SCHEDULING STATUS

S2

TRIFEN® EXPECT PAEDIATRIC solution

Pseudoephedrine hydrochloride, Codeine phosphate, Triprolidine hydrochloride,

Guaiphenesin

Contains sugar:

Liquid glucose: 1 g/5 ml

Sorbitol 70 %: 1,29 g/5 ml

Contains sweetener: Saccharin sodium: 5 mg/5 ml

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

- TRIFEN® EXPECT PAEDIATRIC is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use TRIFEN® EXPECT PAEDIATRIC carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share TRIFEN® EXPECT PAEDIATRIC with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your child's symptoms worsen or do not improve.

What is in the leaflet

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

1. What TRIFEN® EXPECT PAEDIATRIC is and what it is used for

TRIFEN® EXPECT PAEDIATRIC contains contains pseudoephedrine hydrochloride, codeine phosphate, triprolidine hydrochloride and guaiphenesin. Triprolidine belongs to a group of medicines called antihistamines, which act to relieve the symptoms of allergic reactions. Pseudoephedrine hydrochloride is a decongestant which unblock your nose and sinuses helping you breathe more easily. Codeine acts on the brain to suppress a cough. Guaiphenesin is an expectorant that reduces the thickness of mucous.

TRIFEN® EXPECT PAEDIATRIC is used for the relief of cough.

2. What you need to know before you give TRIFEN® EXPECT PAEDIATRIC

Do not give TRIFEN® EXPECT PAEDIATRIC

- if your child is allergic to pseudoephedrine hydrochloride, codeine phosphate, triprolidine hydrochloride and guaiphenesin, or any of the other ingredients of TRIFEN® EXPECT PAEDIATRIC (listed in section 6).
- if your child has heart problems.
- if your child suffers from high blood pressure.
- if your child have thyroid problems.
- if your child has a problem with their bladder.
- if your child has high pressure in the eye (glaucoma).
- if your child has a condition called phaeochromocytoma (a rare tumour of the adrenal gland, which sits near the kidney).
- if your child is being treated with monoamine oxidase inhibitors (medicine for depression) and within two weeks of stopping such treatment.

- if your child is being given a medicine called ephedrine or a medicine from a group of medicines called sympathomimetics (e.g. medicines used to treat a blocked nose, appetite suppressants).
- if your child is having an asthma attack.
- if your child has or had a head injury or been told by the doctor your child has increased pressure in the brain.
- if your child has lung problems including being unable to breathe with the skin turning blue or purple and having excessive phlegm.
- if your child is under the age of 2 years.

Warnings and precautions

Take special care with TRIFEN® EXPECT PAEDIATRIC:

- as exceeding the prescribed dose and continuous use of TRIFEN® EXPECT PAEDIATRIC may lead to lead to dependency and addiction.
- if you have been told by your doctor that your child has a problem with their blood vessels.
- if your child has diabetes mellitus.
- if your child suffer from fits.
- if your child has blockages in your intestines.
- if your child has liver or kidney problems.
- if your child has a disorder of the muscles known as myasthenia gravis.
- if your child is in shock.
- if you have been told by your doctor that your child has a problem with your adrenal gland.
- if your child is in a weakened state of health.
- if you are elderly

TRIFEN® EXPECT PAEDIATRIC may mask the warning symptoms of damage caused by medicines which cause damage to the ear.

TRIFEN® EXPECT PAEDIATRIC may interfere with the results of some laboratory test; inform your doctor that your child is using this medicine before going for any test.

Other medicines and TRIFEN® EXPECT PAEDIATRIC

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

- Furazolidone used to treat infections caused by certain organisms.
- Guanethidine, reserpine and methyldopa used to treat high blood pressure.
- Medicines to treat or prevent clinical depression (e.g. monoamine oxidase inhibitors, tricyclic antidepressants).
- Any of the group of medicines called antimuscarinics (e.g. atropine).
- Medicines which make you drowsy or sleepy (CNS depressants) (e.g. barbiturates, hypnotics, narcotic analgesics, phenothiazines, sedatives and tranquillisers).
- Medicines used to treat fits.
- Oral contraceptives.

TRIFEN® EXPECT PAEDIATRIC with food and drink

TRIFEN® EXPECT PAEDIATRIC should not be taken with alcohol.

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 healthcare provider for advice before taking TRIFEN® EXPECT PAEDIATRIC.

Driving and using machines

TRIFEN® EXPECT PAEDIATRIC may cause drowsiness and impair your concentration. If you experience these side effects, do not drive or operate machinery.

