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PACKAGE LEAFLET: INFORMATION FOR THE USER

histallay

120 mg Film-Coated Tablets
Fexofenadine hydrochloride

Histallay 120 mg Film-Coated Tablets will also be referred to in this leaflet as Histallay.
Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice
- This medicine is for your use only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after taking Histallay.

What is in this leaflet:

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

1. WHAT HISTALLAY IS AND WHAT IT IS USED FOR

Histallay contain fexofenadine hydrochloride, which is a non-drowsy antihistamine.
Histallay is used in adults and adolescents over 12 years of age to relieve the symptoms that occur with hay fever (seasonal allergic rhinitis) such as sneezing, itchy, runny or blocked nose and itchy, red and watery eyes.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE HISTALLAY

Do not take Histallay
- If you are allergic to fexofenadine or any of the other ingredients of this medicine listed in Section 6.

Warnings and precautions
Talk to your doctor or pharmacist before taking Histallay if you:
- have problems with your liver or kidneys
- have or ever had heart disease, since this kind of medicine may lead to a fast or irregular heart beat
- are elderly.

If any of these apply to you, or if you are not sure, tell your doctor before taking Histallay.

Other medicines and Histallay
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
If you are taking apalutamide (a medicine to treat prostate cancer), as the effect of fexofenadine may be decreased.
Indigestion remedies containing aluminium and magnesium may affect the action of Histallay, by lowering the amount of medicinal product absorbed. It is recommended that you leave about 2 hours between the time that you take Fexofenadine Tablets and your indigestion remedy.

Pregnancy and breastfeeding
Histallay should not be taken during pregnancy and whilst breast-feeding unless advised by a doctor.

Driving and using machines
Histallay 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.

Histallay also contain Allura Red AC Lake, which may cause allergic reactions.

For a full list of ingredients, please see 'Contents of the pack and other information'.

3. HOW TO TAKE HISTALLAY

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

For adults and children aged 12 years and over
The recommended dose is one tablet (120 mg) daily. Take your tablet with water before a meal.
This medicine starts to relieve your symptoms within 1 hour and lasts for 24 hours
Histallay is not recommended for children under 12 years of age

If you take more Histallay than you should
If you take too many tablets, contact your doctor or the nearest hospital emergency department immediately. Symptoms of an overdose in adults are dizziness, drowsiness, fatigue and dry mouth.

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If you forget to take Histallay
Do not take a double dose to make up for a forgotten tablet. Take the next dose at the usual time.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately and stop taking Histallay if you experience:

- swelling of the face, lips, tongue or throat and difficulty breathing, as these may be signs of a serious allergic reaction.

The following undesirable effects have been reported in clinical trials, with an incidence similar to those observed in patients who did not receive the drug (placebo).

Common side effects (may affect up to 1 in 10 people):
- headache
- drowsiness
- feeling sick (nausea)
- dizziness.

Uncommon side effects (may affect up to 1 in 100 people):
- tiredness
- sleepiness.

Additional side effects (frequency not known: cannot be estimated from the available data) which may occur are:
- difficulty sleeping (insomnia)
- sleeping disorders
- bad dreams
- nervousness
- blurred vision
- fast or irregular heart beat
- diarrhoea
- skin rash and itching
- hives
- serious allergic reactions which can cause swelling of the face, lips, tongue or throat, flushing, chest tightness, and difficulty breathing.

Reporting of side effects
If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE HISTALLAY

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage condition.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Histallay contain
The active substance is fexofenadine hydrochloride. Each film-coated tablet contains 120mg of fexofenadine hydrochloride; equivalent to 112mg of fexofenadine.
The other ingredients (excipients) are:
Tablet core: powdered cellulose, mannitol (E421), maize starch, croscarmellose sodium, colloidal anhydrous silica, magnesium stearate.
Tablet coating: opadry pink film-coating mixture containing hypromellose (E464), titanium dioxide (E171), macrogol 400, allura red AC lake (FD&C Red #40) (E129), and iron oxide, black (E172)

What Histallay Tablets look like and contents of the pack
Fexofenadine Tablets are pink coloured, oval, tablets marked with "FXF" on one side and "120" on the other side.
Fexofenadine Tablets are packed in blister strips packaged in cartons.
The cartons contain 7, 10, 15, 20, 30 tablets. Not all packs may be marketed.

Marketing Authorisation Holder and Manufacturer
Dr. Reddy's Laboratories (UK) Ltd, 410 Cambridge Science Park, Milton Road, Cambridge, CB4 0PE, United Kingdom

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Submission

Brand:	DR Reddy's
Country:	UK
Product Name:	Histallay - Fexofenadine
Strength:	120 mg
Form:	film Coated Tablets
Component:	Leaflet
Pack Size:	Various
Date Created:	05 OCT 2022
Date Modified:	04 AUG 2023
Project:	**CC1000103630**
Previous DR No:	DR000842P-4C
Previous Material Number:	150093661

Commercial

DR No:	**DR**
DRUGS Code:	N/A
Material Code:	1500xxxxx
Third Party Material Code:	xxxxxx
Barcode Type:	EAN xx
Barcode Number:	xxxxxxxxx
Magnification:	xx %
Pharmacode No:	xxx
Implementation Date:	**xx xxx xxxx**

Technical Information

Die Cut	Guides	XXXXX	XXXXX

Min Font Size:	9 pt
Printer	India
Dimensions:	180 x 290 mm

Colours

Process Black	XXXXX	XXXXX	XXXXX
XXXXX	XXXXX	XXXXX	XXXXX

Dr.Reddy's
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