1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S0

TRIPARC

Sugar free

TRIPARC BLACKCURRANT

Sugar free

Contains sweetener: Sucralose 37,80 mg

TRIPARC ORANGE

Sugar free

Contains sweetener: Sucralose 37,80 mg

TRIPARC LEMON

Sugar free

Contains sweetener: Sucralose 21,06 mg

Powders

Aspirin, Paracetamol and Caffeine

453,6 mg/ 324,00 mg/ 64,80 mg

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

TRIPARC is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use TRIPARC carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.

- Do not share TRIPARC 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 10 days.

What is in this leaflet

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

1. What TRIPARC is and what it is used for

TRIPARC is an analgesic combination of aspirin, paracetamol and caffeine and is used for the symptomatic relief of mild to moderate pain and fever such as headaches, toothache, colds and flu.

2. What you need to know before you take TRIPARC

Do not take TRIPARC:

- If you are hypersensitive (allergic) to aspirin, paracetamol, caffeine or any of the other ingredients of TRIPARC (listed in section 6).
- If you have a history of hypersensitivity reactions e.g. asthma, bronchospasm (sudden constrictions of the muscles of the passage ways by which air passes through the nose to the air sacs of the lungs), rhinitis, irritation and inflammation of the mucous membranes inside the nose, urticaria (hives), nasal polyps (sac like growths of inflamed tissue lining the nose or sinuses) when you take aspirin or non-steroidal anti-inflammatory drugs (NSAIDs).

- If you have a history of internal bleeding of the stomach or intestines, ulcers or perforation (PUBs) related to previous non-steroidal anti-inflammatories (NSAIDs) treatment, or if you have an active recurrent ulcer, bleeding or perforation of the stomach or intestines.
- If you suffer from haemophilia (bleeding disorder), that is if you have or ever had a problem of your blood not clotting properly.
- If you have kidney failure.
- If you have liver failure.
- If you are currently receiving oral anti-coagulant therapy (warfarin).
- If you suffer from heart failure.
- If you have a history of gout.
- If you are breastfeeding (see section on Pregnancy and breastfeeding).
- If you are pregnant and you are in the last 3 months of pregnancy.
- If your child is under the age of 12 years (see Children and adolescents).

TRIPARC contains paracetamol which may be fatal in overdose. In the event of overdosage and notwithstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or Poison Control Centre must be contacted immediately.

Warnings and precautions

Take special care with TRIPARC:

- If you are taking more than the recommended dosage as this may cause severe damage to your liver.
- If you suffer from heart disease as TRIPARC could make your condition worse (see Do not take TRIPARC).

- If you have liver or kidney disease as paracetamol as in TRIPARC should be used under medical supervision.
- Do not use continuously for more than 10 days without consulting your doctor.
- If you have a history of hypertension (high blood pressure) and/or heart disease as TRIPARC can make your condition worse. You may experience water retention and swelling (see Do not take TRIPARC).
- If you are an elderly person or you are suffering from dehydration as side effects are more common.
- If you have a history of stomach ulcers or are of advanced age, the risk of internal bleeding of the stomach or intestines or ulcers is higher if you take large amounts of TRIPARC. If you suspect that you have an ulcer, treatment with TRIPARC should be stopped and you should consult your doctor (see Do not take TRIPARC).
- If you have a history of stomach and intestinal diseases e.g. inflammatory disease of the stomach and intestine, stomach pushing up into the chest, digestive disorder which affects the lower gut sphincter and vascular malformation of the gut, as these conditions may worsen (see Do not take TRIPARC).
- If you are scheduled to undergo any surgical procedures as the use of TRIPARC should be stopped several days before any scheduled surgical procedures.
- If you suffer from G-6-PD deficiency (a hereditary condition leading to low red blood cell counts), you should consult your doctor, pharmacist or healthcare professional.
- You should not use TRIPARC long term as it may cause iron deficiency anaemia (decreased number of red blood cells).
- If you are a diabetic as TRIPARC may interfere with your insulin.
- If you are checking your thyroid function as TRIPARC may interfere with the test.
- If you suffer from asthma or other allergic conditions as TRIPARC may make your allergies worse.

