

SYNERGIST JOB NO: 6935

CATEGORY: Health
BRAND: Boots Own Brand
RANGE: Seasonal Healthcare
PROJECT NO.:
PRODUCT TITLE: Fexofenadine Hydrochloride 120mg Film-coated Tablets
FILE NAME: WBA-6394-Boots Fexofenadine Hydrochloride 120mg Film-coated Tablets Leaflet
PROOF NUMBER: 3
PROOF DATE: 06/08/2024
ARTWORKER: Martyn

ITEM CODE: 9047670-9047689
COMPONENT CODE: XXXX
PHARMA CODE NO.: XXXX
BARCODE TYPE: N/A
BARCODE NO.:

PACK TYPE: Leaflet
FINISH:
FINISH TYPE:
SUBSTRATE: Paper
SUBSTRATE COLOUR: White
NUMBER OF COLOURS: 1
BRAILLE: Yes

PRINTING COLOURS
PMS 282 C

TECHNICAL & NON-PRINTING
Cutter Guides
SPECIAL FINISHES & FOILS

SUPPLIER CONTACT: hdavis@drreddys.com
SUPPLIER DETAILS:

PRINTER CONTACT: hdavis@drreddys.com
PRINTER DETAILS:

THIS SCALE MEASURES 50MM WHEN ARTWORK IS AT 100%
0 10 20 30 40 50

UNDER NO CIRCUMSTANCES SHOULD THIS ARTWORK BE ALTERED WITHOUT PRIOR PERMISSION FROM WK360.

TECHNICAL INFORMATION, PRINTER PLEASE NOTE: WK360 HAVE CREATED THIS ARTWORK TO A GENERIC PRINT PROCESS SPECIFICATION AND REPRO HAS NOT BEEN APPLIED. PLEASE CALL YOUR CLIENT CONTACT TO DISCUSS ANY AMENDS OR IF ANYTHING FALLS BENEATH YOUR PRINT TOLERANCES

Artwork Only

QUERIES FOR CLIENTS
ANY 'CLIENT QUERY' BOXES WILL BE VISIBLE IN RED AND WILL BE AUTOMATICALLY REMOVED ON APPROVAL OF THE ARTWORK.
APPROVAL BY THE ADMIN 'MASTER' APPROVER WILL SIGNIFY THAT YOU ARE HAPPY TO PROCEED TO PRINT WITHOUT ACTION BEING TAKEN WITH REGARDS TO THE CLIENT QUERY.

ARTWORK TEXT SIZES
LEAFLETS MIN 9PT, OTHER 7PT
MAIN HEADINGS: 13pt
SUB HEADINGS: 9.5pt
BODY HEADINGS: 9.5pt

PACK MOCK UP
PRODUCT NAME: Fexofenadine Hydrochloride 120mg Film-Coated Tablets
PRODUCT LICENCE NO.: PL 08553/0718
WORDING REF: Boots Fexofenadine HCl PIL (GSL PIL labelling text)
STATUS: Internally approved
PACK DETAILS: Aluminium/PVC-PE-PVdC blisters

PACK SIZE: 10 or 30 tablets

VERSION NO.	DATE ISSUED	REASON FOR CHANGE
1	22/07/2024	New OLS product

QUERIES FOR CLIENTS
If Pharmacode is required please advise positioning

20 mm
180 mm

PACKAGE LEAFLET: INFORMATION FOR THE USER

Fexofenadine Hydrochloride 120mg Film-Coated Tablets

fexofenadine hydrochloride

Fexofenadine Hydrochloride 120mg Film-Coated Tablets will also be referred to in this leaflet as Fexofenadine Tablets.

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 Fexofenadine Tablets.

Other medicines and Fexofenadine Tablets

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 Fexofenadine Tablets, 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 breast-feeding

Fexofenadine Tablets should not be taken during pregnancy and whilst breast-feeding unless advised by a doctor.

Driving and using machines

Fexofenadine Tablets are 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.

Fexofenadine Tablets 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 Fexofenadine Tablets

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 (120mg) daily. Take your tablet with water before a meal. This medicine starts to relieve your symptoms within 1 hour and lasts for 24 hours. Fexofenadine Tablets are not recommended for children under 12 years of age.

If you take more Fexofenadine Tablets 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.

If you forget to take Fexofenadine Tablets

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.

20 mm
180 mm

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 Fexofenadine Tablets 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 heartbeat
- 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 at: 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 Fexofenadine Tablets

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.