TRIFEN® EXPECT PAEDIATRIC contains glucose and sorbitol

TRIFEN® EXPECT PAEDIATRIC which may have an effect on the control of your blood sugar if your child has diabetes mellitus. If you have been told by your doctor that your child has an intolerance to some sugars, contact your doctor before giving TRIFEN® EXPECT PAEDIATRIC.

TRIFEN® EXPECT PAEDIATRIC contains sorbitol 70 % solution. Sorbitol is a source of fructose. If your doctor has told you that your child have an intolerance to some sugars or if your child has been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before your child receives TRIFEN® EXPECT PAEDIATRIC.

3. HOW TO TAKE/GIVE TRIFEN® EXPECT PAEDIATRIC

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

Always give TRIFEN® EXPECT PAEDIATRIC 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.

The usual dose is:

Children 6 to 12 years – 5 ml to 10 ml

Children 2 to 5 years – 2,5 ml to 5 ml

May be given three times daily.

If you give more TRIFEN® EXPECT PAEDIATRIC than you should

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

If you forget to give TRIFEN® EXPECT PAEDIATRIC

If you forget to give a dose, give it as soon as you remember. Do not give a double dose to make up for a forgotten dose.

4. Possible side effects

TRIFEN® EXPECT PAEDIATRIC can have side effects.

Not all side effects reported for TRIFEN® EXPECT PAEDIATRIC are included in this leaflet. Should your child's general health worsen or if your child experiences any untoward effects while taking TRIFEN® EXPECT PAEDIATRIC, please consult your healthcare provider for advice.

If any of the following happens, stop giving TRIFEN® EXPECT PAEDIATRIC and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching, flaking of the skin,
- fainting.

These are all very serious side effects. If your child has them, your child may have had a serious reaction to TRIFEN® EXPECT PAEDIATRIC. 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:

- bleeding or increased tendency to bleed, persistent sore throat and frequent infections, fever, and/or anaemia,

- anxiety, confusion, fear, seeing, hearing, or believing things that are not real,, irritability, a feeling of intense excitement and happiness, mood changes, restlessness, depression, agitation
- chest pain, tightness of the chest, changes in the way your heart beats,
- prolonged unconsciousness, increase pressure in the brain, bleeding in the brain with symptoms such as a sudden, severe headache, include numbness or weakness in part of the face, difficulty speaking or difficulty walking,
- constriction of the pupil of the eye,
- difficulty in urination, less urine than is normal for you, no urination,
- sudden loss in body heat (temperature).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- sedation varying from slight drowsiness to deep sleep,

Less frequent side effects:

- abdominal pain that lasts and gets worse when you lie down, nausea, vomiting

Side effects with unknown frequency:

- thirst, loss of appetite, disturbance of glucose metabolism, dry mouth, anorexia,
- insomnia, nightmares
- giddiness, headache, tremors, dizziness, inability to concentrate, lack of energy, incoordination, tingling, heaviness and weakness of the hands,
- ringing in the ears,
- increase or decrease in blood pressure,

- reddening of the skin, sweating
- nausea, vomiting, diarrhoea, constipation, stomach pain,
- muscle weakness, stiffness of the muscles.

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

Reporting of side effects

If your child gets 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 TRIFEN® EXPECT PAEDIATRIC.

5. How to store TRIFEN® EXPECT PAEDIATRIC

- Store all medicines out of reach of children.
- Store at or below 25 °C and protect from light.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label or 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 TRIFEN® EXPECT PAEDIATRIC contains

The active substances are 12 mg pseudoephedrine hydrochloride,

3 mg codeine phosphate, 0,6 mg triprolidine hydrochloride, 50 mg guaiphenesin

Preservatives:

Methyl hydroxybenzoate 0,12 % *m/v*

Propyl hydroxybenzoate 0,02 % *m/v*

Contains propyl gallate 0,05 % *m/v*

The other ingredients are:

Citric acid monohydrate, liquid glucose, methyl hydroxybenzoate, propyl hydroxybenzoate, purified water, raspberry red H1277 (C.I. no. 14720), raspberry special essence, propyl gallate, saccharin sodium, sodium citrate, sorbitol 70 %.

What TRIFEN® EXPECT PAEDIATRIC looks like and contents of the pack

Clear red solution with raspberry odour and taste.

100 ml and 200 ml amber glass bottles.

Holder of Certificate of Registration

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South Africa

This leaflet was last revised in

13 March 2023

Registration numbers

27/10.1/0536 (South Africa)

Zambia: P168/014

Namibia: NS1 04/19.1/1006 Malawi: PMPB/PL4/29

Access to the corresponding Professional Informat ion

To follow