- If you suffer from malnutrition or you are an alcoholic as caution should be exercised before taking TRIPARC. Drinking alcohol at the same time as taking aspirin increases the risk of bleeding.
- Serious skin reactions, including Drug Rash with Eosinophilia and Systemic Symptoms (DRESS), can occur while taking TRIPARC. TRIPARC should be discontinued and your doctor or healthcare professional should be consulted at the first appearance of skin rash or any other sign of allergy.
- Do not take TRIPARC if you are already taking other medication that contains paracetamol.
- Avoid excessive intake of caffeine (e.g. coffee, tea and some canned drinks) while taking TRIPARC.
- If you think you are dehydrated (you may feel thirsty with a dry mouth).
- TRIPARC is not for use during the last 3 months of pregnancy, as it could harm your unborn child or cause problems at delivery (see Do not take TRIPARC).
- Mothers using TRIPARC should not breastfeed their babies as aspirin passes into breast milk.
- Consult your doctor or pharmacist for further information if you are pregnant or breastfeeding.
- If you are between 12 and 16 years old and you are recovering from an infection caused by a virus (such as chickenpox or flu-like symptoms), as there is a risk of developing Reye's syndrome (see section Children and adolescents below).

Children and adolescents

TRIPARC should not be used in children under the age of 12 (see section Do not take TRIPARC). There is a possible association between aspirin as in TRIPARC and Reye's syndrome when given to children and teenagers. Reye's syndrome is a rare disease which

affects the brain and liver and can be fatal. For this reason, children and teenagers (between 12 and 16 years of age) who have or are recovering from chicken pox or flu-like symptoms should not take TRIPARC, unless prescribed by a health practitioner (see Warnings and precautions).

Other medicines and TRIPARC

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

Tell your doctor if you are taking any of the following:

- Non-steroidal anti-inflammatory drugs (NSAIDs): Used to treat inflammation e.g. indomethacin and piroxicam. If you use two or more medicines in this class you could experience an increase in side effects.
- Corticosteroids e.g. betamethasone, (medicines used to reduce inflammation) can cause an increased risk of stomach ulcers.
- Barbiturates (CNS depressants) and other sedatives (medicines which cause drowsiness) may mask the respiratory symptoms of aspirin, as in TRIPARC, overdosage.
- Water tablets e.g. amiloride: Used to treat high blood pressure.
- Metoclopramide and domperidone: Used to treat nausea and vomiting.
- Phenytoin and valproate: Used to treat epilepsy.
- Methotrexate: Used to treat certain types of cancers and autoimmune diseases.
- Alcohol.
- Gold compounds: Used in rheumatoid arthritis.
- Dipyridamole: Used to prevent clot formation.
- Metoprolol: Used to treat heart attacks and high blood pressure.
- Carbonic anhydrase inhibitors: Used to treat glaucoma e.g. acetazolamide.

- Antacids e.g. aluminium hydroxide.
- Certain types of diabetic medicines e.g. glibenclamide may be enhanced when used with TRIPARC.
- Zafirlukast: Used in asthma.
- Probenecid and sulfinpyrazone: Used to treat gout. TRIPARC may diminish the effects of medicines used in the treatment of gout.
- Medicines used in the treatment of depression, anxiety disorders and some personality disorders (SSRI's) e.g. venlafaxine may increase the risk of stomach and intestinal bleeding.
- Anti-platelets (medicines that decrease formation of blood clots), may increase the risk of stomach and intestinal bleeding.
- Cholestyramine: Used to treat high cholesterol.
- Warfarin (anticoagulant): Used to thin the blood. TRIPARC may enhance the effects of anticoagulants.
- Methoxsalen: Used to control severe psoriasis.
- Oral contraceptives and hormone replacement therapy: Used as birth control or replacement therapy during menopause e.g. oestrogens.
- Chloramphenicol, ciprofloxacin and pipemidic acid: Antibiotics used to treat infections.
- Allopurinol: Used to treat gout.
- Lithium: Used for bipolar disorder.
- Cimetidine: Used for heartburn, ulcers, increased acid production and other associated symptoms.