20 mm
180 mm

6. Contents of the pack and other information

What Fexofenadine Tablets 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 Fexofenadine 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 pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Dr. Reddy's Laboratories (UK) Ltd, 410 Cambridge Science Park, Milton Road, Cambridge, CB4 0PE, UK.

Distributed by

The Boots Company PLC Nottingham NG2 3AA

This leaflet was last revised in July 2024.

Reference number: PL 08553/0718

If you would like any further information about this medicine, please contact The Boots Company PLC Nottingham NG2 3AA.

9047670-9047689

20 mm
180 mm

290 mm

290 mm

40 mm

40 mm

40 mm

40 mm

40 mm

40 mm

40 mm

10 mm

40 mm

40 mm

40 mm

40 mm

40 mm

40 mm

40 mm

10 mm

20 mm
180 mm

PACKAGE LEAFLET: INFORMATION FOR THE USER

Fexofenadine Hydrochloride 120mg Film-Coated Tablets

fexofenadine hydrochloride

Fexofenadine Hydrochloride 120mg Film-Coated Tablets will also be referred to in this leaflet as Fexofenadine Tablets.

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 Fexofenadine Tablets.

Other medicines and Fexofenadine Tablets

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 Fexofenadine Tablets, 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.

1. What Fexofenadine Tablets are and what they are used for

Fexofenadine Tablets contain fexofenadine hydrochloride, which is a non-drowsy antihistamine. Fexofenadine Tablets are used in adults and adolescents over 12 years of age to relieve the symptoms of allergic rhinitis (for example hayfever) such as sneezing, itchy, runny or blocked nose and itchy, red and watery eyes.

2. What you need to know before you take Fexofenadine Tablets

Do not take Fexofenadine Tablets:

- 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 Fexofenadine Tablets 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 heartbeat.
- are elderly.

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

3. How to take Fexofenadine Tablets

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 (120mg) daily. Take your tablet with water before a meal. This medicine starts to relieve your symptoms within 1 hour and lasts for 24 hours. Fexofenadine Tablets are not recommended for children under 12 years of age.

If you take more Fexofenadine Tablets 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.

If you forget to take Fexofenadine Tablets

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.

20 mm
180 mm

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 Fexofenadine Tablets 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 heartbeat
- 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 at: 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 Fexofenadine Tablets

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.

9047670-9047689

SYNERGIST JOB NO: 6935		
CATEGORY:	Health	
BRAND:	Boots Own Brand	
RANGE:	Seasonal Healthcare	
PROJECT NO.:		
PRODUCT TITLE:	Fexofenadine Hydrochloride 120mg Film-coated Tablets	
FILE NAME:	WBA-6394-Boots Fexofenadine Hydrochloride 120mg Film-coated Tablets Leaflet	
PROOF NUMBER:	3	
PROOF DATE:	06/08/2024	
ARTWORKER:	Martyn	
ITEM CODE:	9047670-9047689	
COMPONENT CODE:	XXXX	
PHARMA CODE NO.:	XXXX	
BARCODE TYPE:	N/A	
BARCODE NO.:		
PACK TYPE:	Leaflet	
FINISH:		
FINISH TYPE:		
SUBSTRATE:	Paper	
SUBSTRATE COLOUR:	White	
NUMBER OF COLOURS:	1	
BRaille:	Yes	
PRINTING COLOURS		
PMS 282 C		
TECHNICAL & NON-PRINTING	SPECIAL FINISHES & FOILS	
ARTWORK TEXT SIZES LEAFLETS MIN 9PT, OTHER 7PT		
MAIN HEADINGS:	13pt	
SUB HEADINGS:	9.5pt	
BODY HEADINGS:	9.5pt	
PACK MOCK UP		
PRODUCT NAME:	Fexofenadine Hydrochloride 120mg Film-Coated Tablets	
PRODUCT LICENCE NO.:	PL 08553/0718	
WORDING REF:	Boots Fexofenadine HCl PIL (GSL PIL labelling text)	
STATUS:	Internally approved	
PACK DETAILS:	Aluminium/PVC-PE-PVdC blisters	
PACK SIZE:	10 or 30 tablets	
VERSION NO.	DATE ISSUED	REASON FOR CHANGE
1	22/07/2024	New OLS product
QUERIES FOR CLIENTS		
If Pharmacode is required please advise positioning		

Artwork Only

