

SCHEDULING STATUS: **S0**

PANADO PAEDIATRIC SYRUP - STRAWBERRY, 120 mg/5 mL, Syrup

Preservative: Sodium benzoate (0,3 % *m/v*)

Contains sweeteners: Each 5 mL contains sodium cyclamate 7,50 mg and sorbitol 280 mg

Sugar free

Tartrazine free

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

PANADO PAEDIATRIC SYRUP - STRAWBERRY is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use

PANADO PAEDIATRIC SYRUP - STRAWBERRY carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share PANADO PAEDIATRIC SYRUP - STRAWBERRY 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 and fever symptoms worsen or do not improve after 5 days.

What is in this leaflet

1. What PANADO PAEDIATRIC SYRUP - STRAWBERRY is and what it is used for
2. What you need to know before you give PANADO PAEDIATRIC SYRUP - STRAWBERRY
3. How to give PANADO PAEDIATRIC SYRUP - STRAWBERRY
4. Possible side effects
5. How to store PANADO PAEDIATRIC SYRUP - STRAWBERRY
6. Contents of the pack and other information

1. What PANADO PAEDIATRIC SYRUP - STRAWBERRY is and what it is used for

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

PANADO PAEDIATRIC SYRUP - STRAWBERRY is therefore used for the symptomatic treatment of mild to moderate pain and fever.

2. What you need to know before you give PANADO PAEDIATRIC SYRUP - STRAWBERRY

Do not give PANADO PAEDIATRIC SYRUP - STRAWBERRY if:

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

Warnings and precautions

Take special care with PANADO PAEDIATRIC SYRUP – STRAWBERRY

PANADO PAEDIATRIC SYRUP - STRAWBERRY 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 specialised treatment is essential as soon as possible.

- Be sure to give the correct dosage of PANADO PAEDIATRIC SYRUP - STRAWBERRY. Severe liver damage may occur if the child is given doses higher than those recommended.
- If no pain relief is achieved, if fever persists or get worse with the recommended doses, if new symptoms occur, or if redness and swelling is present, please consult your doctor as these could be signs of a more serious condition.
- Do not use continuously for more than 10 days without consulting a doctor.
- Excessive and prolonged use of PANADO PAEDIATRIC SYRUP - STRAWBERRY may be dangerous.
- If your child suffers from hepatitis (disease of the liver) or is recovering from any form of liver disease, do not give excessive quantities of PANADO PAEDIATRIC SYRUP - STRAWBERRY.

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- If the child suffers from liver or kidney disease, a doctor must monitor his/her condition while he/she is taking PANADO PAEDIATRIC SYRUP - STRAWBERRY.
- Use with caution if your child has kidney disease, chronic malnutrition or dehydration or if your child has not eaten in a few days.
- If the child is also taking a medicine that contains flucloxacillin, they may have a higher risk of developing a blood and fluid abnormality (high anion gap metabolic acidosis). Close monitoring, including measurement of 5-oxoproline in the child's urine, is recommended.
- Serious skin reactions such as toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS) acute generalised exanthematous pustulosis (AGEP), drug-reaction with eosinophilia and systemic symptoms (DRESS)/Drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE) 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 - STRAWBERRY immediately and contact your doctor (see section 4).
- If the child is going to have any laboratory tests (such as a blood test, urine analysis, skin allergy test, etc.), you should tell your doctor that the child is taking PANADO PAEDIATRIC SYRUP - STRAWBERRY as it could affect the results of these tests.

