

SYNERRV FEXOFENADINE 120MG (FEXOFENADINE HYDROCHLORIDE 120MG TABLETS USP)

SYNERRV FEXOFENADINE 180MG (FEXOFENADINE HYDROCHLORIDE 180MG TABLETS USP)

Fexofenadine hydrochloride (120mg & 180mg)

What is in this leaflet

1. What SYNERRV FEXOFENADINE is used for
2. How SYNERRV FEXOFENADINE works
3. Before you use SYNERRV FEXOFENADINE
4. How to use SYNERRV FEXOFENADINE
5. While you are using it
6. Side effects
7. Storage and Disposal of SYNERRV FEXOFENADINE
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial number

What is SYNERRV FEXOFENADINE used for

SYNERRV FEXOFENADINE (120mg & 180mg) is used in adult and adolescents of 12 years and older to relieve the symptoms that occur with hay fever (seasonal allergic rhinitis) such as sneezing, itchy, watery or red eyes, and itchy or runny nose.

Additionally, SYNERRV FEXOFENADINE (180mg only) is also used to relieve the symptoms of long-term hives (chronic idiopathic urticaria – a raised, itchy rash of unknown cause)

How SYNERRV FEXOFENADINE works

SYNERRV FEXOFENADINE contains Fexofenadine hydrochloride, which is an antihistamine. It works by blocking

the action of histamine in order to treat allergy symptoms.

Before you use SYNERRV FEXOFENADINE

-When you must not use it

Do not take SYNERRV FEXOFENADINE if you are allergic (hypersensitive) to Fexofenadine or any of the other ingredients of this medicine listed at the end of this leaflet.

-Before you start to use it

Check with your doctor before taking SYNERRV FEXOFENADINE if:

- You have problems with your liver or kidneys.
- You are an elderly.

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

Pregnancy and breastfeeding:

Tell your doctor before taking this medicine if you:

- Are pregnant or plan to get pregnant.
- Are breastfeeding or plan to start breastfeeding.

Fexofenadine hydrochloride should be used during pregnancy and breastfeeding only if the potential benefit justified the potential risk to the fetus.

-Taking other medications

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- Indigestion remedies (antacids) containing aluminium and magnesium may affect the action of SYNERRV FEXOFENADINE by lowering the amount of medicinal products absorbed. It is recommended to avoid taking your indigestion remedies within 15 minutes before or after taking SYNERRV FEXOFENADINE.
- Erythromycin (antibiotic used to treat bacterial infections) or Ketoconazole (used to treat fungal infections)

Do not take SYNERRV FEXOFENADINE with fruit juices such as grapefruit, orange and apple. It is recommended to take SYNERRV FEXOFENADINE with water to maximize the effects of Fexofenadine.

How to use SYNERRV FEXOFENADINE

Always take SYNERRV FEXOFENADINE exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Swallow your tablets orally in whole with plenty of water.

-How much to use

Adults and children 12 years of age and older: the recommended dose is one tablet daily.

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Fexofenadine hydrochloride (120mg & 180mg)

SYNERRV FEXOFENADINE is not recommended in use for children below 12 years of age.

Kidney impairment:

The recommended starting dose in adults with decreased kidney function is 60mg once daily.

-When to use it

Take SYNERRV FEXOFENADINE at about the same time each day unless your doctor tells you otherwise.

-How long to use it

Keep taking until your doctor tells you to stop. Do not stop taking SYNERRV FEXOFENADINE just because you feel better. If you stop, your symptoms may return.

-If you forget to use it

- If you forget to take your tablet, leave out that dose completely and take the next tablet at the usual time.
- Do not take a double dose to make up for a forgotten tablet.
- If you have any further questions on the use of this product, ask your doctor or pharmacist.

-If you use too much (overdose)

If you take too many tablets than you should, tell a doctor or go to a hospital casualty department straight away.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take the medicine pack with you. The

following effects may happen: dizziness, drowsiness and dry mouth.

While you are using it

-Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking SYNERRV FEXOFENADINE.
- Tell your doctor immediately if you become pregnant while taking this medication.

-Things you must not do

- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not use this medicine to treat any other complaints unless your doctor tells you to.
- Do not stop taking SYNERRV FEXOFENADINE or change the dosage, without checking with your doctor.
- Do not swallow SYNERRV FEXOFENADINE with fruit juice.

-Things to be careful of

Driving and using machines:

SYNERRV FEXOFENADINE is unlikely to affect your ability to drive or operate machinery. However, you should check that these tablets do not make you feel sleepy or dizzy before driving or operating machinery.

Side effects

Like all medicines, SYNERRV FEXOFENADINE can cause side effects, although not everyone gets them.

Tell your doctor immediately if you notice any of the following side effects:

- Menstrual pain
- Headache
- Back pain
- Cough
- Upper respiratory tract infection
- Fever
- Inflammation of the middle ear
- Vomiting
- Diarrhoea
- Tiredness
- Runny nose
- Dizziness
- Stomach discomfort
- Pain in limbs

Other side effects not listed above may occur in some people.

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

Storage and Disposal of SYNERRV FEXOFENADINE

-Storage

Keep this medicine in a safe place where children cannot see or reach it.

Do not use SYNERRV FEXOFENADINE after the expiry

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SYNERRV FEXOFENADINE 180MG (FEXOFENADINE HYDROCHLORIDE 180MG TABLETS USP)

Fexofenadine hydrochloride (120mg & 180mg)

date which is stated on the label and carton. The expiry date refers to the last day of that month.

Store below 30°C in original box.

-Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

-What it looks like

SYNERRV FEXOFENADINE 120MG: peach coloured, oblong shaped, biconvex film coated tablets with both sides plain. The tablets are approximately 15.5 mm in length and 7 mm in breadth.

SYNERRV FEXOFENADINE 180MG: peach coloured, oblong shaped, biconvex film coated tablets with both sides plain. The tablets are approximately 18 mm in length and 8 mm in breadth.

-Ingredients

- Active ingredient(s)
Each tablet contains 180mg/120mg of Fexofenadine hydrochloride.
- Inactive ingredient(s)
Lactose, Croscarmellose sodium, Maize starch, Colloidal anhydrous silica, Povidone, Magnesium stearate & Opadry pink (03B54819).

-MAL number

SYNERRV FEXOFENADINE 120MG: MAL22086027AZ

SYNERRV FEXOFENADINE 180MG: MAL22086028AZ

Manufacturer

Ind-Swift Laboratories Limited, Off- NH-21, Village Jawaharpur, Tehsil Derabassi, Distt. S.A.S Nagar, (Mohali) Punjab (India) Pin -140507

Product Registration Holder

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Date of revision

29/09/2025

Serial Number

NPRA(R2) 21/144