PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

VARIPAN SUGAR FREE SYRUP, 120 mg/5 mL

Paracetamol

Sugar free.

Contains sweetener (18,5 mg sodium saccharin per 5 mL).

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

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

- Keep this leaflet. You may need to read it again.
- Do not share VARIPAN SUGAR FREE 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 5 days.

What is in this leaflet

1. What VARIPAN SUGAR FREE SYRUP is and what it is used for
2. What you need to know before your child takes VARIPAN SUGAR FREE SYRUP
3. How to give VARIPAN SUGAR FREE SYRUP
4. Possible side effects
5. How to store VARIPAN SUGAR FREE SYRUP
6. Contents of the pack and other information.

1. What VARIPAN SUGAR FREE SYRUP is and what it is used for

VARIPAN SUGAR FREE SYRUP contains paracetamol. Paracetamol has analgesic (to relieve pain) and antipyretic (to prevent or reduce fever) properties.

VARIPAN SUGAR FREE SYRUP is used to treat mild to moderate pain and fever.

2. What you need to know before your child takes VARIPAN SUGAR FREE SYRUP

Do not take VARIPAN SUGAR FREE SYRUP:

- If your child is hypersensitive (allergic) to paracetamol or to any of the other ingredients of VARIPAN SUGAR FREE SYRUP (listed in section 6).
- If your child has liver problems.

Warnings and precautions

Take special care with VARIPAN SUGAR FREE SYRUP:

- Consult your doctor if your child's pain or fever persist or gets worse, if other symptoms occur or if redness or swelling is present (this may be signs of a more serious condition).
- Do not use VARIPAN SUGAR FREE SYRUP continuously without consulting your doctor:
    - For pain – for more than 5 days.
    - For fever – for more than 3 days.
- If your child has liver or kidney problems.
- If your child is malnourished and dehydrated.
- 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 VARIPAN SUGAR FREE 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.

Other medicines and VARIPAN SUGAR FREE SYRUP

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

The following medicines may interact with VARIPAN SUGAR FREE SYRUP and should not be used together:

- Medicines causing damage to the liver (including alcohol).
- Metoclopramide (used to treat nausea and vomiting).
- Colestyramine (used to treat high cholesterol levels).
- Salicylates (used to treat mild to moderate pain and fever).
- Warfarin and anticoagulant medicines (used to thin your blood and prevent blood clots from forming).
- Carbamazepine, phenobarbital, phenytoin, primidone (used to treat epilepsy).
- Probenecid (used to treat gout).
- Rifampicin, isoniazid (used to treat tuberculosis (TB)).
- Zidovudine (used in the treatment of HIV (human immunodeficiency virus) and AIDS (acquired immune deficiency syndrome)).
- Co-trimoxazole, flucloxacillin (used to treat certain bacterial infections).
- Interferon alfa (used to treat hepatitis B and C).

VARIPAN SUGAR FREE SYRUP with food or drink

VARIPAN SUGAR FREE SYRUP can be taken with or without food.

Pregnancy and breastfeeding

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 VARIPAN SUGAR FREE SYRUP. Safety and efficacy in pregnancy and breastfeeding have not been established.

Driving and using machines

VARIPAN SUGAR FREE SYRUP has no or negligible influence on the ability to drive a vehicle or use machines.

VARIPAN SUGAR FREE SYRUP contains sodium

VARIPAN SUGAR FREE SYRUP contains less than 1 mmoL sodium (23 mg) per 5 mL, that is to say essentially sodium-free.

3. How to give VARIPAN SUGAR FREE SYRUP

Do not share your child's medicines with any other person.

Always give VARIPAN SUGAR FREE SYRUP exactly as instructed. You should check with your doctor or pharmacist if you are not sure.

DO NOT GIVE MORE VARIPAN SUGAR FREE SYRUP than prescribed by your doctor.

VARIPAN SUGAR FREE SYRUP is only to be taken by mouth.

Infants:

Under 3 months:	10 mg/kg (0,41 mL/kg)
3 months to 1 year:	2,5 – 5 mL (60 – 120 mg)

Children:

1 to 5 years:	5 – 10 mL (120 – 240 mg)
6 to 12 years:	10 – 20 mL (240 – 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.

If your child takes more VARIPAN SUGAR FREE SYRUP than should be taken

VARIPAN SUGAR FREE SYRUP contains paracetamol which may be fatal in overdose. Paracetamol may cause liver damage if your child takes more than the recommended dosage. In the event of an overdosage or suspected overdose, consult your doctor or pharmacist even if your child has no symptoms. If neither is available, contact the nearest hospital or poison control centre. Take this leaflet and any remaining syrup with you, so that the doctor knows what you have taken.

If you forget to give VARIPAN SUGAR FREE SYRUP to your child

Give the missed dose as soon as you remember. If it is almost time for the next dose, skip the missed dose and give VARIPAN SUGAR FREE SYRUP at the next regularly scheduled time. Do not give a double dose to make up for forgotten individual doses.

4. Possible side effects

VARIPAN SUGAR FREE SYRUP can have side effects. Not all side effects reported for VARIPAN SUGAR FREE SYRUP are included in this leaflet. Should your child's general health worsen or if your child experience any untoward effects while taking VARIPAN SUGAR FREE SYRUP, please consult your health care provider for advice.

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

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If your child has them, your child may have had a serious reaction to VARIPAN SUGAR FREE SYRUP. 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:

- Signs of recurrent infections such as fever or sore throat.
- Bleeding or bruising more easily than normal.
- Changes in the way your heart beats, for example, if you notice it beating faster or irregular (skipping beats).
- Yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver

problems.

- Skin reactions such as toxic epidermal necrolysis (TEN), Stevens-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). These reactions can be life-threatening and are characterised by redness, inflamed or swollen skin, blisters, hives, and sometimes peeling or pain.
- Passing more urine than is normal for you, painful when passing urine, bloody or cloudy urine.

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

Tell your doctor if you notice any of the following:

Less frequent side effects:

- Nausea, vomiting, fever, pain in your stomach area radiating to your back.

Side effects with frequency unknown:

- Loss of hearing.

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 or pharmacist. 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 VARIPAN SUGAR FREE SYRUP.

5. How to store VARIPAN SUGAR FREE SYRUP

- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Store at or below 25 °C.
- Store in well-closed containers, protected from light.

- Do not use after the expiry date printed on the label or carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What VARIPAN SUGAR FREE SYRUP contains

Each 5 mL contains 120 mg paracetamol.

The other ingredients are Brilliant Blue H7250 (CI 42090), chocolate flavour R102, citric acid monohydrate (E330), glycerine (E422), hypromellose (Methocel E4M) (E464), methylhydroxybenzoate (E218), peppermint essence, propylene glycol (E1520), propylhydroxybenzoate (E216), purified water, sodium citrate (E331), sodium saccharin (E954), Quinoline Yellow (CI 47005).

Contains 0,2 % *m/v* methylhydroxybenzoate and 0,02 % *m/v* propylhydroxybenzoate as preservatives.
Tartrazine free.

What VARIPAN SUGAR FREE SYRUP looks like and contents of the pack

Clear, sweet, chocolate mint flavoured, green syrup.

White HDPE bottle of 100 ml with a white LDPE cap.

Holder of certificate of registration

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Access to the corresponding Professional Information

Request via the email address: info@lebasi.co.za