Other medicines and PANADO PAEDIATRIC SYRUP - STRAWBERRY

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 (i.e., PANADO PAEDIATRIC SYRUP - STRAWBERRY) 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.
- Medicines used to treat epilepsy: Antiepileptic medicines such as carbamazepine, fosphenytoin, phenytoin, phenobarbital, primidone may increase liver toxicity.
- Medicines used to treat depression (e.g., tricyclic antidepressants, such as amitriptyline and St. John's wort) may increase liver toxicity.
- Medicines for nausea and vomiting: metoclopramide or domperidone may increase the absorption of paracetamol.
- Medicine to lower blood cholesterol: Cholestyramine reduces the absorption of paracetamol.
- Prolonged concurrent use of PANADO PAEDIATRIC SYRUP - STRAWBERRY with salicylates (e.g. aspirin (acetylsalicylic acid)) increases the risk of adverse kidney effects.
- Medicines to thin the blood: If your child is taking warfarin or other blood thinning medicines (anticoagulants) PANADO PAEDIATRIC SYRUP - STRAWBERRY 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 anticoagulant.
- Medicines used to treat epilepsy and oral contraceptives, also known as 'the pill', may reduce the effectiveness of PANADO PAEDIATRIC SYRUP - STRAWBERRY.
- Medicine used to treat high levels of uric acid in the blood stream i.e., gout: Probenecid may affect the excretion of paracetamol and plasma (blood) concentrations altered when taken together.
- Medicines to treat tuberculosis: Use of PANADO PAEDIATRIC SYRUP - STRAWBERRY 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.
- Flucloxacillin (an antibiotic) taken together with PANADO PAEDIATRIC SYRUP - STRAWBERRY may result in a serious higher-than-normal level of acid in your blood, especially if you have risk factors such as kidney impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.
- Taking PANADO PAEDIATRIC SYRUP - STRAWBERRY together with certain antiviral medicines, such as zidovudine, and co-trimoxazole, can cause severe toxic damage to the liver.
- The antiviral effect of interferon alfa (used to treat hepatitis B and C) may be increased if taken with PANADO PAEDIATRIC SYRUP - STRAWBERRY.

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- Paracetamol (i.e., PANADO PAEDIATRIC SYRUP - STRAWBERRY) may extend the duration of action of chloramphenicol.

PANADO PAEDIATRIC SYRUP - STRAWBERRY with food, drink and alcohol

There is no significant effect on absorption of PANADO PAEDIATRIC SYRUP - STRAWBERRY when taken with meal.

Do not drink alcohol (e.g., wine, beer, spirits) whilst taking PANADO PAEDIATRIC SYRUP - STRAWBERRY.

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 PANADO PAEDIATRIC SYRUP - STRAWBERRY.

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

There is no available data on the effects of PANADO PAEDIATRIC SYRUP - STRAWBERRY on fertility.

Driving and using machines

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

It is not always possible to predict to what extent PANADO PAEDIATRIC SYRUP - STRAWBERRY may interfere with your daily activities. You should ensure that you do not engage in driving or operating machinery until you are aware of the measure to which PANADO PAEDIATRIC SYRUP - STRAWBERRY affects you.

PANADO PAEDIATRIC SYRUP – STRAWBERRY contains sorbitol, propylene glycol and sodium benzoate

Sorbitol:

PANADO PAEDIATRIC SYRUP - STRAWBERRY contains 280 mg sorbitol in each 5 mL dose which is equivalent to 56 mg/mL. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive PANADO PAEDIATRIC SYRUP - STRAWBERRY. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

Propylene glycol:

PANADO PAEDIATRIC SYRUP - STRAWBERRY contains 80 mg propylene glycol in each 5 mL dose which is equivalent to 16 mg/mL.

If your child is less than 5 years old, talk to your doctor or pharmacist before giving them PANADO PAEDIATRIC SYRUP - STRAWBERRY, in particular if they use other medicines that contain propylene glycol or alcohol.

If you are pregnant or breastfeeding, do not take PANADO PAEDIATRIC SYRUP - STRAWBERRY unless recommended by your doctor. Your doctor may carry out extra checks while you are taking PANADO PAEDIATRIC SYRUP - STRAWBERRY.

If you suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking PANADO PAEDIATRIC SYRUP - STRAWBERRY.