TRIPARC with food and alcohol

TRIPARC should be taken with water.

The side effects of TRIPARC on the stomach may be worsened by the intake of alcohol. If you take aspirin with alcohol, it could increase the risk of gastrointestinal bleeding. Avoid excessive intake of caffeine (e.g. coffee, tea and some canned drinks) while taking TRIPARC.

Pregnancy and breastfeeding

You should not take TRIPARC if you are pregnant or breastfeeding your baby.

TRIPARC is not for use during the third trimester of pregnancy, as it could harm your unborn child or cause problems at delivery.

Mothers taking TRIPARC should not breastfeed their babies as aspirin passes into breast milk.

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 healthcare provider for advice before taking TRIPARC.

Driving and using machines

TRIPARC may cause headaches and dizziness which may affect your ability to perform skilled tasks, if you are affected, you should not drive or operate machinery.

It is not always possible to predict to what extent TRIPARC may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which TRIPARC affects you (see section 4).

TRIPARC contains sucralose

TRIPARC BLACKCURRANT, TRIPARC LEMON and TRIPARC ORANGE contain the sweetener, sucralose.

3. How to take TRIPARC

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

Always take TRIPARC exactly 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.

Use the lowest effective dose for the shortest possible duration of treatment.

The usual dose of TRIPARC is:

Adults: One powder to be taken with water every three hours.

Do not use more than one powder every 3 to 4 hours if necessary and not more than 6 powders during a 24-hour period.

Maximum daily dose: 6 powder sachets

Minimum dosing interval: 3 hours

Do not take TRIPARC with other paracetamol or aspirin containing medicines.

If you take more TRIPARC than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

ASPIRIN

You may experience the following symptoms related to aspirin overdose:

- dizziness,
- ringing in the ears,

- sweating,
- nausea,
- vomiting,
- mental confusion,
- breathing faster or deeper than normal,
- increase in blood pH,
- increased acid in the blood,
- increase in ketones in the blood,
- reduced functioning of the central nervous system.

In children, serious signs of overdosage may develop rapidly.

PARACETAMOL

In the event of paracetamol, as contained in TRIPARC, overdose seek medical advice immediately even if you feel well because of the risk of delayed and severe liver damage.

You may be prone to paracetamol poisoning if you take repeated high doses (greater than 5 to 10 g/day) of paracetamol for several days, in chronic alcoholism, chronic liver disease, AIDS, malnutrition, and if you use medicines such as barbiturates (for anxiety, insomnia and seizures), isoniazid (for tuberculosis), rifampicin (for tuberculosis), phenytoin (for seizures) and carbamazepine (for seizures).

Symptoms of paracetamol overdosage seen in the first 24 hours and likely to remain for a week or more are:

- pale skin,
- nausea,
- vomiting,

- loss of appetite,
- anorexia,
- abdominal pain.

Other symptoms are:

- liver damage or injury 12 to 48 hours after taking TRIPARC,
- abnormalities of glucose breakdown,
- excess quantity of acid in the blood,
- liver damage which may progress to disease of the brain, coma and death,
- swelling on the brain,
- reduced contractions of the heart muscle may also occur.

You may also develop:

- acute kidney failure with acute death of kidney tubule cells even in the absence of severe liver damage,
- changes in heart rate or rhythm.

The symptoms you experience during the first 2 days of acute poisoning do not reflect the potential seriousness of the overdosage which you may experience later.

