

Applicant/PHCR: Ranbaxy Pharmaceuticals (Pty) Ltd
Product proprietary name: TRIFEN EXPECT ADULT
Dosage form and strength: Solution; Each 5 ml contains Triprolidine hydrochloride 1,25mg, Pseudoephedrine hydrochloride 20mg, Guaiphenesin 100mg, Codeine phosphate 7,5mg
Date of Amendment: March 2024

Patient Information Leaflet

SCHEDULING STATUS

S2

TRIFEN[®] EXPECT ADULT solution

Pseudoephedrine hydrochloride, Codeine phosphate, Triprolidine hydrochloride, Guaiphenesin

Contains sugar:

Liquid glucose: 1 g/5 ml

Sorbitol 70 %: 231,2 mg/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 ADULT is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use TRIFEN[®] EXPECT ADULT carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share TRIFEN[®] EXPECT ADULT 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.

What is in the leaflet

1. What TRIFEN[®] EXPECT ADULT is and what it is used for
2. What you need to know before you take/give TRIFEN[®] EXPECT ADULT
3. How to take/give TRIFEN[®] EXPECT ADULT



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4. Possible side effects
5. How to store TRIFEN® EXPECT ADULT
6. Contents of the pack and other information

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

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

2. What you need to know before you take/give TRIFEN® EXPECT ADULT

Do not take/give TRIFEN® EXPECT ADULT

- if you/your child are allergic to pseudoephedrine hydrochloride, codeine phosphate, triprolidine hydrochloride and guaiphenesin, or any of the other ingredients of TRIFEN® EXPECT ADULT (listed in section 6).
- if you have heart problems.
- if you suffer from high blood pressure.
- if you have thyroid problems.
- if you have prostate problems.
- if you have a problem with your bladder.
- if you have high pressure in the eye (glaucoma).



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- if you have a condition called phaeochromocytoma (a rare tumour of the adrenal gland, which sits near the kidney).
- if you are being treated with monoamine oxidase inhibitors (medicine for depression) and within two weeks of stopping such treatment.
- if you are taking 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 you drink more alcohol than normal.
- if you/your child are having an asthma attack.
- if you/your child have or had a head injury or been told to have increased pressure in the brain.
- if you have lung problems including being unable to breathe with the skin turning blue or purple and having excessive phlegm.
- if you have very high blood pressure (severe hypertension) or hypertension not controlled by your medication.
- if you have severe acute (sudden) or chronic (long-term) kidney disease or kidney failure

Warnings and precautions

Take special care with TRIFEN[®] EXPECT ADULT:

- exceeding the prescribed dose and continuous use of TRIFEN[®] EXPECT ADULT may lead to lead to dependency and addiction.
- if you have been told by your doctor that you have a problem with your blood vessels.
- if you have diabetes mellitus.
- if you are elderly or if you are in a weakened state of health.
- if you suffer from fits.
- if you have blockages in your intestines.
- if you have liver or kidney problems.



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- if you have a disorder of the muscles known as myasthenia gravis.
- if you are in shock.
- if you have been told by your doctor that you have a problem with your adrenal gland.

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

TRIFEN[®] EXPECT ADULT may interfere with the results of some laboratory test; inform your doctor that you are using this medicine before going for any test.

If the patients have a personal or family history of substance abuse or mental health disorders, then there is an increased risk of addiction

Other medicines and TRIFEN[®] EXPECT ADULT

Always tell your healthcare provider if you/your child are 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.



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- Cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) have been reported following use of medicines containing pseudoephedrine. PRES and RCVS are rare conditions that can involve reduced blood supply to the brain. Stop using TRIFEN® EXPECT ADULT immediately and seek immediate medical assistance if you develop symptoms that may be signs of PRES or RCVS (see section 4 "Possible side effects" for symptoms).

TRIFEN® EXPECT ADULT with food and drink

TRIFEN® EXPECT ADULT 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 ADULT.

Driving and using machines

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

TRIFEN® EXPECT ADULT contains glucose and sorbitol

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



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

3. HOW TO TAKE/GIVE TRIFEN[®] EXPECT ADULT

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

Always take/give TRIFEN[®] EXPECT ADULT 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:

Adults and children over 12 years: 5 ml to 10 ml three times a day.

If you take/give more TRIFEN[®] EXPECT ADULT 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 take/give TRIFEN[®] EXPECT ADULT

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

4. Possible side effects

TRIFEN[®] EXPECT ADULT can have side effects.



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

If any of the following happens, stop taking/giving TRIFEN[®] EXPECT ADULT 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.

Stop using TRIFEN[®] EXPECT ADULT immediately and seek urgent medical attention if you develop symptoms, that may be signs of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS). These include:

- severe headache with a sudden onset
- feeling sick
- vomiting
- confusion
- seizures changes in vision

These are all very serious side effects. If you/your child have them, you/your child may have had a serious reaction to TRIFEN[®] EXPECT ADULT. You/your child may need urgent medical attention or hospitalisation.



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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:



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- 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.
- serious conditions affecting blood vessels in the brain known as posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS)

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

Reporting of side effects

If you/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 ADULT.

5. How to store TRIFEN® EXPECT ADULT

- Store all medicines out of reach of children.
- Store between 15 °C - 25 °C and protect from light. Do not refrigerate.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label or bottle.



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- 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 ADULT contains

The active substances are 20 mg pseudoephedrine hydrochloride, 7,5 mg codeine phosphate, 1,25 mg triprolidine hydrochloride, 100 mg guaiphenesin

Preservatives:

Methyl hydroxybenzoate 0,12 % m/v

Propyl hydroxybenzoate 0,02 % m/v

The other ingredients are:

Citric acid monohydrate, liquid glucose, menthol, methyl hydroxybenzoate, propyl hydroxybenzoate, purified water, quinolene yellow (C.I. 47005), saccharin sodium, sodium citrate, sorbitol 70 %, sunset yellow (C.I. 15985)

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

Clear orange-yellow solution with menthol odour and taste.

100 ml and 200 ml amber glass bottles.

Holder of Certificate of Registration

Ranbaxy Pharmaceuticals (Pty) Ltd

14 Lautre Road

Stormill Ext. 1



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Roodepoort 1724

South Africa

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27/10.1/0537 (South Africa)

Zambia: P168/013

Namibia: NS1 04/10.1/1621

Malawi: PMPB/PL4/26

Access to the corresponding Professional Information

To follow