Sodium benzoate (preservative):

PANADO PAEDIATRIC SYRUP - STRAWBERRY contains 16,50 mg sodium benzoate in each 5 mL dose which is equivalent to 3,3 mg/mL. Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

Sodium:

PANADO PAEDIATRIC SYRUP – STRAWBERRY contains less than 1 mmol sodium (23 mg) per 5 mL that is to say it is essentially 'sodium-free'.

3. How to give PANADO PAEDIATRIC SYRUP - STRAWBERRY

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

Always give PANADO PAEDIATRIC SYRUP - STRAWBERRY exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

Do not exceed the recommended dose.

The recommended doses are as follows:

Infants:

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)

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.

Dose to be given orally

Shake the bottle before use.

Consult a doctor if your child's symptoms persist.

PANADO PAEDIATRIC SYRUP - STRAWBERRY – 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.

If you give more PANADO PAEDIATRIC SYRUP - STRAWBERRY than you should

PANADO PAEDIATRIC SYRUP - STRAWBERRY 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.

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 dysrhythmias have been reported.

If you forget to give PANADO PAEDIATRIC SYRUP - STRAWBERRY

If you forget to give a dose, give it as soon as you remember, unless it is almost time for the next dose. Remember to leave at least four hours between doses. Do not give a double dose to make up for forgotten individual doses.

4. Possible side effects

PANADO PAEDIATRIC SYRUP - STRAWBERRY can have side effects.

Not all side effects reported for PANADO PAEDIATRIC SYRUP – STRAWBERRY 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 - STRAWBERRY please consult your health care

provider for advice.

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

- swelling of the hands, feet, ankles, eyelids, face, tongue or lips,
- hives or welts (urticaria),
- difficulty in breathing and shortness of breath (dyspnoea),
- decrease in blood pressure (hypotension),
- severe dizziness,
- mouth ulcers, cold sores and ulcers or soreness of your tongue,
- skin lumps or hives (raised, red or white, itchy patches of skin),
- blisters on your skin or inside your mouth, nose, vagina or bottom,
- the appearance of a rash or sunburn when you have been outside (even on a cloudy day),
- 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 - STRAWBERRY immediately and contact your doctor (see section 2).

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

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

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- 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 a pale complexion.

Frequency unknown:

- if your child has hearing loss or deafness,
- if your child has an increase in blood pressure.

Long term use:

PANADO PAEDIATRIC SYRUP - STRAWBERRY is NOT intended for long term use.

People who use medicines containing paracetamol (i.e., PANADO PAEDIATRIC SYRUP - STRAWBERRY) every day for a long time (several months or more) could get certain side effects, including liver and kidney damage. People taking paracetamol in the usual way for shorter periods have not had these problems, but liver function tests may be affected.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If your child gets side effects, talk to your doctor, pharmacist, or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of PANADO PAEDIATRIC SYRUP - STRAWBERRY.

5. How to store PANADO PAEDIATRIC SYRUP - STRAWBERRY

Store all medicines out of reach of children.

Store in a well closed container protected from light.

Store at or below 25 °C.

Do not refrigerate or freeze.

Exposure to air should be kept to a minimum.

Do not store in a bathroom.

Do not give 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 - STRAWBERRY contains

- The active substance is paracetamol 120 mg/5 mL.
- The other ingredients are glycerol (E 422), polyvinylpyrrolidone K25, propylene glycol (E 1520), sodium benzoate (E 211), xanthan gum, flavour strawberry 216330, colour carmoisine red H.7110, hydrochloric acid (for pH adjustment), sorbitol (E 420), sodium cyclamate, purified water.

What PANADO PAEDIATRIC SYRUP - STRAWBERRY looks like and contents of the pack

A clear, dark pink syrup with an odour and taste of strawberry.

50 mL & 100 mL round bottles (clear glass) with a screw closure (EXPE) packed in unit cartons.

50 mL & 100 mL round bottles (clear PVC) with a snap-on pilfer proof closure packed in unit cartons.

5 mL sachets packed into unit cartons. Sachets are composed of polyester/aluminium foil/metallocene co-extruded.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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