In the event of overdosage consult a doctor or go to the nearest hospital immediately. You will require specialised treatment as soon as possible. If you have taken about 7,5 g of paracetamol in the preceding 4 hours you should undergo gastric lavage (stomach pumping). An antidote such as acetylcysteine or methionine may be necessary to use. Acetylcysteine should be taken by direct venous injection as soon as possible.

A single dose of 50 g activated charcoal must be taken via the lavage tube. If you are prone to paracetamol poisoning (see above), and take amounts smaller than this, you may still require treatment.

Acetylcysteine:

Acetylcysteine should be given as soon as possible, preferably within 8 hours of overdosage.

IV: An initial dose of 150 mg/kg in 200 ml glucose injection, given intravenously over 15 minutes, followed by an intravenous infusion of 50 mg/kg in 500 ml of glucose injection over the next 4 hours and then 100 mg/kg in 1 000 ml over the next 16 hours. The volume of intravenous fluids should be modified for children.

Orally: 140 mg/kg as a 5 % solution initially, followed by a 70 mg/kg solution every 4 hour for 17 doses. Acetylcysteine is effective if administered within 8 hours of overdosage.

CAFFEINE

Large doses of caffeine may cause restlessness, excitement, muscle tremor, ringing in the ears and a fast heartbeat.

If you take large doses, you may experience the following symptoms related to caffeine overdose:

- restlessness,
- excitement,
- anxiety,
- muscle tremor,
- ringing in the ears,

- visual spot disturbances,
- increased rate or rhythm of heartbeat (fast heartbeat),
- abnormal heartbeats.

If you forget to take TRIPARC

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

4. Possible side effects

TRIPARC can have side effects.

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

If any of the following happens, stop taking TRIPARC 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,
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Severe cutaneous adverse reactions (SCARs) including, Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrosis (TEN), Drug Rash with Eosinophilia and Systemic Symptoms (DRESS), acute generalised exanthematous pustulosis (AGEP), Drug-induced hypersensitivity syndrome (DIHS) or fixed drug eruption (FDE).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to TRIPARC. You 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:

- Inflammation of the pancreas (pancreatitis), that may present with symptoms such as severe belly pain that may spread to your back or chest (it may feel worse after you eat), nausea and vomiting,
- inflammation of the liver (hepatitis), liver damage (hepatic necrosis), liver failure (hepatic failure), that may present with symptoms such as dark urine and pale or clay-coloured stools, yellowing of the skin or eyes, loss of appetite,
- kidney failure/dysfunction (renal colic, renal failure), that may present with symptoms such as swollen ankles and feet, foamy urine, urinating more often than usual,
- blood disorders with symptoms such as fever, chills, swelling, sore throat, fatigue, which may be signs of an infection due to low white blood cell count (leucopenia, agranulocytosis, neutropenia), any unusual or unexplained bruising or bleeding due to a low blood platelet count (thrombocytopenia), weakness, bruising or increased likelihood of an infection due to too few blood cells of all types (pancytopenia),
- stomach ulceration or perforation: symptoms could include severe abdominal pain, vomiting blood (or liquid with what looks like coffee grounds), blood in the faeces (stools/motions) or passing black stools,
- bleeding within the skull (intracranial haemorrhage), that may present with symptoms such as extreme headache, sudden tingling, weakness, numbness or paralysis of face, arm or leg, nausea and vomiting,
- breathing problems: wheezing and breathing difficulties may be triggered in patients suffering from or with a previous history of asthma, shortness of breath,

- heart failure,
- irregular heartbeat (palpitations) with high doses,
- bleeding after childbirth,
- occasionally the blood does not clot well, which may result in bruising or bleeding, or yellowing of the skin and eyes may occur (jaundice),
- temporary hearing loss,
- iron-deficiency anaemia after prolonged use, with symptoms such as extreme tiredness, weakness and pale skin,
- Reye's syndrome (in teenagers and children under 16), which can be fatal that causes brain and liver damage. Usually occurs in children who have had a recent viral infection, such as chickenpox or the flu.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Nausea, vomiting, diarrhoea,
- excess amount of air/gas in the stomach, indigestion, stomach irritation, stomach pain,
- sneezing, stuffy, runny nose, swelling or irritation in the nose (rhinitis).

