

# FEDAC SYRUP

Tripolidine HCl, Pseudoephedrine HCl (1.25mg/5ml, 30mg/5ml)

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## What Fedac is used for

Fedac is used to relieve the symptoms of colds, flu and allergies including runny nose, watery eyes, nasal congestion and blocked sinuses.

## How Fedac work

Fedac contains pseudoephedrine hydrochloride, which is a decongestant that relieves nasal and sinus congestion and tripolidine hydrochloride which is an antihistamine that helps stop sneezing, runny nose and watery eyes.

## Before you use Fedac

### -When you must not take it

Do not take Fedac if:

- you are allergic (hypersensitive) to pseudoephedrine hydrochloride, tripolidine hydrochloride or any of the other ingredients
- you have very high blood pressure or severe heart disease.
- you are taking drugs for depression known as Monoamine Oxidase Inhibitors (MAOIs) within the last two weeks.
- you have overactive thyroid (thyroid producing too much thyroid hormone)
- you are pregnant, likely to get pregnant, or are breast-feeding
- you are consuming alcohol

### -Before you start to take it

You should check with your doctor or pharmacist before taking Fedac if:

- you are pregnant or breastfeeding

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Fedac.

## Children

When used for treatment of cough and cold:

- Not to be used in children less than 2 years of age.
- To be used with caution and on doctor's or pharmacist's advice in children 2 to 6 years of age.

## -Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, including the following:

- Sedatives (drugs used to treat anxiety and tension).
- Sympathomimetic drugs (stimulants or appetite suppressants and drugs used to treat congestion and asthma).

## How to take Fedac

### -How much to take

Adults and children over 12 years:

2 teaspoonfuls (10ml) 3 times a day.

Children 6 - 12 years:

1 teaspoonful (5ml)

Children 2 - 5 years:

½ teaspoonful (2.5ml)

Doses to be taken 3 times a day.

### -When to take it

Take Fedac at the same time every day. If you are not sure, check with your doctor or pharmacist.

### -How long to take it

Always take Fedac exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

### -If you forget to take it

If you forget to take a dose, take it as soon as you remember it and then take the next dose at the right time.

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

### -If you take too much (overdose)

If you (or someone else) took a lot of syrup at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately.

Symptoms of overdose includes:

- restlessness
- delirium (a sudden state of severe confusion)
- muscle tremors

## While you are taking Fedac

### -Things you must do

Take Fedac for as long as your doctor recommends. If the symptom still persists or not lighten after a few days, please consult your doctor.

### -Things you must not do

- Do not give Fedac to anyone else, even if they have the same condition as you.
- Do not take Fedac to treat any other complaints unless your pharmacist or doctor tells you to.
- Do not take more than the recommended dose unless your pharmacist or doctor tells you to.

### -Things to be careful of

#### Driving and operating machine

This medicine may cause drowsiness. If affected, do not drive or operate machinery. Avoid alcoholic drink.

## Side Effects

Like all medicines, Fedac may cause side effects, although not everybody gets them.

Consult doctor or pharmacist for further information if you notice any of the following and they worry you:

- drowsiness
- dryness of mouth
- nervousness
- restlessness
- trouble sleeping.

Consult doctor or pharmacist for further information if you notice any other side effects and they worry you.

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You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

## Storage and Disposal of Fedac

### -Storage

Keep all medicines out of the reach of children.

Store below 30°C and protect from light.

### -Disposal

Do not take this medicine after the expiry date stamped on the pack.

Return any unused syrups to your pharmacist to be disposed of. Only keep the syrups if your doctor tells you to. Do not throw them away in your normal household drainage or waste. This will help to protect the environment.

## Product Description

### -What it looks like

Clear mixture, yellow in colour, sweet taste with orange flavour.

### -Ingredients

Active Ingredient

Each 5ml syrup contains 1.25ml Tripolidine HCl and 30mg Pseudoephedrine HCl.

Inactive ingredients

Methyl hydroxybenzoate, Propyl hydroxybenzoate, sodium citrate dihydrate, granulated fine white sugar, FDC Yellow No.6 water soluble 40%-44%, glycerin, essence of orange sweet P97, quinoline yellow E104 water soluble 70%, sodium saccharin, citric acid monohydrate, sodium carboxymethylcellulose, purified water

### -MAL Number

MAL19900593AZ

## Manufacturer

PT Actavis Indonesia  
Jl. Raya Bogor Km. 28,  
Kelurahan Pekayon, Kecamatan  
Pasar Rebo  
Kota Jakarta Timur, Provinsi  
DKI Jakarta, Indonesia

## Product Registration Holder

DCH Auriga (Malaysia) Sdn.  
Bhd.  
Lot 6, Persiaran Perusahaan  
Seksyen 23, 40300 Shah Alam  
Selangor, Malaysia

## Date of Revision

16/05/2023

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