SCHEDULING STATUS

S0

GO-PAIN P 120 mg/5 mL, Syrup

Paracetamol

Contains sugars as

Sucrose 1,565 g/5 mL

Liquid glucose 2,0 g/5 mL

Contains sweeteners as

Sodium cyclamate 15 mg/5 mL

Saccharin sodium 5 mg/5 mL

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

GO-PAIN P is available without a doctor's prescription, for your child treat a mild illness.

Nevertheless, you still need to use GO-PAIN P carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share GO-PAIN P with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 5 days for pain and for fever 3 days.

What is in this leaflet

1 What GO-PAIN P is and what it is used for

2. What you need to know before you give GO-PAIN P

3. How to give GO-PAIN P

4. Possible side effects

5. How to store GO-PAIN P

6. Contents of the pack and other information

1. What GO-PAIN P is and what it is used for

GO-PAIN P contains paracetamol. Paracetamol acts as an analgesic (to relieve pain) and as an antipyretic (to reduces fever).

GO-PAIN P can be used in children (3 months to 12 years of age) for the treatment of mild or moderate pain and feverishness.

2. What you need to know before you give GO-PAIN P

Do not give GO-PAIN P

- If your child is hypersensitive (allergic) to paracetamol or any of the other ingredients of GO-PAIN P (listed in section 6).
- If your child has serious problems with his/her liver.

Warnings and precautions

GO-PAIN P contains paracetamol which may be fatal in overdose. In the event of over dosage or suspected overdose and notwithstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or Poison Centre must be contacted immediately.

Take special care with GO-PAIN P

- If you give more GO-PAIN P than you should as it can cause damage to your child's liver.
- You should tell your doctor if pain or fever persists or gets worse at the recommended dosage, or if new symptoms occur or if redness and swelling is present, as these could be signs of a more serious condition.
- Do not use GO-PAIN P continuously without consulting your doctor:

- for pain for more than 7 days in adults, or 5 days for children,
- for fever for more than 3 days.

- Store GO-PAIN P in a safe place out of reach of children.
- If your child has a liver disease, you should not give more than the recommended dose of GO-PAIN P.
- If your child is recovering from any form of liver disease you should not give more than is necessary of GO-PAIN P.
- If your child has problems with his/her kidneys, your doctor might monitor his/her condition while he/she is taking this medicine.
- If your child has skin rashes, often accompanied by flu-like symptoms after taking GO-PAIN P. The rash may progress to widespread blistering or peeling of the skin. The reaction usually occurs soon after treatment with GO-PAIN P starts and can be a serious skin reaction to GO-PAIN P, called severe cutaneous adverse reactions (SCARs). Stop GO-PAIN P treatment and seek urgent advice from your doctor (see section 4, Possible side effects).

Other medicines and GO-PAIN P

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

- The risk of side effects with paracetamol may be increased when 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 (used to treat nausea or vomiting).
- Cholestyramine (used to lower cholesterol) reduces the absorption of paracetamol as in GO-PAIN P.

- The use of GO-PAIN P with salicylates (e.g., aspirin) for long periods may increase the risk of damage to the kidneys.
- Warfarin or other blood thinning medicines (anticoagulants) together with GO-PAIN P may increase the risk of bleeding. Your doctor might monitor your child's blood clotting factors more regularly.
- Medicines used for epilepsy, such as carbamazepine, phenobarbital, phenytoin, or primidone. Your doctor might lower the dosage of GO-PAIN P.
- Probenecid (used to prevent gout) may affect the excretion of paracetamol as in GO-PAIN P and plasma (blood) concentrations of paracetamol can increase.
- Antibiotics used for the treatment of tuberculosis such as rifampicin and isoniazid may increase the blood concentration of paracetamol as in GO-PAIN P and your doctor might lower the GO-PAIN P dose.
- Zidovudine (used to treat viral infections) and co-trimoxazole (used to treat bacterial infections) together with GO-PAIN P can cause damage to the liver.
- The effect of Interferon alfa (used to treat cancers and viral infections) can be increased when used together with GO-PAIN P and your doctor might change the dose.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care provider for advice before taking GO-PAIN P.

Driving and using machines

It is not always possible to predict to what extent GO-PAIN P may interfere with your child's daily activities. You should ensure that your child do not engage in activities requiring mental alertness, judgment and/or sound coordination and vision until you are aware of the measure to which GO-PAIN P affects him/her.

GO-PAIN P contains tartrazine

The tartrazine in GO-PAIN P may cause allergic reactions.