Less frequent side effects:

- Raised liver enzymes,
- pus in the urine,
- constipation, swelling and ulcer in the mouth or lips (ulcerative stomatitis),
- worsening of inflammation of the colon,
- inflammation of the stomach,

- anxiety, restlessness,
- vertigo,
- tremor (with high doses),
- prolonged pregnancy and labour.

Side effects with an unknown frequency:

- Nose bleeds,
- red or purple discolourations on the skin (purpura),
- confusion, dizziness,
- ringing in the ears, light-headedness,
- swelling due to fluid retention,
- increased blood pressure,
- nervousness, headache,
- insomnia,
- generalised swelling or water retention.

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. You can also report side effects to:

SAHPRA: https://www.sahpra.org.za/Publications/Index/8

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of TRIPARC.

5. How to store TRIPARC

Store all medicines out of reach of children.

Store in a cool, dry place at or below 30 °C.

Keep well closed.

Use sachet immediately after opening.

Do not remove the product from the carton until required for use.

Do not store in bathrooms.

Do not use 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 TRIPARC contains

The active ingredients are 453,6 mg aspirin, 324,00 mg paracetamol and 64,80 mg caffeine.

TRIPARC

The other ingredient is colloidal anhydrous silica.

Sugar free

TRIPARC BLACKCURRANT

The other ingredients are Blackcurrant Flavour Permaseal, sucralose.

Sugar free

Contains sweetener: Sucralose 37,80 mg

TRIPARC ORANGE

The other ingredients are orange flavour, sucralose.

Sugar free

Contains sweetener: Sucralose 37,80 mg

TRIPARC LEMON

The other ingredients are colloidal anhydrous silica, Trusil Lemon Special, sucralose.

Sugar free

Contains sweetener: Sucralose 21,06 mg

What TRIPARC looks like and contents of the pack

TRIPARC is a fine white to off-white granular powder, free from rigid cakes or lumps.

TRIPARC BLACKCURRANT is a fine white to off-white granular powder with a sweet blackcurrant odour and taste, free from rigid cakes or lumps.

TRIPARC ORANGE is a fine white to off-white granular powder with a sweet orange odour and taste, free from rigid cakes or lumps.

TRIPARC LEMON is a fine white to off-white granular powder with a sweet lemon odour, free from rigid cakes or lumps.

TRIPARC is packed in a sachet consisting of a white to off-white paper triple laminated with low-density polyethylene and aluminium foil or a white paper double laminated with low-density polyethylene. 12 or 38 sachets are packed into a unit cardboard carton together with a leaflet. Single doses are packed into a dispenser.

TRIPARC BLACKCURRANT and TRIPARC ORANGE are packed in a sachet consisting of a white paper triple laminated with low-density polyethylene and aluminium foil or a white paper triple laminated with low-density polyethylene and polyester. 10 or 24 sachets are packed into a unit cardboard carton together with a leaflet, and single sachets are packed into a dispenser.

TRIPARC LEMON is packed in a sachet consisting of a white to off-white paper triple laminated with low-density polyethylene and aluminium foil or a white paper triple laminated with low-density polyethylene and polyester. 12 sachets are packed into a unit cardboard carton together with a leaflet.

Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912

This leaflet was last revised in

13 November 2023

Registration numbers

TRIPARC	46/2.8/0139
TRIPARC BLACKCURRANT	46/2.8/0137
TRIPARC ORANGE	46/2.8/0138
TRIPARC LEMON	46/2.8/0140

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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