dose of PANADO® PAEDIATRIC SYRUP is missed:

Do not give a double dose to make up for forgotten individual doses.

4. POSSIBLE SIDE EFFECTS:

PANADO® PAEDIATRIC SYRUP can have side effects.

Not all side effects reported for PANADO® PAEDIATRIC SYRUP are included in this leaflet. Should your child's general health worsen or if your child experiences any untoward effects while being given PANADO® PAEDIATRIC SYRUP please consult your health care provider for advice.

If any of the following happens, stop giving PANADO® PAEDIATRIC SYRUP and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the eyelids, face, tongue or lips
- severe dizziness
- difficulty in breathing
- Serious skin reactions such as swelling, itching, red severe rash especially those covering your whole body (appearing as allergic wheals), stop giving PANADO® PAEDIATRIC SYRUP immediately and contact your doctor.

These are all very serious side effects. If your child has them, he/she may have had a serious allergic reaction to PANADO® PAEDIATRIC SYRUP. Your child may need urgent medical attention or hospitalisation.

Stop giving PANADO® PAEDIATRIC SYRUP and call your doctor at once if your child experiences any of the following:

- nausea, vomiting, upper stomach pain, itching, loss of appetite;
- dark urine, clay-colored stools; or
- jaundice (yellowing of the skin or eyes)

The following side-effects have been reported, tell your doctor if your child has any of the following:

- increase in number of nose bleeds or unusual bleeding
- If your child bruises more easily
- If your child has more infections
- If your child has sudden decrease in the amount of urine or cloudy urine.
- If your child has unusual tiredness or weakness
- if your child has an increase in blood pressure
- if your child has a pale complexion

Reporting of side effects:

If your child gets any side effects, talk to your doctor or pharmacist, or nurse. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"** found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of PANADO® PAEDIATRIC SYRUP

5. HOW TO STORE PANADO® PAEDIATRIC SYRUP

Store all medicines out of reach of children

Store in a well closed container protected from light. Store at or below 25 °C.

Exposure to air should be kept to a minimum

Do not store in a bathroom

Do not take after the expiry date stated on the label

Return all unused medicine to your pharmacist

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

6. Contents of the pack and other information

What PANADO® PAEDIATRIC SYRUP contains:

- The active substance is paracetamol 120 mg/5 ml
- The other ingredients are: Glycerol; polyvinylpyrrolidone K25; propylene glycol, sodium chloride, xanthan gum, vanillin, chocolate flavour, peppermint oil, colour sunset yellow FCF supra, colour spectracol quinoline yellow, colour blue; hydrochloric acid, sodium hydroxide, methylparaben, ethanol, purified water.

What PANADO® PAEDIATRIC SYRUP looks like and contents of the pack.

A green liquid with an odour of peppermint.

50 ml bottles (clear glass and clear PVC) packed in unit cartons.

100 ml bottles (clear glass and clear PVC) packed in unit cartons.

5 ml Sachets packed into unit cartons containing 12 sachets. Sachets are composed of aluminium foil PET/FOIL/Metallocene Laminate (12/20/40) or aluminium foil PET/FOIL/POLY (12/9/40).

Holder of Certificate of Registration:

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Erand Gardens

Midrand, 1685

This leaflet was last revised in:

20/05/2022

Registration Number:

B/2.7/1143

Namibia: NS0 90/2.8/00157

Botswana: S4 B9311225

adcock ingram

31484 09/2022