GO-PAIN P contains sucrose and glucose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

GO-PAIN P contains ethanol

GO-PAIN P contains 422,50 mg of alcohol (ethanol) in each 5 mL which is equivalent to 10,56 % *v/v*. The amount in 5 ml dose of GO-PAIN P is equivalent to 10 ml beer or 25 ml wine. The amount of alcohol in this medicine is not likely to have an effect in adults and adolescents, and its effects in children are not likely to be noticeable. It may have some effects in younger children, for example feeling sleepy.

The alcohol in this medicine may alter the effects of other medicines. Talk to your doctor or pharmacist if you are taking other medicines.

GO-PAIN P contains propylene glycol

GO-PAIN P contains 1,0 mg propylene glycol in each 5 mL. If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol.

GO-PAIN P contains methyl- and propyl parahydroxybenzoate (as preservatives)

Parahydroxybenzoate may cause allergic reactions (possibly delayed).

3. How to give GO-PAIN P

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

Always give GO-PAIN P 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 usual dose per mouth is:

Infants 3 to 12 months: 2,5 mL every six to eight hours

Children 1 to 6 years: 5 mL to 10 mL every six to eight hours

Children 7 to 12 years: 10 mL to 20 mL every six to eight hours

Do not use more than 4 doses per 24 hours.

If needed, repeat the dose to treat the symptoms of pain and fever every six to eight hours for not longer than 5 days.

If you take/give more GO-PAIN P than you should

In the event of overdosage, even if your child may not be showing or experiencing any symptoms, consult your doctor or pharmacist without delay. If neither is available, go to the nearest hospital or poison control centre. GO-PAIN P contains paracetamol which may be fatal in overdose. Prompt specialized treatment is essential as soon as possible.

If you missed a dose of GO-PAIN P

If you forget to give a dose, give it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

GO-PAIN P can have side effects.

Not all side effects reported for GO-PAIN P are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking GO-PAIN P, please consult your health care provider for advice.

If any of the following happens, stop giving GO-PAIN P and tell your doctor immediately or go to the casualty department at your nearest hospital.

- Feeling tired, pale skin, shortness of breath, light-headedness, dizziness or a fast heartbeat, increase in nose bleeds or unusual bleeding (blood test shows changes in blood cell counts).
- An allergic reaction with skin rash, difficulty to breath, and low blood pressure.
  Severe cutaneous adverse reactions (SCARS) are a group of potentially very serious adverse drug reactions that can be fatal and involve the skin and mucous membranes (the moist, inner lining of some organs and body openings, such as the nose, mouth, lungs, and stomach. Examples of SCARs includes toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS), acute generalized exanthematous pustulosis (AGEP), drug reaction with eosinophilia and systemic symptoms (DRESS)/ drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruption (FDE). (see also section 2, Warnings and precautions).
- Pancreas disease with pain in the upper part of the belly, nausea, vomiting.
- Liver disease with nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine.

These are all very serious side effects. If you have them, you may have had a serious reaction to GO-PAIN P. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following

Less frequent side effects

- Loss of hearing
- High blood pressure
- Nausea and vomiting
- Skin rash, itching
- Kidney failure (changed in urination and swelling of ancles)

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. 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 GO-PAIN P.

5. How to store GO-PAIN P

Store all medicines out of reach of children.

- Store in a cool dry place at or below 25 °C.
- Protect from light.
- Store in the original container.
- Keep the container tightly closed.
- Do not use after the expiry date stated on the bottle.

6. Contents of the pack and other information

What GO-PAIN P contains

The active substance is paracetamol.

The other ingredients are Apple Green F1569 (CI19140/44090), Crème de Menthe, ethanol 96 % *v/v,* liquid glucose, methyl hydroxybenzoate, propyl hydroxybenzoate, propylene glycol, purified water, sodium cyclamate, saccharin sodium, sucrose, Toffee Creamy Flavour F1744 (Butterscotch), Vanilla Cream Flavour F646

What GO-PAIN P looks like and contents of the pack

GO-PAIN P is a green syrup.

GO-PAIN P is packed in round amber plastic (PVC – Polyvinyl Chloride) / (PET-Polyethylene Terephthalate) bottles with a white LLDPE (Linear Low-Density Polyethylene) snap on cap or a white Polypropylene (PP) lid with liner, containing 50 mL, 100 mL or 500 mL of syrup, or amber plastic (HDPE- High Density Polyethylene) bottles with a white LLDPE snap on cap containing 2,5 L of syrup.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

Available on SAHPRA's PI and PIL Repository portal