PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S0 ALL PACK SIZES CONTAINING **LESS THAN** 25 TABLETS.

SCHEDULE STATUS :

S1 ALL PACK SIZES CONTAINING **MORE THAN** 25 TABLETS

PAINOGESIC, 500 mg tablet

Paracetamol.

Powdered sucrose 20 mg

Nipastat 0, 1 % m/m & Benzoic acid 0,06 % m/m

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

PAINOGESIC is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use **PAINOGESIC** carefully to get the best results from it. Keep this leaflet. You may need to read it again.

- Do not share **PAINOGESIC** 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** is and what it is used for
2. What you need to know before you use **PAINOGESIC**
3. How to use **PAINOGESIC**
4. Possible side effects
5. How to store **PAINOGESIC**
6. Contents of the pack and other information

1. What PAINOGESIC is and what it is used for

Each **PAINOGESIC** tablets contains the active substance paracetamol.

Paracetamol belongs to analgesic and antipyretic; Paracetamol acts predominantly by inhibiting prostaglandin synthesis.

PAINOGESIC used to relieve mild to moderate pain and fever.

2. What you need to know before you take PAINOGESIC

Do not take PAINOGESIC:

- if you are hypersensitive (allergic) to paracetamol or any of the other ingredients of **PAINOGESIC** (listed in section 6).
- if you have severe renal (kidney) problems
- if you have severe liver problems.

Warnings and precautions

Take special care with PAINOGESIC and tell you doctor:

- If you are suffering from liver or kidney disease.
- Do not use continuously for longer than ten (10 days) without consulting your doctor.
- DO NOT EXCEED THE RECOMMENDED DOSAGE. Dosages in excess of those recommended may cause sever liver damage.
- Consult your doctor if no relief is obtained with the recommended dosage.
- (SCAR) is a severe skin rash that is life-threatening.

Susceptibility to paracetamol toxicity is increased:

- in patients who have taken repeated high doses (greater than 5-10 g/day) of paracetamol for several days,
- in patients with chronic alcoholism,
- in patients with chronic liver disease,
- in patients with AIDs,
- in patients with malnutrition,
- in patients using medicine that induce liver microsomal oxidation (see “Taking other medicine with **PAINOGESIC**”),
- **PAINOGESIC** contains paracetamol which may be fatal in overdose. In the event of overdosage or suspected overdose and notwithstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or Poison Centre must be contacted immediately.

Other medicines and PAINOGESIC:

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

Do not take **PAINOGESIC** with any other medicine that contains paracetamol.

Tell your doctor if you are taking:

- Metoclopramide or domperidone (medicines used for nausea and/or vomiting)
- Probenecid (medicine used for gout)
- Colestyramine (medicine used to reduce blood fat levels)
- Aspirin (medicine for pain, inflammation and fever)

- Warfarin and other anti-blood clotting medicine or anticoagulants (medicines for prevention of blood clots)
- Isoniazid (antibiotic medicine used to treat tuberculosis).

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 **PAINOGESIC**.

Driving and using machines

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

3. How to take PAINOGESIC

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

Always take **PAINOGESIC** exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Do not exceed the recommended dose (see “Take special care with **PAINOGESIC** Tablets”).

The usual adult dosage:

One to two tablets (0,5 to 1 g) with a glass of water every 4 -6 hours up to a maximum of 4 g daily (8 tablets)

Usual paediatric dose (children 6-12 years of age):

250-500 mg (half to one tablet) with a glass of water three to four times a day as required.

Children under 6 years of age: Not suitable.

PAINOGESIC is usually only used for short periods of time.

Use **PAINOGESIC** only when simple measures have failed to provide adequate relief.

Don't use for more than 10 (ten) days without consulting your doctor (**see "Taking special care with PAINOGESIC"**).

If you take more PAINOGESIC than you should

If you take more **PAINOGESIC** than you should consult your doctor or pharmacist. If neither is available seek help at the nearest hospital or poison control centre.

A delay in starting treatment may mean that an antidote is given too late to be effective. Evidence of liver damage is often delayed until after the time for effective treatment has lapsed.

Symptoms of paracetamol overdosage in the first 24 hours include:

- Paleness
- Nausea
- Anorexia (eating disorder-weight loss)

- Possible abdominal pain

  Liver damage may become apparent 12 to 48 hours, or later after ingestion, and may lead to abnormal brain function (encephalopathy), coma and death.

- Acute kidney failure with damage to the kidney tubular cells (acute tubular necrosis) may develop even in the absence of severe liver damage.
- Abnormalities of glucose metabolism and too much acid in body fluids (metabolic acidosis) may occur.
- Irregular heartbeat (cardiac arrhythmias) has been reported.

If you forget to take PAINOGESIC

Take the missed dose as soon as you remember it. However, if it is almost time for your next regular dose, do not take your missed dose. If you miss two or more doses, consult your doctor or pharmacist.

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

4. Possible side effects

PAINOGESIC can have side effects.

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

If any of the following happens, stop taking **PAINOGESIC** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- ‘Allergic reactions, including skin rashes,

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

Tell your doctor if you notice any of the following:

Less frequent side effects:

- feeling or being sick (nausea, vomiting), stomach pain or cramps, diarrhoea, loss of appetite.
- liver problems (toxicity and failure),
- gastrointestinal tract bleeding, inflammation of the pancreas (pancreatitis).
- convulsions, respiratory depression, cerebral swelling, coma.
- skin rashes and other allergic reactions. The skin rash is usually red or hives but it is sometimes more serious and may be accompanied by fever and mucosal lesions.
- blood disorders-changes in numbers and types of blood cells
- irregular heartbeat (cardiac arrhythmias).
- Acute kidney failure with acute damage to the kidney tubular cells (tubular necrosis).
- severe skin rash

If you notice any side effects not mentioned in this leaflet, 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 via http:///www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store PAINOGESIC

Store all medicines out of reach of children.

Store at or below 25 ºC.

Store in the original package/container.

Keep the container in the outer carton.

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** contains

The active substance is paracetamol.

PAINOGESIC: each tablet contains 500 mg paracetamol.

Contains Sugar: Powdered sucrose 20 mg

Contains preservatives: Nipastat 0, 1 % m/m & Benzoic acid 0,06 % m/m

The other ingredients are:

Benzoic acid

Chloroform spirits

Green apple (TF 1196)

Magnesium stearate

Modified starch

Nipastat

Powdered sucrose

Purified water

Starch maize

What PAINOGESIC looks like and contents of the pack

A flat green tablet, 12,7 mm in diameter, with a breakline on the one side and plain on the other side.

White polypropylene securitainers of 100 tablets.

White/Amber PVC/HOPE containers of 100, 500 and 1000 tablets.

H.D.P.E. buckets of 5000 tablets.

Blister packs of 10 and 20 tablets.

Patient ready packs of different pack sizes.

HOLDER OF CERTIFICATE OF REGISTRATION

Innovata Pharmaceuticals (Pty) LTD

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Johannesburg

2091

South Africa

Registration number

A 34/2.7/0466