

Applicant/PHCR: Innovata Pharmaceuticals (Pty) Ltd

Product Proprietary Name: Painogesic Syrup

Dosage Form & Strength: Paracetamol 120 mg / 5ml

CTD, Module 1

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

PAINOGESIC SYRUP

Paracetamol 120 mg/ 5 ml

Sweeteners: Inverted sugar 2 ml & Glycerin 5 ml

Alcohol 11,2 %v/v

Sugar free

Tartrazine free

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

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

- Keep this leaflet. You may need to read it again.
- Do not share **PAINOGESIC 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 symptoms worsen or do not improve after 10 days.

What is in this leaflet:

1. What **PAINOGESIC SYRUP** is and what it is used for
2. What you need to know before you use **PAINOGESIC SYRUP**
3. How to use **PAINOGESIC SYRUP**
4. Possible side effects
5. How to store **PAINOGESIC SYRUP**
6. Contents of the pack and other information

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1. What PAINOGESIC SYRUP is and what it is used for

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

PAINOGESIC SYRUP is therefore used for the relief of mild to moderate pain and fever.

2. What you need to know before you take PAINOGESIC SYRUP

Do not use PAINOGESIC SYRUP if:

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

Warnings and precautions

Take special care with PAINOGESIC SYRUP:

PAINOGESIC 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 specialised 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.

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- If no pain relief is achieved or if the fever persists with the recommended doses, please consult your doctor.
- Excessive and prolonged use of **PAINOGESIC 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 **PAINOGESIC 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.
- If you develop any skin adverse reaction, such as toxic epidermal necrolysis (TEN), Steven Johnson syndrome (SJS), acute generalised exanthematous pustulosis (AGEP), drug rash with eosinophilia and systemic symptoms (DRESS) or drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE), treatment with **PAINOGESIC SYRUP** must immediately be discontinued. These reactions can be life-threatening and are characterised by redness, inflamed or swollen skin, blisters, hives, itching and sometimes peeling or pain. Should you experience any of these symptoms, contact your doctor immediately.
- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **PAINOGESIC SYRUP**.

Other medicines and PAINOGESIC SYRUP:

Always tell your healthcare professional if you are 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.

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- 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 **PAINOGESIC 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) **PAINOGESIC 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 anticoagulant.
- Use of **PAINOGESIC 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 **PAINOGESIC 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 **PAINOGESIC 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.

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Driving and using machines

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

PAINOGESIC SYRUP contains inverted sugar:

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

3. How to take PAINOGESIC 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:

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.

While symptoms persist, repeat every 4 to 6 hours if needed to a maximum of 4 doses in 24 hours.

Consult a doctor if your child's symptoms persist.

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If more than the recommended dosage of PAINOGESIC SYRUP is given:

PAINOGESIC 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 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 arrhythmias have been reported.

If a dose of PAINOGESIC SYRUP is missed

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

4. Possible side effects

PAINOGESIC SYRUP can have side effects.

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Not all side effects reported for **PAINOGESIC SYRUP** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **PAINOGESIC SYRUP**, please consult your healthcare provider for advice.

If any of the following happens, stop giving **PAINOGESIC 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 **PAINOGESIC 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 **PAINOGESIC SYRUP**. Your child may need urgent medical attention or hospitalisation.

Stop giving **PAINOGESIC 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-coloured 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

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- 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 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 via

<http://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of **PAINOGESIC SYRUP**.

5. How to store PAINOGESIC SYRUP

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 use after the expiry date stated on the carton/bottle.

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 **PAINOGESIC SYRUP** contains

The active substance is paracetamol 120 mg/5 ml.

Contains sweeteners: Inverted sugar 2 ml Glycerin 5 ml

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Contains preservatives: Alcohol 11,2 % v/v

The other ingredients are:

Ethanol 96 % v/v

Glycerin

Hexacol red (2G Supra CI no. 18050)

Invert sugar

Propylene glycol

Purified water

Raspberry essence

Spirits chloroform

What PAINOGESIC SYRUP looks like and contents of the pack

A red raspberry flavoured syrup.

100 ml amber or white opaque plastic bottles.

2.5 L amber bottles.

HOLDER OF CERTIFICATE OF REGISTRATION

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